

**SPIROMETRY FINDINGS AMONG CHILDREN PRESENTING
WITH A WHEEZE AND OR NOCTURNAL COUGH AT MOI
TEACHING AND REFERRAL HOSPITAL, ELDORET KENYA**

BY

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**A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF MASTERS OF
MEDICINE CHILD HEALTH AND PAEDIATRICS, MOI
UNIVERSITY**

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DECLARATION

This thesis is my original work and to the best of my knowledge, it has not been presented before for another degree in any other university.

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I dedicate this work to my late dad Mr. John Mutunga Kivindu for his encouragement, support and prayers throughout the development of my thesis.

ACKNOWLEDGEMENT

I am indebted to a number of individuals for their valuable input. First to God for His never ending love, my supervisors Prof. Constance Tenge and Dr. Irene Marete for their continuous input and guidance throughout the development of the thesis. My colleagues in the department of child health and pediatrics for their objective and constructive criticism. Mr. Henry Mwangi for the biostatistics consultation and last but not the least to my entire family for each and every effort put in during this process.

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LIST OF ABBREVIATIONS

ATS	American Thoracic Society
BC	British Columbia guidelines on asthma.
CDC	Center for Disease Control.
FENO	Fractional Exhaled Nitric Oxide.
FEV1	Forced expiratory volume in one second
FVC	Forced Vital Capacity.
GINA	Global Initiative for Asthma.
IREC	Institutional Research and Ethics Committee.
ISAAC	International Study for Asthma and Allergic diseases in Childhood.
LABA	Long Acting Beta Agonists
MRTH	Moi Teaching and Referral Hospital.
NIH	National Institute of Health
PEF	Peak Expiratory Flow.
PHC	Primary Health Care.
PICU	Pediatric Intensive Care Unit.
SABA	Short Acting Beta Agonists.
WHO	World Health Organization.

OPERATIONAL DEFINITION OF TERMS.

1. **A wheeze-** it is the audible or auscultated sound which is picked by the clinician
2. **Nocturnal cough** -is a dry cough occurring at night
3. **Abnormal Spirometry** - FEV1 change of >12% after short acting beta agonists inhalation.
4. **Asthma-** respiratory tract disease condition with abnormal spirometry findings

SPIROMETRY FINDINGS AMONG CHILDREN PRESENTING WITH A WHEEZE AND OR NOCTURNAL COUGH AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET KENYA

ABSTRACT

Background: Wheeze and nocturnal cough are common symptoms of various disease conditions including bronchial asthma, whose diagnosis can be confirmed by spirometry. Challenges of diagnosis of bronchial asthma in children have been associated with overreliance on clinical symptoms, resulting in inappropriate management. Spirometry is the gold standard for diagnosis of asthma in children. This study sought to determine the spirometry findings among children presenting with a wheeze and or nocturnal cough at Moi Teaching and Referral Hospital (MTRH).

Objective: To determine socio-demographic and clinical characteristics, spirometry findings and to describe factors associated with abnormal spirometry findings among children aged 6-14 years, presenting with a wheeze and or a nocturnal cough at MTRH.

Methods: Cross-sectional study design was conducted in MTRH at the outpatient clinic during the period between June 2019 to February 2020. A census was conducted and 114 participants were recruited. Interviewer administered questionnaire was used to obtain socio demographic and clinical characteristics. Spirometry was performed using an MIR Spiro lab III spirometer device. Descriptive statistics was applied to explore and summarize variables. Categorical variables were summarized in frequencies, proportions and reported in tables, while numeric variables were summarized in median, interquartile ranges and presented in tables. Chi square test was used to test for association between abnormal spirometry findings and other categorical variables such as gender, while Mann Whitney U test was used to compare median age among those who had abnormal spirometry findings.

Results: The median age was 9.7 years, majority were aged between 6-9 years at 60(52.63) with a male: female ratio of 1.1:1. Urban dwellers were 59(51.75%), versus rural 55(48.725%). The participants who came from households that used charcoal for cooking were 74(64.04%). Allergens included household cigarette smoke at 23(20.8%) and household pets 69(60.53%). The participants who presented with cough were 21(18%), those who presented with wheeze were 13(11.40%) and 80(70.18 %) had presented with both cough and wheeze. Duration of cough, median IQR 5(3, 7) and wheeze median IQR 4 (3, 7). Among the study participants who presented with wheeze and or nocturnal cough, 28(24.6%) demonstrated positive reversibility test. Male gender was associated with abnormal spirometry findings at (P=0.022).

Conclusion : Majority of the participants were aged between six to nine years of age, more than half resided in an urban set up and three quarters of them presented with both wheeze and nocturnal cough. Asthma was confirmed in a quarter of the participants who presented with both wheeze and or nocturnal cough. Being male was associated with abnormal spirometry findings.

