PREDICTORS OF TREATMENT OUTCOMES OF CHILDHOOD TUBERCULOSIS AMONG PATIENTS ATTENDING THE TB CLINIC AT MBAGATHI COUNTY HOSPITAL, NAIROBI COUNTY, KENYA

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Predictors of Treatment Outcomes of Childhood Tuberculosis among Patients Attending the TB Clinic at Mbagathi County Hospital, Nairobi County, Kenya

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DECLARATION

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

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DEDICATION

I dedicate this research to my mum Wambui, my wife Mbela and my sons Ndegwa, Kiangi, Munene and Maina.

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Foremost, I wish to thank the Almighty God for his mercies and strength through this journey. I then wish to acknowledge all my supervisors for walking along with me and tirelessly guiding me through this *safari* of writing this thesis. In particular, I wish to recognize Prof. Simon Karanja, Dr. Evans Amukoye, Dr. Justus Simba and Dr. Elijah Mwangi for their individual efforts and assistance. I also wish to thank the staff of KEMRI Graduate School and JKUAT (School of Public Health) for their kind assistance that saw me get through this task. May the work of your hands be blessed. Finally, to my colleague and close associate Ms. Eunice Chelogoi for your valuable inputs without which this work could not have been completed. Thank you.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
ARV	Antiretroviral
BMI	Body Mass Index
CaP TB	Catalysing Paediatric Tuberculosis Innovations
CDC	Centers for Disease Control and Prevention
CHVs	Community Health Volunteers
CPT	Cotrimoxazole Preventive Therapy
DNTLD-P	Division of Tuberculosis, Leprosy and Lung Disease Program
DOTS	Directly Observed Treatment-Short Course
EPTB	Extra Pulmonary Tuberculosis
HAART	Highly Active Anti-Retroviral Therapy
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
IERC	Institutional Ethical Review Committee
JKUAT	Jomo Kenyatta University of Agriculture and Technology
MAM	Moderate Acute Malnutrition
MoH	Ministry of Health
MOH-Kenya	Ministry of Health-Kenya
MTB	*Mycobacterium tuberculosis*
NMS	Nairobi Metropolitan Services
PTB	Pulmonary Tuberculosis
SDGs	Sustainable Development Goals

SPSS	Statistical Package for Social Sciences
TB	Tuberculosis
TB_4	Tuberculosis Facility Register
VCT	Voluntary Counselling and Testing
WHO	World Health Organization
Xpert MTB/RIF	(commonly called **GeneXpert**) is a rapid, automated molecular test used to diagnose **tuberculosis (TB)** and detect **rifampicin resistance** at the same time

DEFINITION OF OPERATIONAL TERMS

Cured This denotes a patient who had bacteriologically confirmed pulmonary TB at initiation of treatment but turned smear or culture negative during the end of treatment and on at least any one other previous occasion.

Died This refers to a TB patient who dies from any cause before starting or during treatment.

Extensive drug resistance This refers to resistance to at least any three second-line injectable drugs, a fluoroquinolone in addition to the patient having multidrug resistance.

Extra pulmonary tuberculosis (EPTB) This refers to a case when TB disease is occurs outside the lung tissues.

Loss to follow-up This refers to a patient diagnosed with TB but who did not start treatment or one who had their treatment interrupted for a period of two or more consecutive months.

Mono-resistance This denotes resistance to any one of the first-line anti-tuberculous drugs.

Multi-drug resistance This is resistance to Rifampicin and Isoniazid with or without any other first-line anti-tuberculous drugs

New patients This denotes a TB patient with no previous treatment for TB before or one who has not taken anti-TB drugs for a period one month or more.

Not evaluated This is a TB patient for whose treatment outcome is not indicated at the reporting site.

Poly-drug resistance This denotes resistance to two or more first-line anti-TB drugs but excluding Isoniazid and Rifampicin together.

Previously treated patients This is a patient who has received TB treatment for one or more months in the past.

Pulmonary TB (PTB) - This denotes presence of TB disease in the lung tissue.

Relapse patients This denotes patients that were previously treated for TB, declared treatment completed or cured in their most recent course of treatment but has new diagnosis of the disease.

Rifampicin resistance This denotes resistance to Rifampicin using genotypic or phenotypic methods, in the presence or absence of resistance to any other anti-TB drug.

Treatment completed This refers to a TB patient who has completed the whole schedule of treatment but do not have a record to show negative culture or sputum smear results at the end of treatment and in at least one previous occasion.

Treatment after failure patients This refers to a previously treated patient for TB but treatment failed during their most recent course of treatment.

Treatment after loss to follow-up patients This refers to a previously treated patient for TB but declared lost to follow-up during the most recent course of treatment.

Treatment failure This is a TB patient whose culture or/or sputum smear result is positive at the 5^{th} month of treatment or any time later.

Treatment outcome This is the final state of the patient during the course of TB treatment or after completion of the full schedule of treatment.

Treatment success This is the sum of the cured and treatment completed TB patients.

Type of patient Standard description of whether the patient is a newly diagnosed case, a re-treatment or otherwise.

ABSTRACT

Tuberculosis (TB) is a serious worldwide health problem that wreaks havoc on health systems, communities, and economies worldwide. The World Health Organization (WHO) ranked tuberculosis (TB) as the thirteenth biggest cause of death and the world's second most infectious killer after corona virus disease (COVID-19) (Chilyabanyama et al., 2024). Kenya ranks among the global 30 high TB burden countries which accounted for 87% of the world's cases. Unlike studies on TB in adults, less is published on the predictors of treatment outcomes in children. The aim of TB treatment policy is to cure patients and therefore alleviate suffering and prevent death from the disease. It's also aimed at preventing long-term complications arising from the disease and prevent relapse. Treatment is also aimed at preventing the transmission of the infection and development of drug resistance. Benefits of TB treatment is attributed to both the individual patient, family and the community as a whole. Outcomes of treatment is a good indicator of performance of the TB program. The broad objective of the study was to determine predictors of treatment outcomes amongst children registered for TB treatment between 1st January, 2018 and 31st December, 2020 at Mbagathi County Hospital. A cross-sectional study design was used that utilised secondary data of children registered for treatment of TB during the three-year period under review from the facility TB register. Data from all 126 children aged < 15 years registered in the years under review was analysed. A structured pre-coded data abstraction tool was used to record patient and clinical variables such as age, sex, weight, nutritional status, type of TB, TB sub-type, Genexpert test, HIV test and treatment outcomes. Data was analysed using Statistical Package for Social Sciences (SPSS) version 27 tool. Descriptive variables were analysed for frequencies. Fischer's exact test was carried out to determine the association and significance between the predictor and outcome variables. Bivariate analysis was carried out to identify the strength of the relationship of the independent variables and the treatment outcome. Statistical significance was considered at *p*-value <0.05. The findings of the study showed that the proportion of males and females was comparable at 62 (49.2%) and 64 (50.8%), respectively. Of these children, 64 (50.8%) were aged below one year and among 114 assessed for nutritional status, 47 (41.2%) had severe acute malnutrition. Among all study subjects, 84 (66.7%) had pulmonary tuberculosis, while 39 (31.0%) had extra-pulmonary tuberculosis; patients with miliary tuberculosis were classified as pulmonary TB cases. HIV testing was conducted in 115 (91.2%) children, with an HIV positivity rate of 28 (22.2%). Genexpert testing was performed in 54 (42.9%) children, of whom 30 (55.6%) had *Mycobacterium tuberculosis* detected. Good treatment outcomes were observed in 68 (53.9%) of the children. Among those aged between one year and less than five years, 13 out of 19 (68.4%) achieved good treatment outcomes, the highest proportion across age groups. Of the 47 children with severe acute malnutrition, 29 (61.7%) had good treatment outcomes. Among 116 children whose DOT supporter was a household member, 63 (54.4%) achieved good treatment outcomes. Children with pulmonary tuberculosis had better outcomes, with 50 (61.0%) achieving favourable results compared to 18 (43.9%) of the 41 children with extra-pulmonary tuberculosis. Binary logistic regression was used to determine whether the patient and clinical level predictors were associated with the likelihood of having favourable/good TB treatment outcome. Out of all variables, type of TB was the only one that significantly contributed to the model. Children below one year of

age contributed the highest TB burden and malnutrition being a very important factor associated with TB disease. Pulmonary TB remained the predominant type of the disease and HIV positivity rate was double the national scale. Most children were self-referrals and those whose treatment outcomes were not evaluated contributed a high proportion of poor treatment outcomes. It is recommended that a good referral framework is implemented so as capture data particularly for treatment outcomes. The more representative multi-centre research is also recommended.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Tuberculosis (TB) is a serious worldwide health problem that wreaks havoc on health systems, communities, and economies worldwide. The World Health Organization (WHO) ranked tuberculosis (TB) as the thirteenth biggest cause of death and the world's second most infectious killer after corona virus disease (COVID-19) (Chilyabanyama et al., 2024). Worldwide, approximately 10.8 million people fell ill with TB in the year 2023 reflecting a TB incidence rate of 134 per 100,000 population. The disease caused approximately 1.25 million deaths, including 1.09 million among HIV-negative people in the same year. The disease remains the leading global cause of death from a single infectious agent (WHO, 2024). TB is caused by *Mycobacterium tuberculosis* and is almost exclusively a droplet infection transmitted from a person with active pulmonary tuberculosis (Azit et al., 2019; Huerga et al., 2019; Sharma et al., 2018). Although TB is preventable and treatable, it remains one of the major causes of death among children. Approximately one million children develop tuberculosis disease, and an estimated 233,000 die from complications of TB each year, corresponding to about 23 deaths every hour (Wobudeya *et al*., 2019; Tao *et al*., 2019). According to World Health Organization (WHO), majority of the patients who developed TB in the year 2019 were in the WHO region of South-East Asia (44%) with Africa contributing 25% of the total burden. Although globally the TB incidence rate is falling it is but not fast enough to attain the 2020 milestone of a 20% reduction between 2015 and 2030. The African region has progressed relatively well with a reduction of about 16% (WHO, 2020b)

Even though there is increased awareness that tuberculosis is a major cause of morbidity and mortality in young children in tuberculosis-endemic areas (Marais *et al*., 2014; Wang *et al*., 2020), childhood TB usually has lower priority compared to adult disease since in the latter, cases are usually few, largely non-infectious and an assumption that controlling adult TB prevents childhood illness (Satyanarayana *et al*., 2010; Onyango *et al*., 2018)). Important to note is the latest TB prevalence survey in

Kenya whose target population comprised only of adult persons but not children aged below 15 years (Enos et al., 2018). In reference to diagnosis, management and reporting of TB cases, the World Health Organization defines children as all persons below the age of 15 years (Brooks et al., 2021) while patients aged 15 years and above are considered as adults (Enos et al., 2018). This has been adopted globally in TB programmes and management.