Recommendations: Spirometry should be done for all children presenting with wheeze and or nocturnal cough (considered to have asthma) since not all participants were found to have abnormal spirometry findings.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Asthma is a chronic inflammatory lung disease characterized by airway hyperresponsiveness with typical episodic symptoms of nocturnal cough, wheezing and chest tightness (Gina 2021). There are two common variants of asthma, intrinsic and extrinsic asthma. Intrinsic asthma is the variant that occurs due to chronic or recurrent viral infections and it is not associated with allergens. The extrinsic type of asthma is the variant that has inheritance tendency classified as type I immune reaction which is a form of hypersensitivity reaction whereby symptoms are triggered by allergens such as dust, pollen and dander's. According to the asthma and allergy foundation of America the extrinsic form of asthma is the commonest, affecting half of asthma patients. The third variant of asthma is the mixed or combination form which has both the intrinsic and extrinsic features (Ulrik et al., 1995).

According to the latest World Health Organization (WHO) information, bronchial asthma is estimated to affect 339 million people worldwide (WHO, 2018). The strategy for prevention and control of asthma recognizes that it is of a major public health importance and one of the key WHO objectives is to improve access to health care, provide cost effective interventions in medicine and improve quality standards (Murray et al., 2017). The number of people with asthma continues to increase, 1 in every 12 people (about 25 million or 8%) of the US population in 2009 had asthma compared to 1 in 14 (about 20 million or 7%) in 2001. 46.9%, with children having a higher rate asthma attacks (47.5%) compared to adults. (CDC, 2011).

In many parts of the world asthma remains underdiagnosed and undertreated leading to a poor quality life. Previous studies have shown that the classical symptoms of wheezing, dyspnea and cough were found in one third of patients with asthma while

in other patients, chronic cough was the sole presenting symptom. Diagnosis of asthma can be done through history and physical exam however the use of tools such as spirometers could actually improve on the diagnostic accuracy, management plan.

The National Institute of Health (NIH) guidelines recommends the use of specific spirometry tests such as forced expiratory volume in one second (FEV1), Forced vital capacity (FVC) and the ratios of forced expiratory volume measured in the first second and Forced vital capacity (FEV1/FVC) for diagnosis of childhood asthma. This becomes of added value in its ability to document the reversibility of asthma symptoms demonstrated by the use of short acting beta agonists which has been correlated with the degree of airway obstruction (Debley., 2011).

Spirometry is a safe noninvasive low risk test performed on children above 5 years of age ,which forms an important basis in primary care of patients, (Bacharier et al., 2008). However, this test is dependent on the patient's effort and attention for optimum performance and accuracy.

Many studies have shown that asthma diagnosis and management has been done clinically without use of lung function tests such as spirometry of which it is the ideal and gold standard tool for diagnosis and monitoring for asthma. Spirometry also provides objective assessment of asthma severity and therapy response (Lamb et al., 2015). A published survey with data from 360 primary care practices revealed that only 52% used spirometry for patients with a diagnosis of asthma, and of those, only 35% of them practiced pediatrics compared to 75% in family medicine practice, who used spirometry in clinical practice (Ayuk et al., 2017).

In Kenya and majority of the developing countries, spirometry has not been well utilized and this has contributed to diagnostic challenges such as under diagnosis and

over diagnosis of asthma in this area (Ayuk et al., 2017). This study will help prove the value of spirometry use in the diagnosis of childhood asthma in MTRH and hence influence the procurement and use of spirometers benefiting the larger community in improving asthma diagnosis and management.

1.2 Problem Statement.

There is a demonstration of rising prevalence of childhood asthma in Eldoret and in the entire Kenyan population, (ISAAC 2000). There are challenges in the diagnosis of childhood asthma due to unavailability of objective tests such as spirometry. Childhood asthma is a heterogeneous disease requiring that clinical diagnosis should be augmented by spirometry. Despite both national and international guidelines advocating for use of spirometry, there is overreliance on clinical asthma diagnosis, hence resulting in inaccurate diagnosis.

1.3 Justification

The prevalence of childhood asthma is on the rise, as demonstrated in the ISAAC studies. Spirometry has been shown to be superior and more accurate diagnostic tool, compared to clinical diagnosis that relies majorly on the symptomatology i.e. cough, wheezing, chest tightness and shortness of breath (Gina, 2020). Despite this there is a low uptake of spirometry in diagnosis of childhood asthma, occasioned by unavailability of this service in most public hospitals including Moi Teaching and Referral Hospital. However studies have shown that spirometry is possible in children over 6 years of age. This study will demonstrate how much we are likely to over treat asthma if we make use of clinical symptoms alone, which is the common practice currently. Due to diagnostic inaccuracy we are likely to incur extra costs treating asthma, we are also likely to miss out on other diagnosis that present like asthma

hence mismanagement. This study aimed at determining the proportion of children with abnormal spirometry findings. The findings will be used to advise policy makers on the importance of spirometry in diagnosis of childhood asthma.