Gaps in reporting for childhood TB exist even at the global scene with 19 countries out of the 30 high TB burden countries providing data on the overall treatment success rate (that is the sum of the cured and treatment completed TB patients) for children aged 0–14 years in 2018 while the rest did not. Such scenario among others have prompted to start initiative such as Catalysing Paediatric Tuberculosis Innovations (CaP TB) that is being implemented in nine sub-Saharan African countries (including Kenya) and India whose aim is to increase the uptake of innovative approaches to TB diagnosis, treatment, and care in children and adolescents aged 14 years or under (WHO, 2020b). All this is against the backdrop of the Childhood TB Roadmap whose goal is to have zero TB deaths in children by the year 2025 and also highlights the importance of identifying strategies to support the children and their families to improve treatment completion percentages and prevent loss to follow-up (Brooks et al., 2021).

Kenya is among the 30 high TB burden countries which combined accounts for approximately 87% of the world's TB cases (Ngari et al., 2023). In 2023, 97,126 TB cases were notified in Kenya among which 12,884 were children aged below 15 years, accounting for 13.3% of all reported case. The younger children (0-4 years) contributed 60% (7,839) of the total pediatric TB cases notified while the 5-9 age group contributed 17% and 9-14 contributed 22%. Treatment success rate for pediatric TB cohort notified in 2022 was 92% while poor treatment outcomes accounted for 8% with 4.8% death rate included (*Annual TB Report, 2023*). Childhood TB should be a priority area of focus for the national TB control program, because infection with *M. tuberculosis* rapidly progresses to disease in young children and are also predisposed to severe or disseminated forms of TB (Onyango et al., 2018). Treatment outcomes for childhood TB, particularly in Africa, have shown high rates of poor treatment

outcomes (died and loss to follow-up) of between 10 to 19% or more (Satyanarayana et al., 2010) while in Kenya, it is about 8% (*Annual TB Report, 2023*).

According to Kenya TB report (2019), bacteriological diagnosis among children was 5% out of which 30% had Xpert MTB/RIF (Genexpert) results while 18% had an initial smear test done. The human immunodeficiency virus (HIV) co-infection rate among the children was 14.4% with anti-retroviral therapy (ART) uptake of 96.3%. During the same period, an estimated 24% of children were severely malnourished while 9% were moderately malnourished. In the year 2018, childhood treatment cure rate was 87%, death rate 5% and loss to follow-up was 3.9%. Children are infected either directly from an index adult or adolescent case or from reactivation of latent TB (MoH-Kenya, 2020a). in the 2019 childhood TB cohort, treatment success rate was about 89% and cure rate was 66%. Death rate and loss to follow-up were each 4% among these children (Ronoak, 2021).

Once children are diagnosed with first line drug sensitive TB, they are put on a standard 6 months treatment regimen as per the national treatment guidelines. The duration consists of 2 months of the intensive phase with 4 drugs namely rifampicin, isoniazid, pyrazinamide and ethambutol followed by 4 months of the continuation phase with isoniazid and rifampicin. Exceptional treatment regimen is provided for patients with tuberculous meningitis and osteo-articular TB where the continuous phase lasts for 10 months. At the end, treatment outcomes are declared as either cured, treatment completed, treatment failure, died, lost to follow up or not evaluated. All children initiated on treatment are also tested for HIV per the national TB treatment guidelines and those found to be positive initiated on ART immediately (MoH-Kenya, 2020b). Ensuring that children register good treatment outcomes is in tandem with the WHO's End TB Strategy and the United Nations Sustainable Development Goals (SDGs) Health Goal No.3 that aims to ‘ensure healthy lives and promote well-being for all at all ages.’ Target 3.3 aims to, end the epidemics of Acquired Immune Deficiency Syndrome (AIDS), tuberculosis, malaria among other diseases. Translated into numerical targets this means that TB incidence and death rates should be reduced by 80% and 90%, respectively (Lönnroth & Raviglione, 2016) (Teferi et al., 2021)

Several risk factors are associated with poor success of treatment. Malnutrition is well known as a strong risk factor for progression from TB infection to disease and account for about 26% of TB incident globally (Bhat *et al*., 2013). Identifying under-nutrition during TB diagnosis helps to establish baseline nutritional indicators for monitoring the response to treatment (WHO, 2019b). Malnutrition is also associated with a delay in treatment completion. HIV co-infection is also listed as an important risk factor for poor drugs adherence in both adults and children. Other known risk factors for poor TB treatment outcomes in children include being less than five years of age, HIV positivity, smear positivity, low body weight, (Lopez-Varela et al., 2017) as well as the site of TB disease (Hamid et al., 2019). Other independent risk factors for TB mortality include sex of patient and history of prior TB treatment (Adamu et al., 2017) and having smear-positive PTB (Tilahun & Gebre-Selassie, 2016a).

The WHO recommends greater prioritization for quality of TB notification data for children, as well as consistency of case definitions and higher-level coverage of reporting (WHO, 2020a). The key responsibility for successful TB treatment is assigned to the health-care provider, not the patient, and the TB control program should assist the health-care professional and community health volunteers (CHVs) in evaluating patient barriers to adherence and make timely recommendations through the use of a strategy referred to as case management. The strategy's goal is to provide patient-centred care aimed at ensuring all public health activities related to stopping TB transmission are done and that the patient completes treatment. This form of care ensures successful treatment outcomes as it emphasizes tailoring treatment to address both the patient's social and clinical concerns (CDC, 2014).

As a country, Kenya has adopted the WHO guidelines on management of TB. According to policy, the key aim of TB treatment is foremost to cure patients and therefore alleviate suffering and death from the disease. It is also aimed at preventing long-term complications or sequelae arising from the disease and prevent relapse. Treatment is also aimed at preventing the transmission of the infection and curb development of drug resistance. Benefits of TB treatment is attributed to both the individual patient, family and the community as a whole. Any health provider undertaking to treat a patient with tuberculosis assumes an important public health

function that includes not only prescribing an appropriate treatment regimen but also ensuring adherence to the drug regimen until treatment is completed (MoH-Kenya, 2020b). The WHO (2020) TB report raised two issue which are equally very important in our set-up. First was the need to understand the reasons for the relatively high proportion (9.5%) of children for whom the treatment outcome was not evaluated. The second concern was that although nine (9) out of the thirty (30) high TB burden countries reached or exceeded a 90% treatment success rate, the validity of treatment outcome data was not always ascertained (WHO, 2020a).

But patients suffering from TB also have the responsibility to follow the prescribed treatment plan and to strictly comply with the instructions given so as to protect their health and that of others. They are responsible for informing the health providers of any problems or difficulties with following treatment as agreed. The complex relationship between the patient and health care workers is an important determinant of the outcome of TB treatment. A positive relationship or interaction leads to good outcome of treatment and vice versa. At the health care worker level, this interaction is affected by their knowledge on the disease and treatment protocol, skills on patients counselling and education and their attitude towards the patients. Poorly counselled or educated patient on TB and its treatment may end up with poor outcomes; similarly a negative attitude of the health care workers towards the patients will cause them to stop or interrupt the treatment (Ibrahim et al., 2014)

1.2 Statement of the Problem

Childhood TB continues to be a global public health problem. Favourable or good TB treatment outcomes include those classified as treatment completed and cured, while unfavourable or poor treatment outcomes include death, loss to follow-up, treatment failure, or not evaluated. The latter outcomes remain major challenges amongst children with TB despite the high efficacy of first-line anti-TB drugs of up to 95% (Sileshi et al., 2021). In 2019, children accounted for 12% among 7.1 million people that were newly diagnosed and notified with TB worldwide (WHO, 2019a). TB programmes face operational challenges to first ensure that all children diagnosed with TB are notified and treated under the programme and secondly, address challenges

associated with drug logistic management aimed to achieve effective adherence to therapy for optimal treatment outcomes (Satyanarayana et al., 2010). In Kenya, there remain critical challenges to be overcome to eliminate the epidemic that brings needless deaths and suffering to communities. Approximately 50% of the population remains unreached with adequate TB services. Other country challenges include high TB/HIV coinfection, inadequate funding for TB of over 60% funding gap, and inefficiency of active case finding activities (*Annual TB Report, 2023*). Programmes can overcome these challenges by obtaining and evaluating data that already exist within their settings and identifying priority areas such as case notification and treatment outcomes to help them plan for interventions (Satyanarayana et al., 2010). But this is not always the case. HIV is considered an important factor that fuels the TB epidemic. Among other factors, co-infection of TB and HIV often results in severe disseminated disease, particularly in the advanced stages of HIV infection and results in poorer survival compared to HIV-negative children (Belay & Wubneh, 2020). In 2023, the childhood TB/HIV coinfection was 9.3% (1193) out of the total 12,884 cases diagnosed with TB (*Annual TB Report, 2023*).

The Kenya national TB program policy emphasizes case recording and reporting as an important process for monitoring and evaluation disease control activities at the health facility, county and national levels. The indicators for quality of recording and reporting are accuracy, completeness and timely data collection and is the overarching guiding principle for the program. Every health care provider who treats TB has the professional responsibility to record and report all cases treated using the standardized tools provided by the program and which should be used at all service delivery points. This in turn should be aggregated at national level to establish how well the NTLD-P is closer to achieving the currently set programmatic performance indicators (MoH-Kenya, 2023). Non-conformity to all these factors together affects the outcome of treatment and lead to depressed treatment success rates. In the area of study, unlike TB in adults, there is much less published work on characteristics of childhood TB patients, their treatment outcomes and the association between patient and clinical factors with the outcomes.

Kenya's National Tuberculosis, Leprosy and Lung Disease Program prioritizes improving treatment success for childhood TB and reducing TB-related mortality, in line with the WHO End TB Strategy. However, current programmatic data largely report aggregate treatment outcomes without identifying facility-specific predictors of poor outcomes among children. This limits the ability to implement targeted, risk-based interventions. By identifying patient and clinical predictors of treatment outcomes among childhood TB patients at Mbagathi County Hospital, this study addresses a critical evidence gap. It generates context-specific data to support policy refinement, risk stratification, and quality improvement initiatives within Kenya's TB control program.

1.3 Justification

Surveillance data on management of TB in children is an important factor as it helps to define the epidemiological patterns and identify predictors of both good and poor TB treatment outcomes. The WHO recommends that all children diagnosed with TB should be treated and notified through the national TB control programme (Hailu et al., 2014). Childhood TB diagnosis and treatment in Kenya is coordinated by the National TB Control Program and managed according to the national treatment guidelines for management of TB in children, which are adopted from WHO recommendations (Onyango et al., 2018). Results of treatment outcome serve as a crucial indicator and a significant pointer of the quality of care for TB patients that a health care system provides. Treatment cure and treatment success are key outputs that any TB control program aims to achieve (Tilahun & Gebre-Selassie, 2016b).