1.4 Research Question.

What are the spirometry findings among children aged 6-14 years, presenting with a wheeze and or nocturnal cough in MTRH sick child clinic?

1.5 Objectives

1.5.1 Broad Objectives.

To determine the spirometry findings among children aged 6 to 14 years, presenting with a wheeze and or a nocturnal cough at MTRH sick child clinic

1.5.2 Specific Objectives.

1. To describe the socio-demographic and clinical characteristics of children aged 6-14 years presenting with a wheeze and or a nocturnal cough in MTRH sick child clinic.
2. To determine the proportion of children with abnormal spirometry findings among children aged 6-14 presenting with a wheeze and or a nocturnal cough in MTRH sick child clinic.
3. To describe factors associated with abnormal spirometry findings among children aged 6-14 years, presenting with a wheeze and or nocturnal cough in MTRH sick child clinic.

CHAPTER TWO

2.0 LITERATURE REVIEW.

2.1 What is Asthma

According to the Global initiative for Asthma guideline (Gina., 2020), asthma is defined as a chronic inflammatory lung disease characterized by airway hyper responsiveness with typical episodic symptoms of nocturnal cough, wheezing and chest tightness (Gina., 2021). The National Institute of Health (NIH) further defines asthma as a complex disorder characterized by variable and recurring symptoms of airflow responsiveness and underlying inflammation followed by exudation of cellular elements such as eosinophil's, mast cells and neutrophils hence causing recurrent episodes of cough, early morning breathlessness and chest tightness in affected individuals(Barbato et al., 2006). The global asthma report defines asthma as a chronic inflammatory and reversible airway obstruction disease with enhanced bronchial reactivity leading to wheezing, chest tightness, cough and shortness of breath (Anon., 2015). There are two main variants asthma, Extrinsic and intrinsic. The Extrinsic variant of asthma is the commonest type, affecting half of asthma patients. It has genetic predisposition, with its immunological aspect classified as type I immune reaction which is a form of hypersensitivity reaction, whereby symptoms are triggered by allergens such as dust, pollen and dander's while intrinsic asthma is the variant that has no association with allergens and usually occurs secondary to chronic or recurrent infections of the bronchi such as tonsillitis, viral, bacterial infections and physiologic stress. Childhood asthma can be classified in terms of its severity by clinical features before treatment, as mild intermittent asthma whereby symptoms occur in less than once a week with brief exacerbations and nocturnal symptoms occurring not more than twice a month, a peak expiratory flow (PEF) of less than 80% predicted and peak

variability of less than 20%. In mild persistent asthma symptoms occur more than once a week but less than once a day and nocturnal symptoms occurring more than twice a month. A child may present with brief exacerbations and PEF less than 80% predicted and PEF variability of <20-30%. In moderate persistent asthma child presents with daily symptoms of asthma with exacerbations that affect activity and sleep while nocturnal symptoms occur more than once a week and there is daily use of inhaled short acting beta agonists, PEF is between 60-80% of predicted, PEF variability is >30%. In Severe persistent form, child presents with daily asthma symptoms with frequent exacerbations that are associated with frequent nocturnal asthma symptoms and limitation of physical activity. PEF is < 60 of predicted with PEF variability of > 30% (PHC manual, 2010). According to the Gina guidelines childhood asthma can further be classified according to the level of symptom control such as well controlled, not well controlled and very poorly controlled (Gina 2019). Various asthma management patterns have been adopted in the classification of childhood asthma and this includes: easy to treat, difficult to treat, exacerbations and Refractory asthma. (Becker et al., 2017)

2.2. Wheezing

A wheeze is a high pitched musical sound occurring as a result of narrowed or obstructed airway. It can occur in both inspiratory phase and expiratory phase of breathing, more commonly being the expiratory phase. The major conditions presenting with wheeze include: asthma, bronchiolitis, foreign body aspiration and congenital anomalies such as tracheomalacia.

2.2.1 Diagnosis of a wheeze.

Diagnosis of wheeze can be done on history, physical examination. Important history includes age of onset, which can be used to distinguish between congenital and acquired causes of wheezing. Persistent wheezing since birth may be due congenital anomaly or anatomic anomalies like tracheomalacia. The pattern of wheezing is also an important factor in that; episodic wheezing that is seasonal can be associated with environmental exposure to allergens. The time of onset of wheezing is also an important factor since sudden onset of a wheeze can be associated with foreign body aspiration, which manifests with episodes of gagging and choking, while a child with chronic forms of wheezing should be evaluated for conditions such cystic fibrosis. Family history of wheezing becomes integral when assessing a child who presents with a wheeze. In addition to this associated factors such as cough should be put into consideration since a cough that occurs after feeding in a wheezing child is suggestive of Gastro esophageal reflux disease. Moreover a dry cough that worsens at night could be as result of asthma and allergies. Obstructive sleep apnea should also be considered in children whose coughing awakens them at night. Other associated factors include postural changes in that wheezing occurring with positional change can be associated with conditions such as tracheomalacia(Brand et al., 2008).