The results of the study, therefore, highlighted both good and poor treatment outcomes with factors such as age of respondent, type of TB, treatment supporter, and results of Genexpert test showing significant influence in predicting these in children. Both the central and county governments will apply the results to improve on the existing health policies regarding childhood tuberculosis management. The results evaluated the treatment outcomes and identified inadequate level of care especially on follow-up of patients who have transferred for continuum of care from one facility to another. This gap is evidence from the fact that more that 40% of the respondents had unknown

treatment outcomes. This will guide on programmatic as well as financial framework (including donor support) that will be necessary for improved results. The results also highlighted evidence from a high-volume TB facility on the nature of data recorded in the primary data recording tool. This, in turn, will inform planning strategies through interventions such as creating clear linkages for patients transferring from one service delivery point to another and ensure treatment outcome data is also relayed back to the primary treatment site. Death of respondents was also found to be an important factor for poor treatment outcomes and efforts will be made to address contributory factors such as malnutrition and treatment of comorbidities such as HIV infection. Recording of patient-level, clinical-level and diagnostic data that were found to support good treatment outcomes will be enhanced. This will also be used as a guide to other diagnostic and treatment centres on best practices; by providing important information which can be used to improve the current management guidelines that will potentially result to improved child survival. The results will strive to recommend immediate and actionable solutions that will promote success in treatment and therefore alleviate pain and suffering in childhood patients. The impact of this will be overall improvement in child survival.

1.4 Research Questions

i. What are the treatment outcomes among childhood TB patients treated at the TB clinic at Mbagathi County Hospital?
ii. What are the patient-level factors among childhood TB patients attending the TB clinic at Mbagathi County Hospital?
iii. What are the clinical-level factors among childhood TB patients attending the TB clinic at Mbagathi County Hospital?
iv. What are the types of diagnostics for TB among children treated at the TB clinic at Mbagathi County Hospital?

1.5 Objectives

1.5.1 Broad Objective

To determine the predictors of treatment outcomes of childhood tuberculosis among patients attending the TB clinic at Mbagathi County Hospital, Nairobi County.

1.5.2 Specific Objectives

i. To determine treatment outcomes among childhood TB patients attending the TB clinic at Mbagathi County Hospital.
ii. To determine the patient-level factors among childhood TB patients attending the TB clinic at Mbagathi County Hospital.
iii. To determine clinical-level factors of childhood TB patients attending the TB clinic at Mbagathi County Hospital.
iv. To determine the type of diagnostics for TB among children treated at the TB clinic at Mbagathi County Hospital.

1.6 Hypothesis

1.6.1 Null hypothesis (H_0):

There is no significant relationship between patient-level and clinical-level factors and tuberculosis treatment outcomes among childhood TB patients.

1.6.2 Alternative hypothesis (H_1):

There is a significant relationship between patient-level and clinical-level factors and tuberculosis treatment outcomes among childhood TB patients.

1.7 Conceptual Framework

The framework demonstrates that TB treatment outcomes are not determined by a single factor but result from the combined and interacting effects of patient characteristics, clinical care processes, and diagnostic practices. Optimizing these interacting factors increases the likelihood of good TB treatment outcomes**,** while weaknesses at any level increase the risk of poor outcomes among childhood TB patients. This study lacks intervening variables since the framework is designed to assess the direct relationship between patient-level and clinical-level factors and TB

treatment outcomes. Introducing intervening variables would shift the focus from association to causal pathways, which may be beyond the study objectives. Again, we used routine program data whereby intervening variables such as adherence behavior, caregiver health literacy, or immune response are not routinely captured and therefore difficult to measure retrospectively. Thus, the framework excludes intervening variables to maintain data validity and feasibility.

1.7: Conceptual Framework

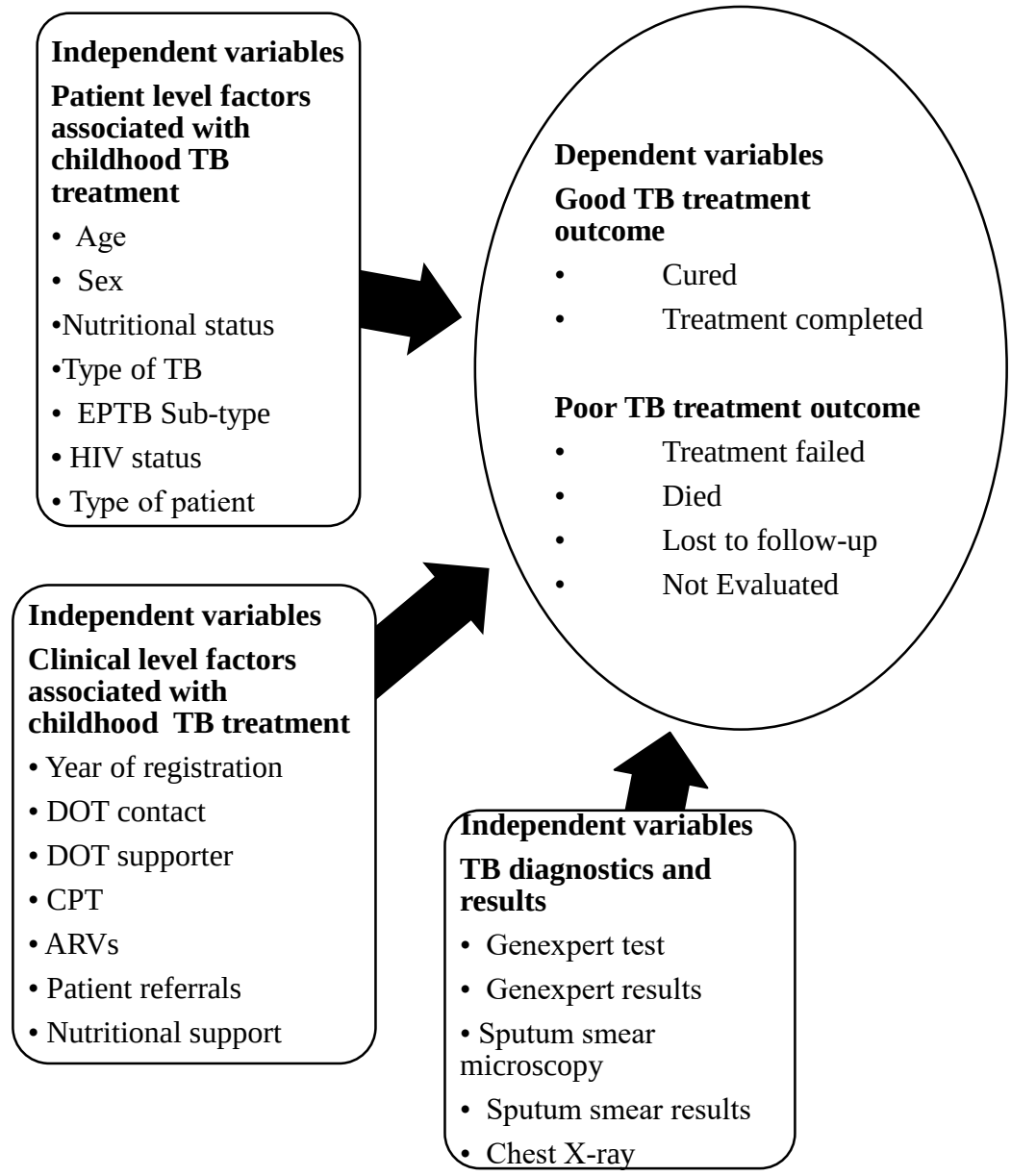

Figure 1.1: Conceptual Framework

CHAPTER TWO

LITERATURE REVIEW

2.1 Epidemiology of Tuberculosis

Although TB is preventable and treatable, it remains one of the major causes of death among children (*Global Tuberculosis Report 2023*, 2023). In 2022, an estimated 1.25 million children and young adolescents aged <5 years fell ill with tuberculosis, an estimated 12% of the total TB incidence of 10.6 million. During the same year, approximately 214,000 children and young adolescents died from TB corresponding to almost 600 deaths daily to this preventable disease. (Verkuijl et al., 2024). According to WHO, majority of the patients who developed TB in 2022 were in the WHO region of South-East Asia (46%) with Africa contributing 23% of the total burden. The global TB incidence rate is estimated to have increased by approximately 3.9% between 2020 and 2022 although African region has seen a steady but not fast enough to attain the 2020 milestone of a 20% reduction between 2015 and 2030. (*Global Tuberculosis Report 2023*, 2023).

2.2 Classification and Treatment of TB

According to the World Health Organization (WHO) guidelines which are adopted by the Division of National Tuberculosis, Leprosy and Lung Disease Program (DNTLD-P) in Kenya, a case of TB can be defined using three classifications. They can be classified based on the anatomical site affected, on the basis of history of previous TB treatment or based on drug resistance according to drug susceptibility test (Final-Paed-Guideline, MoH, 2017). This is illustrated in **Table 2.1.**

Table 2.1: Classification of Tuberculosis

A patient with both pulmonary and extra pulmonary TB should be classified as a case of PTB.	
Classification based on history of previous TB treatment (patient registration group)	
New patients	Patient who has never been treated for TB or has taken anti-TB drugs for less than one month.
Previously treated patients	Patient who has received 1 month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment as follows: • Relapse patients: previously treated for TB, declared cured or treatment completed at the end of their most recent course of treatment and are now diagnosed with a recurrent episode of TB. • Treatment after failure patients: previously treated for TB and whose treatment failed during their most recent course of treatment. • Treatment after loss to follow-up patients: previously treated for TB, and declared lost to follow-up during their most recent course of treatment. (These were previously known as return after default patients)
Patients with unknown previous TB treatment history do not fit into any of the categories listed above.	
Classification of TB patients based on HIV status	
HIV positive	TB patient who has a positive result from HIV testing conducted at the time of TB diagnosis or other documented evidence of HIV diagnosis.
HIV-negative .	TB patient who has a negative result from HIV testing conducted at the time of TB diagnosis. Any HIV-negative TB patient subsequently found to be HIV-positive should be reclassified accordingly.
Unknown HIV status	TB patient who has no HIV test result and no other documented evidence of HIV diagnosis. If the patient's HIV status is subsequently determined, he or she should be reclassified accordingly.

Classification based on drug resistance according to Drug Susceptibility Testing	
Monoresistance the first	Resistance to any one of line anti-TB drugs.
Polydrug resistance	Resistance to both Isoniazid and Rifampicin ± any other first-line anti-TB drugs
Polyresistance	Resistance to more than one first-line anti-TB drug (other than both Isoniazid and Rifampicin).
Multidrug resistance	Resistance to both Isoniazid and Rifampicin ± any other first-line anti-TB drugs
Extensive drug resistance	Resistance to any fluoroquinolone (Levofloxacin, Moxifloxacin) and to at least one of three second-line injectable drugs (Capreomycin, Kanamycin and Amikacin), in addition to multidrug resistance
Rifampicin resistance	Resistance to Rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance

Source: FINAL-PAED-GUIDELINE, MoH, 2017

Recording and monitoring of TB treatment is done using several tools but the primary and most important is the tuberculosis treatment Facility Register (TB_4). This book holds the records of all the patients who have been treated in a particular facility. It is a confidential document safely kept at the TB clinic and is filled by the clinical personnel manning the TB clinic and is filled and dully updated every time the patient comes to the clinic for treatment monitoring and replenishment of anti-TB drugs. Some of the information in the register is transferred ideally immediately the same day to the patient record card. The information contained therein is used to compile the case finding and cohort reports. Several terms are applied to describe treatment outcomes and include cured, treatment completed, treatment success, treatment failure, died, loss to follow up or not evaluated (MoH-Kenya, 2020b).