On physical examination the airway patency, breathing and circulation, signs of respiratory distress such as central cyanosis, grunting, head nodding, flaring of alae nasae should be assessed. The respiratory rate, oxygen saturation and the other vital signs such as temperature and blood pressure should also be taken. We should always auscultate the chest and characterize the wheeze as inspiratory or expiratory, bilateral or unilateral wheeze.

Investigations that can be performed to support the diagnosis include chest imaging, which is indicated in children who present with wheeze that is recurrent and unresponsive to bronchodilators. A plain radiograph film can further be used to identify a foreign body, congenital lung lesions. Other imaging modalities include chest MRI that can identify complex fluid collection, tumors and fibrosis. Pulmonary function testing such as spirometry can be used to diagnose a wheeze due to obstructive lung diseases such as asthma (Anon., 2015). Bronchoscopy should be done if a foreign body is suspected. In specific infections such as bacterial and viral causes, swabs for specific diagnostic tests should be performed. PH monitoring, barium swallow and endoscopy can be performed when gastro esophageal reflux disease (GERD) is suspected (Brand et al., 2008).

2.2.2. Causes of wheeze and Nocturnal cough

Causes of wheezing can be classified into common causes, less common causes and rare causes. Most common causes of wheezing include: Allergies, asthma and other airway reactive diseases such as Gastro esophageal reflux diseases (GERD), infections such as bronchiolitis, pneumonia and upper respiratory tract infections (URTI). Less common causes include foreign body aspiration while rare conditions include Bronchiolitis obliterans, congenital vascular anomalies, cystic fibrosis, mediastinal masses, primary ciliary dyskinesia and tracheobronchial anomalies (Guilbert et al., 2004). Nocturnal cough is a common asthma symptom which is a persistent nonproductive variant that occurs at night causing sleep disturbance. It occurs in response to an irritant substance that forces the bronchial tubes to constrict promoting this type of dry cough which is specific for asthma and usually accompanied by wheezing.

2.3. Spirometry

Spirometry is the accepted and gold standard tool for diagnosing airway obstruction, through measurement of Forced expiratory volume in one second (FEV1), Forced vital capacity (FVC) and the ratio of Forced expiratory volume in one second to Forced vital capacity FEV1/FVC, together with post bronchodilator reversibility test. It becomes a useful tool to the clinician when distinguishing normal from abnormal lung function (Bernstein, 2012). Spirometry is an instruction oriented test performed on children aged 5 years and above due to their ability to take instructions as they are being coached (Bacharier et al., 2008).

2.3.1 Importance of Spirometry

Spirometry is an important lung function test used in the evaluation of patients in order to assess and establish various obstructive lung diseases. It can be used to quantify and confirm individual functional lung status. In addition spirometry can also be used in the evaluation of regimen effectiveness together with determination of other possible deformities (Bernstein.,2012).Spirometry has been used to offer objective measurement of asthma severity and response to therapy. It becomes useful in the evaluation of patients who may under or over report their symptoms. In addition to this it is important to consider spirometry in the initial diagnosis of asthma and as part of its differential diagnosis (Prajapati et al., 2010).Spirometry findings can also be used to classify current severity of a disease and act as a guide in management decisions for patients with new or previous diagnosis of asthma who may not be on medication. Finally it plays a key role in the assessment of treatment response together with asthma control (Alavaikko et al., 2011)

2.3.2 Indications and contraindications for Spirometry

Spirometry being a basic test for lung functions, its performance is necessary for evaluation and follow up of respiratory diseases. The present guidelines are aimed at assessing all healthcare professionals who use this test which is intended to serve as a reference for decision making based on the best results available. Indications for use of a spirometer include diagnostic evaluation of respiratory signs and symptoms, screening children who are at risk of developing asthma, estimation of the severity of asthma, monitoring and evaluation of various therapeutic interventions and finally it is used in public health especially in epidemiological studies for generation of reference equations. Contraindications for spirometry use can be absolute and relative. Absolute contraindications include use in conditions presenting with hemodynamic instability, pulmonary embolism, recent pneumothorax, acute hemoptysis and intractable hypertension. Relative contraindications include children under 5 years of age, children with facial, abdominal and thoracic deformities(Giner et al., 2013).