2.3 TB Treatment Outcomes

2.3.1 Globally

In a TB study done in India among 1064 children aged < 15 years, 984 (92.5%) had favourable outcomes while 80 (7.5%) had unfavourable outcomes (Jackson et al., 2017). In a study done in four hospitals in Pakistan, results of 1404 children aged < 15

years showed that most children (1,322, 94.2%) had successful TB treatment outcomes while 68 (4.8%) experienced unsuccessful treatment outcomes. The latter category included 20 (1.4%) treatment failure, 14 (1.0%) deaths, and 34 (2.4%) lost to follow-up patients. Of the remaining 14 (1.0%) children who were transferred out to other facilities, they were excluded from the primary analysis (Brooks et al., 2021). In another study done in an urban city of central India in children below 15 years of age, 4.84% were declared cured, 93.33% had outcome completed treatment, and 0.60% patients each were transferred out, declared treatment failure and died respectively. There was no statistical significance associated with age and sex with treatment outcome (Joshi, 2018).

Yet in another study done in Delhi, India, there were more female than male children, and the majority (89.6%) of children were aged 5 and below 15 years. Approximately two-thirds (63.3%) of patients had EPTB and the commonest (45.6%) subtype was peripheral lymph-node, followed by abdominal (13.5%) and pleural TB (11.3%), respectively. Among the PTB cases, 42% were sputum smear-positive. Among the re-treatment TB patients, 55.6% had extra-pulmonary TB, 26.4% were sputum smear-positive pulmonary TB cases, while 18.1% were sputum smear-negative pulmonary TB cases (Satyanarayana et al., 2010).

In a study done in Addis Ababa, Ethiopia, children aged 10 years and above were nearly half of the study subjects, while 23.7%. were younger than 5 years. Twenty-three (0.9%) of the children were registered as TB retreatment cases, whereas 47.4% were registered as extra-pulmonary cases. 80% of the smear-positive cases were children aged 10 years and above, with a much higher proportion of females to males having smear-positive TB. The cure rate was 65.3% based on follow-up smear results. The study also found that children below 10 years of age had a much higher proportion (33.8%) of HIV co-infection compared to older children (19.8%). Of all the children registered, 4.9% had no documentation of the treatment outcomes while those with documented treatment outcomes, 85.5% were successfully treated. Older children aged more than 5 years had treatment success rate of 87.3% compared to 78.1% among younger children ($p < 0.001$) (Hailu et al., 2014).

In a study conducted in Accra, Ghana on childhood tuberculosis and treatment outcomes, the majority of the children were registered as new TB cases while 3.8% were relapse and retreatment cases. Among the TB children who were sputum smear positive, 66.3% were aged < 5 years. Of the 37 (17%) children with extra-pulmonary TB, lymph nodes were most commonly affected. The HIV status was documented for almost all the children (97.7%), with 44% of them HIV positive. Among 214 children with documented outcome, 194(90.7%) had good treatment outcome consisting of 9.4% who were cured and 81.3% who completed treatment. Poor outcome was recorded for 20 patients, in which 18 (8.4%) died, one failed treatment and one was not evaluated. Among the children with clinically diagnosed pulmonary TB, treatment completion rate was 91.6% and the children in the age group 10–14 years had the highest (35.6%) proportion of those cured. The death rate was highest among those who were HIV positive (12.6%) and those in age group 1 to 4 years (13.3%) and the smear positive pulmonary TB (12%). There was no child reported to have been lost to follow up (Ohene et al., 2019).

A study in Pakistan looking into the risk factors for unsuccessful TB treatment outcomes in children, had a total of 1,665 children aged less than 15 years who were initiated on treatment with first-line anti-TB drugs and evaluated. There were 933 (56.0%) female and were proportionately 444 (26.7%), 644 (38.7%) and 575 (34.6%) aged 0–4 years, 5–9 years and 10–14 years respectively. There were 565 (40.5%) children who were malnourished. Among all the children, 1,252 (75.2%) were diagnosed with PTB, while 413 (24.8%) had EPTB. A total of 1,421 (85.4%) children evaluated had successful treatment outcomes while among those with poor treatment outcomes, 154 (9.3%) children were lost to follow-up, 27 (1.6%) died, 16 (1.0%) in whom treatment failed and 47 (2.8%) children were not evaluable.(Hamid et al., 2019).In another study conducted in Baluchistan, Pakistan on treatment outcomes of childhood tuberculosis, 66.6% of the study participants were aged < 5 years and 65% had pulmonary TB. Among all patients, 45 (2.3%) were cured, 1680 (86.6%) completed treatment, 15 (0.8%) died, 195 (10%) lost to follow up, 5 (0.3%) failed treatment and 1 (0.1%) was not evaluated for outcomes (Abdullah *et al*., 2020).

2.3.2 In Africa

In a study done in Mozambique on adherence to childhood tuberculosis treatment in 2017, 100% of the cases had documented treatment outcomes and 88.0% of the children successfully completed treatment, 4.0% had died while 8.0% were lost to follow-up. None of the outcome was treatment failure (Lopez-Varela et al., 2017).

In a systematic review and meta-analysis study in Ethiopia, the overall pooled childhood TB treatment success rate was 79.62% of which 7.1% were cured and 72.44% were treatment completed. Among the unsuccessful TB treatment outcomes (20.38%), treatment failure, loss to follow-up, and death were 0.15%, 5.36%, and 3.54%, respectively.

Results of a study on TB treatment outcomes of 535 children below 15 years of age in Lagos, Nigeria showed that about 61.3% of the children were aged between 5 and 14 years while 13.0% were <1 year old. About 91% of the children had pulmonary TB, of which 93% were new TB cases. Out of these cases, 69.9% were diagnosed by chest radiographs, 20.6% by smear microscopy and 3.7% were diagnosed clinically. HIV test was not done for 42 (76.9%) children with a positivity rate of 29% (149/493). Treatment success was reported to be 77.4% while 6.0% died and 15.0% were lost to follow-up. Proportionately, treatment success was much higher among children aged 5–14 years (82%) compared with those aged between 1–4 years (75.3%) and those <1 year (59.4%) ($p < 0.001$). The proportion of children that died while receiving treatment (13.0%) and defaulted (27.5%) was higher in those <1 year old compared with the other age groups ($p < 0.05$). About (78%) of the HIV-negative children against 73.4% of those who were HIV positive had successful treatment (p ¼ 0.127). However, 11.2% of the HIV positive children treated for TB compared with 4.0% of HIV-negative children died ($p < 0.001$). The proportion of lost to follow-up among the HIV-positive and HIV-negative children was almost similar. A higher proportion (44.9%) of children <1 year compared with those who were 1–4 years and 5–14 years were HIV positive. The mean age of children who had treatment success was higher ($p = 0.004$). The children gender, HIV status and type of TB were not associated with treatment success (Adejumo et al., 2016).

In a study done in Tigray, Ethiopia for the period September 2007 to August 2016, a total of 1086 cases were children age < 15 years of age. Majority of these, 1082 (99.7%) were new case, with the mean age of children 8 years with (SD ± 4.09). On sex distribution, females were 701 (64.5%) while the predominant form of TB was extra pulmonary tuberculosis 678 (62.4%). In total, 843 (77.6%) children were tested for HIV and 69 (8.3%) TB/ HIV co-infection. Majority of the respondents, 841 (77.4%) had known treatment outcome recorded, 241 (22.2%) cases as transfer out and 4 (0.04%) cases had unknown treatment outcome. Among the respondents with known treatment outcome, 746 (88.7%) had good outcome, 95 (11.3%) cases were unsuccessfully treated in which 35 (4.2%) died (Mirutse et al., 2019).

In another study conducted in Addis Ababa, Ethiopia, the overall successful treatment among 420 respondents was 85.5 % and almost equal between males and females at 85.8 % and 84.9 % respectively. Treatment success among new TB cases compared to relapse cases was 85.7% and 60 %, respectively (P = 0.32). Children who were HIV seropositive had a lower treatment success of 70.7% compared to 82.5% of those with unknown HIV status (p=0.00) similarly, children aged between 5–9 years had higher treatment success of 123 (88.5 %) against 24 (72.7%) of children under one year of age (P < 0.05). Patients with EPTB had higher treatment success (86.6%) compared to 81.0 % for sputum positive PTB and 85.0 % of smear negative PTB. The poor outcome of treatment identified showed that 9 (1.8 %) died, 3 (0.6 %) were defaulters from treatment, 55 (11.2 %) were transferred out and 2 (0.4 %) were treatment failure. Childhood treatment outcomes were not indicated in 3 (0.6 %) cases of the children. The death rate was higher in children aged 1–4 years which was 3/74 (4.1 %) followed by 4/245 (1.6 %) among the age group 10 to below 15 years (Tilahun & Gebre-Selassie, 2016b).

In a retrospective study done in rural Southern Mozambique, out of 933 children enrolled for treatment of TB, 22 (2.4%) were excluded for analysis due to missing data. Of the 911 cases included in the analysis, 493 (54.1%) were male and 452 (49.6%) were < 5 years of age. Among these, majority 863 (94.7%) were new TB cases. Among the 733 (80.4%) cases classified as pulmonary tuberculosis, 18 (2.5%) were diagnosed by Genexpert. Comparatively, 74 (10.0%) were diagnosed by chest

radiograph and 49 (6.7%) were diagnosed by smear microscopy. All 178 cases classified as extra-pulmonary tuberculosis cases and 592 (80.8%) PTB were clinically diagnosed. Among the children with extra-pulmonary TB, (39.8%) had lymph nodes involvement, pleura (6.7%), followed by abdomen (5.6%), and bone/joint (5%). Among those classified as EPTB, forty-one percent had no data recorded for site of disease with no cases of TB meningitis were documented. Five hundred sixty-five (62%) of the children in the study were HIV-positive and seven hundred sixty-two (83.6%) had a good treatment outcome (cured and treatment completed). Out of 149 (16.3%) children with an poor treatment outcome, 28 (18.8%) were lost to follow-up, 97 (65.1%) died, 19 (12.8%) were listed as unknown, and 5 (3.3%) had treatment failure. The proportion of poor treatment outcomes was higher among children 0–4 years of age (65.8% vs. 34.2%) for those 5 and below 15 years of age (Moon *et al*., 2019).