2.4 Diagnosis of asthma.

Many studies have shown that asthma diagnosis can be done with the identification of a compatible history of recurrent wheezing, cough, chest tightness, dyspnea (shortness of breath), that present in a particular pattern. This important pattern of symptoms includes symptoms that vary in intensity and are often worse at night or early morning. Despite the pattern of presentation of asthma symptoms there are certain features that decrease the probability that respiratory symptoms are due to asthma such as isolated cough, chronic sputum production, shortness of breath, chest pain and noisy inspiration, occurring as a result of exercise induced dyspnea .The symptoms are mostly triggered by allergens such as pollen and non-allergens such as physical

exercise. According to the Primary health care guidelines childhood asthma is diagnosed according to the severity of the exacerbations where we have mild, moderate and severe and whereby parameters such as breathlessness, ability to speak, pulse rate, respiratory rate and oxygen saturation are assessed. For the mild form, the child is able to walk and can sometimes lie down, talks in complete sentences, is moderately wheezing, often only end expiratory type of a wheeze, with increased respiratory rate (as compared to the standard normal respiratory rates as per age), not using accessory muscles of respiration, oxygen saturations of less than 90% (normal being 90-100%), with a pulse rate between 70-120 beats per minute. In the moderate form of exacerbation child has difficulties in feeding talks in phrases, agitated, has a loud wheeze, there is use of accessory muscles of respiration, pulse rate of between 100-120 beats per minute (in reference to the normal pulse rates as per age), talks in a more softer tone and prefers a sitting position with oxygen saturations between 91%-95%. In the severe state of exacerbation's child is breathless at rest talks in words, usually agitated with a loud wheeze, a pulse rate of more than 120 beats per minute and oxygen saturations of less than 90%. Having a conclusive symptomatology presentation and examination findings that support the diagnosis of asthma, spirometry can be done to obtain lung volumes such as Forced expiratory volume in one second FEV1 and Forced vital capacity FVC of <80% and FEV1/FVC ratio of less than 0.85, when there is air flow limitation and more than 12% improvement of FEV1 after short acting beta agonists (SABA) such as salbutamol given through inhaler at 200-400ug is specific for asthma (Gina.,2019). However a negative spirometry finding does not rule out asthma and in such a situation spirometry can be repeated after a period of time and if it is negative then it is likely not to be asthma (Becker et al, 2017).

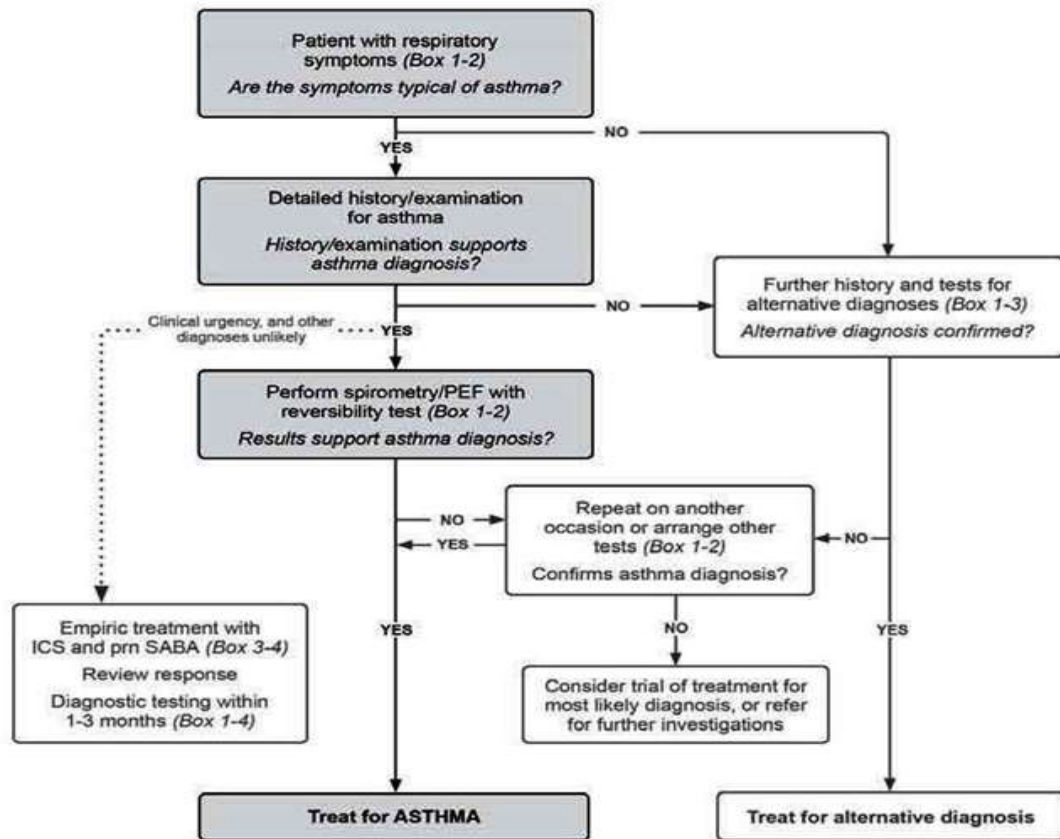


Figure 1: Diagnosis of asthma (Gina ., 2020)