2.3.3 In Kenya

In a epidemiological study in Kenya involving 23,753 children, 21,493 (90%) had good treatment outcome, 1833 (8%) of children were reported to have poor outcomes while 427 (2%) transferred out and their final treatment outcome was unknown (Onyango et al., 2018). In another study done among nomadic pastoralists in Kenya, children who were under five years constituted the highest proportion (61%). Most of the patients had completed their treatment (69.5%), lost to follow up 6.8%, transferred out 11.9%, died 8.5% while those who were not evaluated were 3.4%.(Godfrey M *et al.*, 2023). While it is important to improve access to laboratory-based diagnosis for children in order to obtain bacteriological confirmation of TB disease whenever possible, the performance of currently available diagnostic tests, including the rapid molecular assays, remains limited in children. Therefore, a negative Genexpert test should not rule-out active TB disease. In the presence of TB signs and symptoms, all children with a negative test should be further evaluated through CXR and clinical assessment. In order to support the clinical-radiological diagnosis of pediatric TB (Catalyzing-Pediatric-Tuberculosis-Project-in-Kenya-2021).

Overall, poor or unsuccessful childhood TB treatment outcomes have been cited in a vast majority of the studies and therefore, relevant strategies need to be adopted to address them. Addressing the predictors concerned will greatly enhance childhood TB care.

2.4 Factors Associated with Treatment Outcomes

Individual-level predictors such as children who have HIV co-infection, are less than five years old, are bacteriologically sputum positive, and have a low body weight have an increased risk of experiencing unsuccessful treatment outcomes. There is, however, limited predictor evidence on the strength of facility-level characteristics which may vary by setting and population (Brooks et al., 2021). These factors, which include the level of care, diagnostic capacity, and staffing expertise, could not be studied from secondary data. In a study done in Botswana, the factors associated with unfavourable outcomes were positive HIV status (AOR 2.71, 95% CI: 2.09–3.52), unknown HIV status (AOR 2.07, 95% CI: 1.60–2.69) and retreatment category (AOR 1.92, 95% CI: 1.30–2.85). Compared with the 0–4 years age category, the 5–9 years (AOR 0.62, 95% CI: 0.47–0.82) and 10–14 years (AOR 0.76, 95% CI: 0.60–0.98) age categories were less likely to experience the unfavourable outcomes (Siamisang et al., 2022). From a study done in Lusaka, Zambia, the univariate analysis showed that, age, sex, type of TB, HIV status, treatment history, and diagnostic type were all not significantly associated with the unsuccessful treatment. In multivariable logistic regression, children with extrapulmonary TB had 1.64 times greater odds of having unsuccessful treatment outcomes than children with pulmonary TB (AOR 1.64; 95% CI: 1.022.62) and this was statistically significant (Ngosa & Lupenga, 2024). Another study done in Sierra Leone found that out of the 689 children, 222 (32.2%) had favourable outcomes (cured 1.3%; treatment completed 30.9%) and 467 (67.8%) had unfavourable outcomes (death 7%; loss to follow-up 29.9%; and not evaluated 30.9%). Treatment success was 46.6% after excluding patients classified as ‘not evaluated’. HIV positive children had a higher risk of unfavourable outcomes compared to HIV-negative children (aRR = 1.2, 95% CI: 1.0–1.3). Children with an unknown HIV status had the highest risk, with all cases (100%) classified as having unfavourable outcomes (aRR

= 1.5, 95% CI: 1.4–1.7). EPTB was associated with higher risk (aRR = 1.2, 95% CI: 1.0–1.3) compared to pulmonary TB (Sesay *et al*., 2026).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

The study was based at the TB clinic in Mbagathi County Hospital, Nairobi County bordering Kenyatta National Hospital in Kibra Sub-County. This is a public health facility under the department of health services in the county government of Nairobi. The facility started as an infectious disease hospital and now offers a wide range of health services as well as running medical training programs in collaboration with the Kenya Medical Training College and University of Nairobi among many other institutions. It is a 300-bed capacity hospital offering promotive, preventive, curative and rehabilitative health care services including special clinics like the TB and Leprosy clinic. Under the Division of National Tuberculosis, Leprosy and Lung Disease Program, the hospital implements the directly observed treatment-short course (DOTS) strategy in diagnosis and management of TB in children. The TB clinic is a fully functional centre offering all services pertaining to diagnosis and treatment of tuberculosis with services running throughout the week-days. Mbagathi County Hospital is located near Kibera slums which is the most expansive informal settlement in the East African region. The facility is the major referral hospital for tuberculosis country-wide with a very high case load of children undergoing treatment. The facility was purposely selected as the study centre for being the single largest high volume referral TB diagnostic and treatment facility in Kenya.

3.2 Study Design

This study adopted the cross-sectional study design using secondary data extracted from routinely collected health records during treatment for children diagnosed with TB in the three years under study.

3.3 Study Population

This included all entries of patients under the age of fifteen years registered in the Facility TB Register (MoH TB_4) between 1st January, 2018 and 31st December, 2020.

A total of 126 patients were registered during this period. During the patient's initiation of treatment, demographic information of date of initiation of treatment, residence, name, age, sex, nationality, weight (at initiation of treatment), physical address and contact phone number of both patient and treatment supporter is recorded. The DOT supporter during the intensive phase of treatment is noted. Other variables recorded are type of TB, type of patient (standard description of whether the patient is a newly diagnosed case, a re-treatment or otherwise), investigations done and their results, date treatment was started, treatment regimen and results of HIV test. On HIV positive patients, cotrimoxazole preventive therapy (CPT) and anti-retroviral therapy if given and dates started is recorded, whether the patient is given nutritional support and any other co-morbidity is captured. Finally, the date and outcome of treatment is recorded.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

i. Records of patients aged below 15 years during the identified study period.
ii. Patients with confirmed clinical or bacteriological diagnosis for tuberculosis.
iii. Patient registered in the facility TB_4 register at the TB clinic, Mbagathi county hospital.

3.4.2 Exclusion Criteria

i. Entries missing more than five variables that are part of the study.
ii. Patients with multi-drug resistant (MDR) TB.
iii. Patient registered but later found not to be a case of TB.

3.5 Sample Size

The sample size of this research was calculated using Taro Yamane's (Yamane, 1973) formula with 95% confidence level.

$n=N/(1+N(e)^2)$

Where:

n= sample size required

N = number of people in the population

e = allowable error (%)

Thus

$$n=126/(1+126(0.05)2)$$

$$=126/1.315$$

$$= 95.8$$

$$=96$$

The calculated sample size is 96 entries.

A census was used due to the small population size.

3.6 Sampling Method

Since the calculated sample size was almost equal to the study population, and other sampling methods are not appropriate, the census method was applied, where all eligible entries for the duration under study were included. This method was also used since the data were readily available for the children under study.

3.7 Variables

3.7.1 Dependent Variable

i) Good TB treatment outcome categorized as cured and treatment completed.

ii) Poor TB treatment outcome such as, died, lost-to-follow-up and those not evaluated.

3.7.2 Independent Variables

i) Patient-level factors such as age, sex, nutritional status, type of TB, EPTB Sub-type, HIV status and type of patient

ii) Clinical-level factors associated with TB such as DOT supporter, CPT, ARVs, patient referrals and type of nutritional support.
iii) TB Diagnostic method and results such as Genexpert test, sputum microscopy and chest X-ray.

3.8 Data Collection

3.8.1 Data Collection Tool

Data was recorded on a pre-coded structured data abstraction form. The tool was developed from the specific objectives and aligned to the entries in the tuberculosis treatment Facility Register (TB_4), which was the data source document. Therefore, all the information in the tool is routinely recorded for all the patients at registration and during treatment.

3.8.2 Data Collection Procedure

Initially, all the TB_4 registers in which patients were notified for the years 2018, 2019, and 2020 were identified, and verified that none were missing. They were all available and found to be in good physical condition and not defaced. Then, verification for the actual starting and ending dates was done. Thereafter, names and registration numbers of the patients were occluded using removable cello tape so that no identifiable information was available. Two health records and information officers were recruited as research assistants to extract and record data. They received standardized one full-day training on study objectives, variable definitions aligned with World Health Organization and Kenya Ministry of Health guidelines, ethical considerations, and data extraction procedures. A pilot test, structured abstraction tool, and detailed coding manual were used to ensure consistency. Data reliability was strengthened through inter-rater reliability checks using Cohen's kappa on a sample of records, resolution of discrepancies by consensus, supervisory review of extracted data, double data entry, and routine validation checks to minimize errors and inconsistencies. The research assistants accessed identifiable hospital records only within the facility for data extraction, but no personal identifiers were recorded, and all data were de-identified before analysis. They signed confidentiality agreements, received training on research

ethics and data protection, and worked under the close supervision of the principal investigator to ensure compliance with ethical standards. The principal investigator was part of the data extraction team as well as the overall supervisor of the process. All the data for children aged below 15 years of was then extracted and recorded individually in the abstraction tool. Preparation and actual exercise of data collection were carried out over a period of three months. Data was cleaned on-site daily. All entries had adequate data points and were deemed appropriate for this study.

3.9 Data Management and Analysis

3.9.1 Data Management

All the filled data abstraction tools were stored safely under lock and key. The only persons allowed access to the information were the principal researcher, the research assistants, or any other authorized researchers, and only for the purposes of the study. The principal researcher was the custodian of the master file database and all the backup copies. A linking file was created and stored separately from the data set. The soft-copy data files contained no personal identifiers. Phone numbers were only documented as whether recorded in the register or not, but the actual contact numbers were not captured. Additionally, the files in the computer were encrypted and password-protected to ensure that there was no unauthorized access to them.

3.9.2 Data Analysis

The collected data was then entered into the Statistical Package for Social Sciences (SPSS) version 27 tool database for analysis. Predictor variables were analysed for frequencies while Fischer's exact test was carried out to determine significance association between the predictor and outcome variables. Fisher's exact test was chosen because the study involved assessing associations between categorical variables, some of which had small cell counts with expected frequencies less than 5 in contingency tables. Unlike the chi-square test, it does not rely on large-sample assumptions and provides an exact p-value. This made it more appropriate and statistically reliable for analyzing sparse data, thereby improving the validity of the study findings. Bivariate analysis was used to show the relationship between the

predictor variables and the outcome variable. Statistical significance was considered at p-value <0.05.

3.10 Ethical Considerations

Ethical approval for this study was given by the National Commission for Science, Technology and Innovations (NACOSTI) under licence number NACOSTI/P/22/15160. The protocol was also reviewed by the Jomo Kenyatta University of Agriculture and Technology (JKUAT) institutional ethical review committee (IERC) and the approval was granted vide approval number JKU/IERC/02316/0429. Since the study design was retrospective where records of patients were used, a waiver of consent was requested from the in-charge of the data collection site in the records department. The waiver, however, did not adversely affect the rights and welfare of subjects, that data confidentiality was strictly maintained, and that identifiers were handled to minimize re-identification risk. Once the letters of ethical approval were obtained, they were used to request for permission to collect the data from the Executive Office of the President, Nairobi Metropolitan Services (NMS) which was granted through the letter REF: EOP/NMS/HS/104. Subsequently, the medical superintendent gave permission to collect data from Mbagathi County Hospital. They were all explained the intentions of the study and that the details captured were not be used for any other purpose other than for this research. They were also be informed that no identifying information was to be collected in the data collection tool. In consideration of the confidentiality for human medical records, all protocols were applied while handling the treatment registers. Permission to collect data was subsequently granted. Hospital records were accessed only after obtaining ethical and administrative approval and were reviewed within the hospital premises by authorized research team members. Only relevant variables were extracted using a structured tool, and no original files were removed from the facility. All data were de-identified before analysis by assigning unique study codes and excluding personal identifiers. Hard copies were stored in locked cabinets, and electronic data were password-protected and encrypted, with access limited to the principal investigator and retained according to institutional data protection policies.