2.4.1 Childhood asthma diagnosis using spirometry.

Demonstration of variable airflow obstruction by lung function tests such as spirometry is an important asthma diagnostic procedure that is used in practice and is therefore strongly recommended in children who are able to cooperate. The diagnosis of childhood asthma should be done by combining relevant history and examination with at least a confirmatory diagnostic test such as spirometry (Patil ., 2017). According to the American Thoracic Society, spirometry should include the measurement of Forced expiratory volume in one second FEV₁, Forced vital capacity and Forced expiratory volume in one second and Forced expiratory volume ratio together with the reversibility testing (Bernstein., 2012). Where there is evidence of airways

obstruction, looking for changes in FVC or FEV1 15 minutes after the use of a bronchodilator (reversibility usually taken as >12% subsequent improvement in lung function). Spirometry is a safe and practical procedure its advantages include the provision of objective measures of airway obstruction through the use of specific values such as FEV1, FVC and FEV1 and FVC ratio. Other than being the gold standard asthma diagnostic tool, the use of spirometry ensures accuracy in the diagnosis of childhood asthma. Moreover, spirometry has been shown to play a key role in the screening, monitoring and for follow up purposes. Finally spirometry provides acceptable and repeatable results (Prajapati et al., 2010). However there are several shortcomings associated with its routine use in that spirometry has been shown to be possible in children from 5 years of age who are able to take instructions, co-operate and produce a good effort so it becomes difficult when performed in children below 5 years of age. The performance of spirometry is time consuming; this is because several readings are done before an agreement is reached. Furthermore spirometers are not readily available this is because they are costly to obtain and they require a trained personnel to perform spirometry.

2.4.2 Clinical diagnosis of childhood asthma.

The guidelines for the National Asthma Education and Prevention Program (NAEP) highlight the importance of correctly diagnosing childhood asthma. To establish the diagnosis of asthma the clinician must take a comprehensive history with the following symptoms, in the presence of wheezing, coughing and chest tightness, associated symptom patterns that can be seasonal or continual, affected by exercise or active playing, at night and early morning. Other important history includes a history of early-life injury to airways (e.g. respiratory infections, parental smoking), comorbid

conditions (e.g. rhinitis, eczema), family history of allergies and asthma progress of the disease (Bacharier et al., 2008). The advantages of use of clinical diagnosis are that it is fast, cheap, less time consuming method. However there are several downfalls associated with this method of diagnosis since signs and symptoms may not be the same for all the patients and they could be mistaken for signs of other common airway diseases. Under diagnosis and over diagnosis of childhood asthma has been the most important diagnostic problem, this is could be probably due to the diagnosis of childhood asthma based on clinical signs and symptoms alone (Nantanda et al., 2013). Despite this, clinical diagnosis has been associated with lack of diagnostic accuracy hence missing out on some children, together with giving of improper treatment.

2.5. Global uptake of spirometry.

The international clinical guidelines on the use of spirometry recommend it for both diagnosis and management of asthma. In developed countries like Australia, the uptake of spirometry in the general practice has been low even though the ownership of spirometers is high, estimated between 64% and 76% of practice. There are barriers to performing of spirometry which include: high equipment cost, lack of time for adequate training in both performance of spirometry and the interpretation of results, (Enright.,2008). In developing countries, studies have shown that it is frequently underutilized. A study done in Belgium showed that about 30% of children with asthma were evaluated on spirometry. Underuse of spirometry was evident in two retrospective studies done in South west Nigeria and analysis on spirometry use that showed few children were part of the pool of study participants. In both studies it came to 3.4% and 3.5%. According to a study done in ivory coast by Gome et al

41% of the doctors were not using spirometry as they were totally unaware of its usefulness (Ayuk et al., 2017). A study done in South Africa by (Mash et al., 2017) the findings showed that 60% of the facilities used spirometry in the evaluation of obstructive airway diseases. A related study in South east Nigeria by actioners, reported that only 34% of doctors in their study population used spirometers for the evaluation of their patients. The underuse of spirometry in developing countries was attributed to lack of trained personnel and the high cost of acquisition of equipment (Nwosu et al., 2016).

2.6. Procedure of Spirometry

This starts by explaining to the patient the purpose of the test together with a clear description and demonstrations of what the patient is expected to do, not forgetting the importance of taking a deep breath and blowing out forcefully. Patient information in terms of age, sex and height is recorded together with important history such last bronchodilator use. Patient can be in an upright position, standing or sitting comfortably waiting for the procedure. The first step of the procedure is to attach a clean disposable one way mouth piece to the spirometer, patients' nose is clipped, and he or she is instructed to breathe in fully. The patient should hold their breath long enough to seal their lips tight round the mouth piece then blast the air out forcefully and as fast as possible. The operator should verbally encourage the patient to keep blowing during this expiratory phase ensuring that the mouth piece is in place. The procedure should be repeated at least 3 times until 3 acceptable findings are obtained, (FitzGerald et al., 1996). For the reversibility test, spirometry should be performed before and after bronchodilator, usually salbutamol from MDI or spacer given at 200-400ug. Change in FEV of more than 12% from baseline after 15 minutes to 20 minutes

of administration of bronchodilator at the above dosages, is diagnostic for asthma (Villa et al., 2016).

2.7. Interpretation of spirometry findings.

Spirometry interpretations vary with height, age, gender and ethnicity. Spirometry measures two key factors: Forced vital capacity (FVC) and Forced expiratory volume in one second (FEV1). Clinicians also look at this as a combined value that is known as the FEV1/FVC ratio. In case of airway obstruction, the amount of air that one is able to quickly blow out of his or her lungs will be reduced, henceforth translating to a lower FEV1 and FEV1/FVC ratio. According to the American Thoracic Society the commonly used lung function tests include FEV1 which is the volume air expired in the first second of forced maximal expiration and FVC is the maximum volume of air which can be expired with maximum force after maximal inspiration. When FVC is lower than normal, (a cutoff range of 80%) it means that there is restriction in respiration. FEV1 measurement can be used to grade how severe the obstructive abnormalities are in that. FEV of 80% or more is normal. The two ventilator defects FVC and FEV1 can either be analyzed separately, or as a proportion is the ratio of FEV1 and FVC. The FEV1/FVC ratio is a number that represents the percentage of one's lung capacity that he or she is able to exhale in one second. The higher the percentage derived from FEV1/FVC ratio in the absence of obstructive lung disease, the healthier lungs are. A low ratio of less than 0.85 suggests that there is airway obstruction. Spirometry should be performed before and after bronchodilator, usually salbutamol from MDI or spacer given at 400micrograms. Reversible obstruction is the change in FEV of more than 12% from baseline after 15 to 20 minutes of

administration of bronchodilator at the above dosage, which confirms asthma (Barreiro.,et al 2004).