3.11 Limitations of Study

This study had key limitations, including incomplete outcome data, which may have biased treatment success estimates and affected observed associations. As a retrospective review conducted in a single referral facility, it is also subject to possible selection bias and limited representativeness. Patients managed at this centre may differ from those treated in peripheral facilities, limiting generalizability. These limitations should be considered when interpreting the findings. The nature of the study design being cross-sectional also limited the ability to question the reasons for the few inconsistencies at the time of data collection. The retrospective design and incomplete records may have introduced bias, as missing data could skew associations if certain patient subgroups were systematically undocumented. Transferred-out patients with unknown outcomes could further bias results, affecting both the accuracy and generalizability of the study's findings, which should therefore be interpreted cautiously. We could not understand the mechanism used to communicate information once patients are transferred out from the diagnostic centre where they have already been registered

CHAPTER FOUR

RESULTS

4.1 Patient-Level Factors Associated with TB Treatment Outcomes

Out of 126 respondents, 58 (46.1%) had poor treatment outcomes, of which 55 (43.7%) had unknown treatment outcomes. Including "unknown treatment outcome" in childhood TB reporting is essential for accurate program evaluation because it prevents overestimation of treatment success and reveals gaps in follow-up, documentation, and patient tracking systems. Transparent reporting also uncovers hidden burdens such as deaths or treatment interruption, improving resource allocation, research validity, and overall health system accountability. Otherwise, treatment success was 68 (94.4%) if patients classified as unknown outcome were excluded. In 19 children aged between 1 year and < 5 years, 13 (68.4%) had good treatment outcomes, which was the highest compared to the other age groups. Age was significantly associated with treatment outcome (Fisher's Exact test, $p<0.05$). Among 84 children who had pulmonary tuberculosis, 51 (60.7%), compared to 17 (43.6%) of 39 children who had EPTB got good treatment outcome. Out of 19 children with pleural effusion, 10 (58.8%) had successful treatment outcome and the highest among the other extra-pulmonary TB subtypes. The type of TB was significantly associated with treatment outcome (Fisher's Exact test, $p<0.05$ **(Table 4.1).**

Table 4.1: Comparison between Patient-Level Factors and Treatment Outcomes

	Treatment Outcome					Fisher's Exact Test	
Variable	**Cured**	**Treatment Completed**	**Died**	**Unknown outcome**	**Total**	**Value**	**Exact sig. (2-sided) (p-value)**
Sex							
Male	3 4.8%	32 51.6%	2 3.2%	25 40.3%	62	3.882	0.290
Female	7 10.9%	26 40.6%	1 1.6%	30 46.9%	64		
Age							
< 1 year	0 0.0%	31 48.4%	1 1.6%	32 50.0%	64		
1 < 5 years	2 10.5%	11 57.9%	2 10.5%	4 21.1%	19	22.867	<0.001
5 < 15 years	8 18.6%	16 37.2%	0 0.0%	19 44.2%	43		

	Treatment Outcome					Fisher's Exact Test	
Variable	**Cured**	**Treatment Completed**	**Died**	**Unknown outcome**	**Total**	**Value**	**Exact sig. (2-sided) (p-value)**
Nutritional status							
Severe Acute Malnutrition	6 12.8%	23 48.9%	1 2.1%	17 36.2%	47		
Moderate Acute Malnutrition	1 5.6%	4 22.2%	0 0.0%	13 72.2%	18		
Mild malnutrition	1 6.2%	8 50.0%	1 6.2%	6 37.5%	16	13.873	0.575
Normal	1 3.1%	15 46.9%	1 3.1%	15 46.9%	32		
Overweight	0 0.0%	1 100.0%	0 0.0%	0 0.0%	1		
Not calculable	1 8.3%	7 58.3%	0 0.0%	4 33.3%	12		
Type of TB							
Pulmonary	10 11.9%	41 48.8%	1 1.2%	32 38.1%	84		
Extra-pulmonary	0 0.0%	17 43.6%	2 5.1%	20 51.3%	39	12.263	0.034
Not indicated	0 0.0%	0 0.0%	0 0.0%	3 100.0%	3		
EPTB subtype	0						
TB adenitis	0 0.0%	3 33.3%	0 0.0%	6 66.7%	9		
TB Pleural Effusion	0 0.0%	10 58.8%	0 0.0%	9 41.2%	19		
Not a case of EPTB	10 12.5%	38 47.5%	1 1.3%	31 38.8%	80		
Not indicated	0 0.0%	1 28.6%	2 28.6%	5 42.9%	8	22.575	0.176
Miliary TB	0 0%	3 75.0%	0 0%	1 25.0%	4		
TB Pericarditis	0 0.0%	1 100.0%	0 0.0%	0 0.0%	1		
TB Meningitis	0 0.0%	2 40.0%	0 0.0%	3 60.0%	5		
HIV status							
Positive	3 11.7%	16 57.1%	2 7.1%	7 25.0%	28		
Negative	6 6.8%	35 40.9%	1 1.1%	45 51.1%	87	10.223	0.077
Not recorded	1 9.1%	7 63.6%	0 0.0%	3 27.3%	11		

4.2 Comparison between Clinical Level Factors and Treatment Outcomes

Out of 116 children whose DOT supporter was a household member, 63 (54.4%) had good treatment outcomes. Treatment supporter in the intensive phase of treatment was significantly associated with treatment outcome (Fishers Exact test, $p<0.05$). Among

30 children who were Genexpert test positive on diagnosis, 20 (66.7%) had good outcomes while among 24 children who were Genexpert negative, 10 (41.7%) had successful treatment outcome. Results of Genexpert test was significantly associated with treatment outcome (Fishers Exact test, $p<0.05$). Fisher's Exact Test was used instead of the Chi-square test because some contingency table cells had very small or zero counts, making Chi-square assumptions invalid. It provides exact probabilities and is therefore more accurate and reliable for small samples or rare outcomes, such as childhood TB treatment subgroups **(Table 4.2).**

Table 4.2: Relationship between Clinical Level Factors and Treatment Outcomes

	Treatment Outcome				**Total**	**Fisher's Exact Test**		
Variable	**Cured**	**Treatment Completed**	**Died**	**Unknown outcome**		**Value**	***Df***	**Exact sig. (2-sided) (p-value)**
DOT supporter								
Health Care Worker	1	0	0	0	1			
	100.0%	0.0%	0.0%	0.0%				
Household member,	9	54	2	51	116			
Friend or Relative	7.8%	46.6%	1.7%	44.0%		16.898		0.040
Community Health	0	2	0	0	2			
Volunteer	0.0%	100.0%	0.0%	0.0%				
No DOT supporter	1	1	1	4	7			
	14.3%	14.3%	14.3%	57.1%				
Genexpert results								
Positive, no rifampicin	9	11	0	10	30			
resistance	30.0%	36.7%	0.0%	33.3%				
Negative	0	10	1	13	24			
	0.0%	41.7%	4.2%	54.2%		21.176		<.001
Not applicable	1	37	2	32	72			

4.3 Patient-Level Factors Associated with Childhood TB Treatment Outcomes

Binary logistic regression showed that the model was not statistically significant, $\chi^2(6) = 7.80$, $p = 0.253$, indicating that the predictors did not reliably distinguish between good and poor TB treatment outcomes. The model demonstrated weak explanatory power, accounting for only 6.0% (Cox & Snell R^2) to 8.0% (Nagelkerke R^2) of the variance, suggesting limited strength in predicting outcomes. Although the model correctly classified 62.7% of cases, this may not represent a meaningful improvement over chance. Only the type of TB significantly contributed to the model, with an odds ratio of 0.40, as reflected by odds ratios whose 95% confidence intervals included 1.0,

indicating that patients in that TB category were 60% less likely to have a favourable treatment outcome compared to the reference **(Table 4.3).**

Table 4.3: Results of Bivariate Analysis for Patient-Level Predictors and Outcome Variables

Variables in the Equation								
							95% C.I. for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Sex of Child	-.111	.372	.089	1	.765	.895	.432	1.854
	Age of Child	.197	.218	.814	1	.367	1.218	.794	1.868
	Nutrition Status of Child	.029	.101	.081	1	.776	1.029	.844	1.255
	Type of TB	-.907	.371	5.961	1	.015	.404	.195	.836
	Extra-pulmonary TB Sub-type	.035	.165	.045	1	.832	1.036	.749	1.432
	Child's HIV Status	-.176	.358	.242	1	.623	.838	.416	1.691
	Constant	.406	.658	.381	1	.537	1.501		

4.4 Bivariate Analysis of Clinical Level Factors Associated with TB Treatment Outcomes

Binary logistic regression showed that the model was not statistically significant, $\chi^2(6) = 9.39$, $p = .153$, indicating that the clinical predictors did not adequately distinguish between favourable and poor TB treatment outcomes. The model demonstrated weak explanatory power, accounting for only 7.2% (Cox & Snell R^2) to 9.6% (Nagelkerke R^2) of the variance, suggesting limited predictive strength. Although 58.7% of cases were correctly classified, this accuracy may be close to the base-rate and does not necessarily indicate meaningful improvement. None of the clinical variables significantly contributed to the model, as reflected by odds ratios whose 95% confidence intervals included 1.0, indicating a lack of statistically significant association between the predictors and treatment outcome **(Table 4.4).**

Table 4.4: Results of Bivariate Analysis for Clinical Level Predictors and Outcome Variable

		Variables in the Equation							
								95% C.I. for Exp(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Who is DOT Supporter in Intensive Phase of Treatment?	-.417	.408	1.045	1	.307	.659	.296	1.466
	What was the Genexpert Results?	-.142	.094	2.271	1	.132	.868	.721	1.044
	Sputum Smear Results at 0 month (Diagnosis)	-1.398	1.136	1.515	1	.218	.247	.027	2.290
	Was Patient put on ARVs?	-.210	.174	1.451	1	.228	.811	.576	1.141
	Patient Referred 'By' or 'From'	.133	.087	2.346	1	.126	1.142	.964	1.353
	Type of Nutritional Support	.035	.105	.108	1	.742	1.035	.843	1.272
	Constant	3.504	2.324	2.274	1	.132	33.242		

4.5 Patient-Level Factors among Children Treated for Tuberculosis

Out of 126 children registered for TB treatment during the period of study, the proportion of males and females was comparable 62 (49.2%) and 64 (50.8%) respectively and 64 (50.8%) were aged < 1 year of age. Additionally, out of 114 children, 47 (41.2%) had severe acute malnutrition. The “Not calculable” category under nutritional status refers to cases where the patient’s weight measurement was unavailable, making it impossible to compute standard indicators such as weight-for-age. These were treated as missing data in the analysis and were excluded from calculations involving nutritional status, but they were documented to reflect the extent of incomplete records. Out of the 126 children, 84 (66.6%) had pulmonary TB and 39 (31.0%) had extra-pulmonary tuberculosis. Miliary TB was categorized as pulmonary type of TB. Out of the 39 cases of extra-pulmonary TB, pleural effusion was disproportionately (19/39; 48.7%) the most frequent sub-type. In total, 115 (91.3%)

children were tested for HIV and the HIV positivity rate was (28/115; 24.3%) (**Table 4.5**).

Table 4.5: Description of Patient-Level Factors among Children Treated for TB

Variable	Frequency	Percent
Sex		
Male	62	49.2
Female	64	50.8
Age		
<1 year	64	50.8
1 ≤ t < 5years	19	15.1
5 ≤ t < 15years	43	34.1
Nutritional status		
Severe Acute Malnutrition	47	41.2
Moderate Acute Malnutrition	18	15.8
Mild malnutrition	16	14.0
Normal	32	28.1
Overweight	1	0.9
Not calculable	12	-
Type of TB		
Pulmonary	84	66.6
Extra-pulmonary	39	31.0
Not indicated	3	2.4
EPTB sub-type		
TB Lymphadenopathy	9	23.1
TB Pleural Effusion	19	48.7
Subtype not indicated	5	12.8
TB Pericarditis	1	2.6
TB Meningitis	5	12.8
HIV testing		
Positive	28	22.2
Negative	87	69.1
Not recorded	11	8.7

4.6 Clinical-Level Factors among Children Treated for TB

Out of 126 children, 116 (92.1%) had a household member indicated as the treatment supporter during the intensive phase of treatment. Out of the 28 children who were HIV positive, (23/28; 82.1%) were on cotrimoxazole preventive therapy (CPT) and (22/28; 78.6%) were on highly active ant-retroviral therapy (HAART). Although national policy mandates the immediate initiation of HAART for all HIV-positive TB patients at the time of diagnosis, documentation was missing for 5 patients (17.9%) regarding initiation of antiretroviral therapy (ART) and for 6 patients (21.4%)

regarding initiation of cotrimoxazole preventive therapy (CPT). These cases were retained in the analysis to reflect gaps in data recording, rather than to indicate that the patients had not been started on the respective treatments. Out of 126 children, 89 (70.6%) were self-referrals to the hospital for treatment while 97 (77.0%) were indicated to be referred to the TB clinic **(Table 4.6).**

Table 4.6: Description of Clinical-Level Factors among Children Treated for TB

Variable	Frequency	Percent
DOT supporter in intensive phase		
Health care worker	1	0.8
Household member	116	92.1
Community health volunteer	2	1.6
No DOT supporter	7	5.5
Cotrimoxazole Preventive Therapy		
Yes	23	82.1
Not recorded	5	17.9
Antiretroviral therapy (ARVs)		
Yes	22	78.6
Not recorded	6	21.4
Patient Referred 'From'		
HIV Comprehensive Care Clinic	1	0.8
Private center	7	5.6
Self-referral	89	70.6
Contact invitation	1	0.8
Community Health Volunteer	2	1.6
Hospital ward (inpatient)	19	15.0
Any other site e.g. chemist	7	5.6
Patient Referred 'To'		
Voluntary Counselling and Testing Center	2	1.6
HIV Comprehensive Care Unit	2	1.6
Nutrition Clinic	23	18.2
TB Clinic	97	77.0
Not indicated	2	1.6

4.7 Diagnostic Methods Used among Children Treated for Tuberculosis

Among the 126 children included in the study, 54 (42.9%) underwent Genexpert testing at diagnosis. Of these, 28 (51.9%) tested positive for *Mycobacterium tuberculosis*, with no detected resistance to rifampicin. Additionally, 6 children (4.8%) underwent sputum smear microscopy at diagnosis, of whom 1 (16.7%) had a positive result. Young children often cannot expectorate sputum voluntarily because they lack

the ability to cough deeply and produce a specimen on request unless in older children**.** Paediatric TB is often paucibacillary (low bacterial load), reducing the likelihood of detecting bacilli even if a sample is obtained Chest radiography was performed in 121 children (96.0%) at diagnosis; 92 (76.0%) demonstrated radiological findings suggestive of tuberculosis. Overall, 29 children (24.0%) had bacteriological confirmation of tuberculosis by either Genexpert or sputum smear microscopy. These diagnostic modalities were applied independently, and individual patients could have undergone one, more than one, or all of the investigations (**Table 4.7**).

Table 4.7: Diagnostic Methods Used Among Children Treated for TB at Mbagathi County Hospital

Type of test	Frequency	TB positive (%)	TB negative (%)
Genexpert	54	28 (51.9)	26 (48.1)
Sputum smear	6	1 (16.7)	5 (83.3)
Chest X-ray	121	92 (76.0)	29 (24.0)

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Treatment Outcomes among Childhood TB Patients

A total of 126 children aged below 15 years were evaluated. Among the 62 children categorized as having poor treatment outcomes, 88.7% were classified as "not evaluated" due to transfer-out or unknown treatment status. This indicates that poor outcomes were largely driven by documentation and follow-up gaps rather than confirmed treatment failure or death. Although TB services in Kenya are decentralized, registering patients at diagnosis without a robust mechanism for tracking those who transfer to other facilities may contribute to incomplete outcome evaluation. Since the study site is a major diagnostic centre, strengthened inter-facility coordination and active follow-up systems are necessary to improve outcome documentation.

A major limitation of this study was the high proportion of children classified as "not evaluated," largely due to transfer-out and undocumented outcomes. This substantial missing data may have led to either underestimation or overestimation of the true treatment success rate and may have biased the observed associations between predictors and treatment outcomes. Because many patients were diagnosed at a referral centre but continued treatment elsewhere without robust follow-up mechanisms, outcome documentation was incomplete. Therefore, the findings on treatment success and associated factors should be interpreted with caution, and improved inter-facility tracking systems are needed to enhance data completeness and validity in future studies.

Treatment success was higher among male children and those aged 1 to <5 years compared to other age groups. Treatment success was also higher among children with pulmonary TB (61.3%) compared to those with extrapulmonary TB (46.2%). This may

reflect the greater ease of bacteriological monitoring and clearer clinical response assessment in pulmonary TB compared to extrapulmonary TB.

5.1.2 Patient-Level Factors among Childhood TB Patients

In this study, infants (below one year) constituted more than half of all children registered for TB treatment, despite representing the smallest WHO life-cycle age bracket. Age categories were defined according to the World Health Organization life-cycle classification (below 1 year, 1–4 years, and 5–14 years). This finding differs from Adejumo et al. (2016) and Satyanarayana et al. (2010), who reported that children aged 5–14 years formed the majority, but is consistent with Moon et al. (2019). The predominance of infants in this study may be explained by their immature immune systems, which increase the risk of progression from TB infection to active disease.

This study also found that 51.6% of children had moderate to severe acute malnutrition at diagnosis. This high prevalence may reflect the chronic and debilitating nature of TB, where delayed diagnosis contributes to progressive nutritional deterioration. The finding may also indicate poor health-seeking behaviour among caregivers or a low index of suspicion for TB among healthcare providers, resulting in delayed case detection. Children with moderate acute malnutrition had the lowest treatment success rates, underscoring the negative impact of poor nutritional status on TB outcomes.

HIV screening coverage in this study was high at 91.2%, with an HIV positivity rate of 28.0%. Screening coverage was higher than that reported by Mirutse et al. (2019) and Adejumo et al. (2016). The HIV positivity rate was comparable to Adejumo et al. (2016) but higher than Mirutse et al. (2019) and above Kenya's national average HIV prevalence of approximately 14.0%. This reinforces the strong epidemiological link between HIV infection and childhood TB in this setting. HIV-positive children in this study had a higher proportion of good treatment outcomes (67.9%) compared to HIV-negative children, which may reflect closer monitoring and integrated TB/HIV care services among co-infected patients.

5.1.3 Clinical-Level Factors among Childhood TB Patients

Pulmonary TB was the predominant form of disease in this study, accounting for 66.7% of cases. This finding is similar to that of Moon et al. (2019) but contrasts with Satyanarayana et al. (2010) and Mirutse et al. (2019), who reported extrapulmonary TB as the predominant form. The lower proportion of extrapulmonary TB in this study may reflect diagnostic challenges in children. While pulmonary TB can be confirmed using molecular tests such as Xpert MTB/RIF (GeneXpert), extrapulmonary TB lacks widely accessible and sensitive diagnostic tools. Additionally, extrapulmonary TB presents with diverse clinical manifestations and often involves inaccessible anatomical sites, complicating confirmation.

Among extrapulmonary TB cases in this study, TB pleural effusion was the most common subtype. This differs from findings by Ohene et al. (2019) and Satyanarayana et al. (2010), who identified TB lymphadenopathy as the most frequent extrapulmonary TB presentation. Such variation may reflect differences in diagnostic capacity, clinical suspicion, and local epidemiological patterns.

The majority of children (92.1%) had a household member serving as the Directly Observed Therapy (DOT) supporter during the intensive phase of treatment. This reflects Kenya's decentralized and community-based TB care model, where services are delivered close to patients' homes, workplaces, and schools, as noted by Zhang et al. (2016). However, children supervised by healthcare workers or community health volunteers (CHVs) had better treatment outcomes than those supported by household members or relatives. This suggests that structured and professionally supervised DOT may enhance adherence and monitoring compared to informal household-based supervision.

Community-based referral mechanisms were minimally utilized in this study, with only 1.6% of patients referred by CHVs and 0.8% identified through contact invitation. These findings suggest suboptimal implementation of intensified TB case-finding strategies, particularly contact tracing and community engagement activities. The very low proportion of referrals by CHVs and identification through contact invitation likely reflects broader systemic and contextual barriers such as inadequate training in

paediatric TB detection, limited supervision and facilitation, high workload, stigma related to TB and HIV, and weak documentation systems. Strengthening CHV capacity, supervision, and monitoring systems may improve community-based TB case detection.

5.1.4 TB Diagnostic Methods among Childhood TB Patients

Only 42.9% of children in this study had a GeneXpert test performed at diagnosis. Current national and global TB diagnostic guidelines recommend GeneXpert as the initial test in suspected TB due to its higher sensitivity compared to sputum smear microscopy, rapid turnaround time, and ability to test alternative specimens such as stool, gastric aspirates, and nasopharyngeal aspirates. Since young children are often unable to expectorate sputum, bacteriological confirmation remains challenging. The relatively low utilization of GeneXpert suggests potential gaps in policy implementation or resource availability.

Among children with *Mycobacterium tuberculosis* detected on GeneXpert at diagnosis, 33.3% completed treatment without documented sputum smear follow-up results. According to national guidelines, bacteriologically confirmed cases should undergo sputum smear monitoring at the 2nd, 5th, and 6th months of treatment. Additionally, 33.3% of GeneXpert-positive patients were classified as cured, indicating documented negative sputum smear results at treatment completion. Only six patients underwent sputum smear microscopy at diagnosis, reflecting the ongoing policy shift favouring GeneXpert over smear microscopy due to its higher sensitivity and faster turnaround time.

More than 90% of children had a chest X-ray requested at diagnosis, highlighting the continued reliance on radiological and clinical assessment in pediatric TB diagnosis.

5.1.5 Association between Factors and Treatment Outcomes

Bivariate analysis demonstrated that nutritional status and GeneXpert test results were significantly associated with TB treatment outcomes ($p < 0.05$) at the 95% confidence

level. This finding underscores the importance of early bacteriological confirmation and nutritional support in improving childhood TB treatment outcomes.

These findings therefore provide evidence to reject the null hypothesis and support the alternative hypothesis that there is a significant relationship between selected patient-level and clinical-level factors and tuberculosis treatment outcomes among childhood TB patients.

5.2 Conclusions

i. Treatment outcomes among childhood TB patients were substantially affected by a high proportion of cases classified as "not evaluated," mainly due to transfer-out without documented follow-up. This large proportion of missing outcome data limited the precision of treatment success estimates and highlights the need for stronger inter-facility patient tracking and improved documentation systems to ensure complete evaluation of treatment outcomes.

ii. Among patient-level factors, age of the child was significantly associated with treatment outcomes in this study. Although nutritional status was not statistically significantly associated with treatment outcomes, the high prevalence of moderate to severe malnutrition among respondents indicates that it remains an important clinical concern and may influence treatment outcomes. Further studies with larger sample sizes or prospective designs are recommended to better clarify the role of malnutrition in childhood TB treatment outcomes.

iii. Among clinical-level factors, the type of TB disease and the type of treatment supporter during the intensive phase were significantly associated with treatment outcomes. Children supervised by healthcare workers or community health volunteers appeared to have better treatment outcomes than those supported by household members. However, the small number of patients supported by community health volunteers limits definitive conclusions regarding the effectiveness of community-based treatment support and suggests potential gaps in the implementation of community TB care strategies.

iv. Chest X-ray was the most frequently used diagnostic modality among

respondents, while the proportion of children diagnosed using GeneXpert was lower than recommended by national TB diagnostic guidelines. This finding may suggest gaps in policy implementation, although further investigation is required to determine whether this was influenced by resource limitations, clinical decision-making practices, or documentation gaps.

iv. The study findings demonstrated that selected patient-level and clinical-level factors, including age, type of TB disease, type of treatment supporter, and GeneXpert test results, were associated with tuberculosis treatment outcomes among childhood TB patients. Therefore, the null hypothesis was rejected and the alternative hypothesis accepted, indicating that a significant relationship exists between selected patient-level and clinical-level factors and TB treatment outcomes among childhood TB patients in this setting.

5.3 Recommendations

5.3.1 Recommendations for Action

i. The Ministry of Health, through County governments, should enhance child nutrition programs by strengthening programs targeting the nutritional status of children under five years, including regular growth monitoring, supplementation, and caregiver education.

ii. The National TB Program, in collaboration with County health authorities, should strengthen active TB case-finding by fully implementing active case-finding strategies. This includes enhancing CHV involvement, systematic contact tracing, and community outreach to improve early detection of childhood TB.

iii. County health authorities should improve patient referral and outcome tracking systems. There is need to develop a sustainable framework to ensure smooth referral of patients and backward flow of information about their management. This should include financial and logistical support, provision of necessary tools, training, and supervision for healthcare workers and CHVs to maintain accurate treatment and outcome documentation.

iv. Health facilities should implement robust data management systems and adopt electronic TB registers or integrated patient management systems to reduce missing data, track treatment adherence, and improve timely reporting of treatment outcomes. Regular audits and follow-up mechanisms (e.g., phone calls, SMS reminders, or home visits) should be incorporated to minimize loss to follow-up.

5.3.2 Recommendations for Future Research

i. Conduct multi-site, representative studies across multiple facilities and counties while incorporating perspectives from key stakeholders—including patients, caregivers, healthcare providers, and program managers—to better assess childhood TB outcomes and identify operational barriers and facilitators in diagnosis, treatment, and follow-up.
ii. Investigate determinants of loss to follow-up: Research should explore factors contributing to patient transfer, treatment interruption, and missing outcome data, to inform interventions aimed at improving retention and treatment success.
iii. Studies should assess implementation of national TB policies to evaluate the adherence to and effectiveness of policy guidelines, such as GeneXpert usage, active case-finding, and CHV engagement, to identify gaps and optimize program strategies.

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APPENDICES

Appendix I: Research Contacts

If you have questions or you require any clarifications, please feel free to ask the research assistant collecting the data. In addition, if you have questions in the future, you are also free to directly ask the **Principal Investigator (Mr. George Gichuki Muthui)** on 0722462519, Email: george.muthui@jkuat.ac.ke.

You may also contact: The Chairman, **Jomo Kenyatta University of Agriculture and Technology Institutional Ethical Review Committee** if you have any questions regarding this research study that you feel are best addressed by an independent party: The Chairman, JKUAT/IERC Tel 0702961963; Email: ethics@jkuat.ac.ke.

Appendix II: Request to Conduct Research

Medical Superintendent

Mbagathi County Hospital,

P.O. Box 40205-00200

NAIROBI

SUBJECT: REQUEST TO USE PATIENT HOSPITAL RECORDS FOR RESEARCH PURPOSE

My name is George Gichuki Muthui, the Principal Investigator undertaking a MSc. in Public Health under JKUAT/KEMRI program. The title of my research proposal is **Predictors of Treatment Outcomes of Childhood Tuberculosis at Mbagathi County Hospital, Nairobi.** We therefore request for permission to collect data in the records department of your facility in the month of February and March,2022 from the facility tuberculosis register. We shall adhere to all ethics regarding handling of medical data and specifically maintain utmost confidentiality.

We look forward to a positive response plus information for any prerequisite requirements before conducting the research.

Find attached the study ethical approval letter.

Yours faithfully,

George Gichuki Muthui

Tel: 0722462519

Appendix III: Data Abstraction Form

Serial number……

1. **Year of registration of patient**
   0- 2018
   1- 2019
   2- 2020
2. **Sex of patient**
   0- Male **[ ]** 1- Female [ ]
3. **Age of patient**

   0- 0 to < 5 years [ ]

   1- 5 to <10 years [ ]
   2- 10 to <15 years [ ]
4. **Weight at start of TB treatment (in Kgs)**
   ……Kgs
   Therefore, what is the BMI/BMI for age/Z score? (Using Age vs weight)

   0-Severely malnourished (<-3SD/<16BMI) [ ]

   1-Moderately malnourished (<-2—3SD/16-18.5BMI) [ ]

   2-Normal (>-1/18.5-24.9) [ ]

   3-Overweight (>-+/25-30BMI) [ ]

   4- Obese (>+3/>30) [ ]

5. **Is there cell phone number of treatment supporter?**
   0- Yes [ ] 1- No [ ]
6. **Who is offering DOT during the intensive phase?**
   0- Health Care Worker [ ]
   1- Household member, friend, relative [ ]

2- Community Health Volunteer (CHV) [ ]

3- DOT Not done (ND) [ ]

7. What is the type of TB?

0- Pulmonary [ ] 1- Extra-pulmonary [ ]

8. If extra-pulmonary in question 7, what is the sub-type?

0- TB lymphadenopathy (adenitis)

1- TB pleural effusion

2- Not applicable

3- Not recorded

9. Type of patient

0- New [ ]

1- Treatment after loss to follow-up [ ]

2- Relapse [ ]

3- Previous treatment history unknown [ ]

4- Treatment after failure [ ]

5- Others previously treated [ ]

10. Was a Genexpert test done during diagnosis of TB?

0- Yes [ ] 1- No [ ]

11. If yes to question 11, what was the Xpert results? (if no, skip)

0- MTB detected; rifampicin resistance not detected [ ]

1- MTB detected, rifampicin resistance detected [ ]

2- MTB detected, rifampicin resistance indeterminate [ ]

3- MTB not detected [ ]

4- Invalid/no result/error [ ]

5- Not applicable [ ]

12. Was a sputum smear test (FM or ZN) done during diagnosis of TB?

0- Yes [ ] 1- No [ ]

13. If yes to question 12, what was the sputum result at 0 month?

0- Positive [ ] 1- Negative [ ] 2-Sputum smear not done on diagnosis [ ]

14. Was Chest X-ray done during diagnosis of TB?

Yes [ ] 1- No [ ]

15. What is the child's HIV status?

0- Positive [ ] 1- Negative [ ] 2- Not recorded [ ]

16. If yes to question 22, was patient started on Cotrimoxazole Preventive Therapy?

0- Yes [ ] 1- No [ ] 2- Not recorded [ ] 3- Not applicable [ ]

17. If yes to question 22, was patient started on Anti-Retroviral Therapy?

0- Yes [ ] 1- No [ ] 2- Not recorded [ ] 3- Not applicable [ ]

18. Patient referred BY/FROM?

0- VCT Centre [ ]
1- HIV Comprehensive Care Unit [ ]
2- Diabetes Clinic [ ]
3- Private centre [ ]
4- Antenatal Clinic [ ]
5- Self-referral [ ]
6- Contact invitation [ ]
7- Chemist\pharmacy [ ]
8- Community health volunteer [ ]
9- Health care worker [ ]
10- Ward [ ]

19. Patient referred TO

0- VCT Centre [ ]
1- HIV Comprehensive Care Unit [ ]
2- Community\home Based Care [ ]
3- Nutrition Clinic [ ]
4- Diabetes Clinic [ ]
5- Private centre [ ]
6- Antenatal Clinic [ ]
7- TB clinic [ ]

20. Nutritional support

0- Nutritional counselling [ ]

1- Therapeutic food [ ]

2- Supplementary foods [ ]

3- Vitamin A [ ]

4- Pyridoxine [ ]

5- Not done [ ]

21. What was the treatment outcome?

0- Cured (smear negative) [ ]

1- Treatment completed (No smear results) [ ]

2- Treatment Failure (smear positive at 5\8 month, MDR) [ ]

3- Dead [ ]

4- Lost to follow-up [ ]

5- Not evaluated (Transfer Out and unknown) [ ]

6- Not a TB case [ ]

7- Moved to category IV [ ]

22. **Was the date of treatment outcome documented?**

0- Yes [ ] 1- No [ ]

THE END