Spirometric findings can be expressed as flow –volume curves as shown below

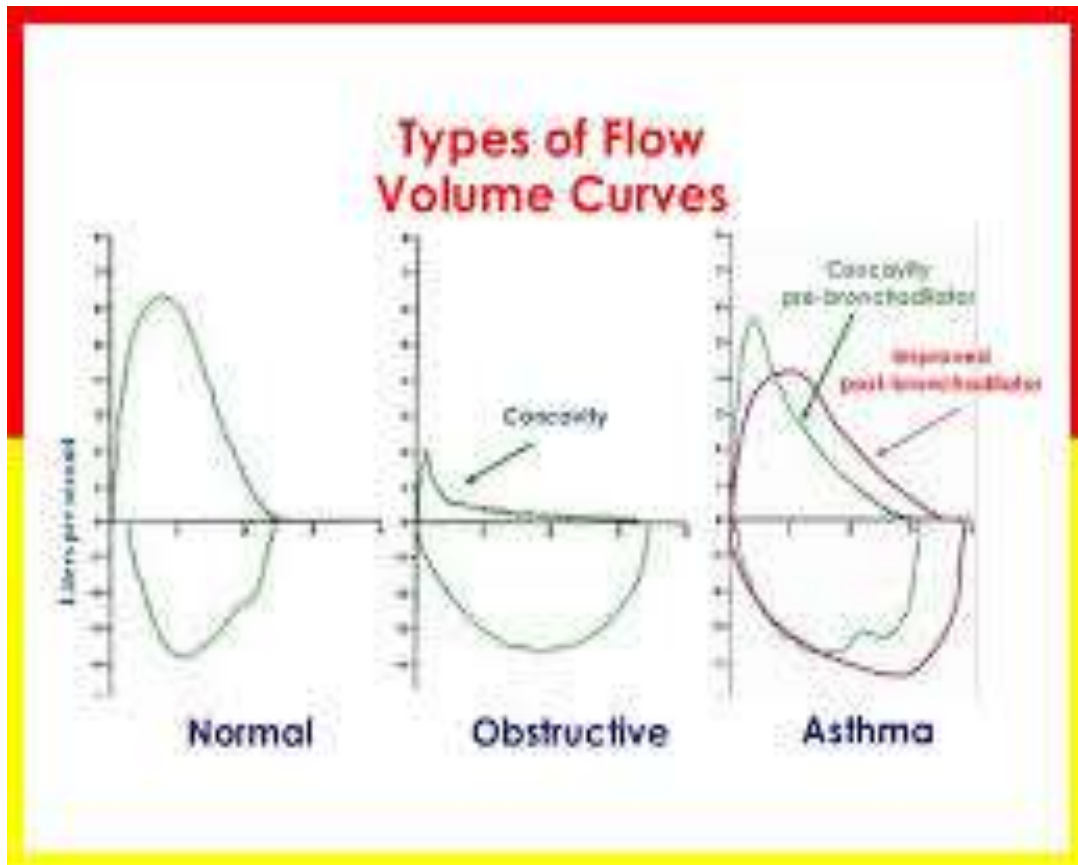


Figure 2: Interpretation of spirometry findings

2.8. Use of Incentives for spirometry in Children.

Computer programs and animations have been developed and used to instruct and stimulate young children in maximal forced expiratory maneuvers. They are normally asked to blowup balloons and candles on the computer screens. These programs are there to help children focus on the task at the same time provide visual motivation to accomplish an optimal maneuver.

2.9. Epidemiology and prevalence of asthma in children.

339 million people worldwide have asthma. 250,000 people globally die every year due to asthma. Death rates in children range from 0.0 to 0.7 per 100000 globally(WHO, 2017).According to the American Academy of Pediatrics ,childhood asthma prevalence doubled from 1980 to 1995 and increased from 2001 to 2009 followed by a plateau in 2010 and 2012 then a decline in 2013.(Akinbami et al., 2002).In Africa the highest incidence of asthma observed in children was in the ages of 6 to 11 years(Akhiwu et al., 2017), in a similar study done in South Africa ,childhood asthma was present in 20% of school going children with 15% of boys having asthma as compared to 13% of females (Green, 2011).The international study for Asthma and Allergies in Childhood (ISAAC) reports that the prevalence of childhood Asthma is on the rise. Kenya being a participant in International study of asthma and allergies in childhood (ISAAC) phase 1 and 3 studies that took place in Nairobi city and Eldoret respectively. The phase one study took place in 1995 and it showed that the prevalence asthma for a period of 12 months in children aged between 13 and 14 years was 17.1% and 10.4% in Nairobi and Eldoret respectively. The ISAAC phase 3 took place in 2000 further examined the rising prevalence of asthma to 18% and 13.8% in both Nairobi and Eldoret(Asher et al., 1995).According to national and state surveillance system report administered by Centre for Disease Control and prevention (CDC), there are total 6132(8.36% children with asthma, further categorized in the age brackets 0-4years of age having prevalence 3.8% compared to 5-14 years of age, who have a prevalence of 10.1% and children from 15-19 years of age with a prevalence of 10%. Prevalence of childhood asthma is higher in boys at 9.2% compared to girls at 7.4 %(CDC 2017).According to the ISAAC studies results, it is estimated that about 10% of Kenyan Population or 4million children have asthma,

with a greater urban prevalence. In a study conducted in 1995 among the rural primary school children in Uasin Gishu district in the western highlands of Kenya, the prevalence of asthma, allergic rhinitis and eczema was 6.6%, 14.9% and 13.9% respectively (Esamai et al., 2002).

2.10. Risk Factors for Asthma.

Risk factors are classified into those that increase the risk of asthma attack and those that increase the risk of developing asthma. Asthma can be familial since genetic factors are important in its development. It is a multiple gene inherited disease although there is no specific asthma gene identified yet and no gene directed therapies that are available. Dietary factors are also important in the development of asthma. Low levels of vitamin C or particular cereals intake may be associated with asthma development. Exposure to tobacco smoke is also a risk factor to the occurrence of asthma. Environmental factors such as dust particles from occupational settings may also increase the risk of developing asthma. Psychological factors such as parental stress, lifestyle risk factors such as obesity, and infections such as helminthes. Other risk factors for exacerbations include children with other respiratory infections such as viral infections, indoor air pollution, strong scents, excessive exercise, air pollution, intense emotional reactions, and drugs such as NSAIDS, (Padmaja et al., 2009).

2.11. Clinical presentation of asthma.

Symptoms are triggered by common events of exposures to allergens (extrinsic asthma) such as pollen, mold, pets, dander's and non-allergens (intrinsic asthma) such as physical exercise, physiologic stress, anxiety, cigarette smoke, respiratory viral infections, drugs such as non-steroidal anti-inflammatory drugs. The most common symptoms of asthma are intermittent dry cough and expiratory wheezing; In addition

to this older children report associated shortness of breath, chest congestion and tightness while younger children are more likely to complain of an intermittent, nonlocal chest pain. These respiratory symptoms are worse at night and are associated with sleep interruption while daytime symptoms are often exercise or play induced. Other nonspecific asthma symptoms include self-imposed limitation to physical activity, general fatigue (resulting from sleep disturbance) history of a dry persistent cough and difficulties in keeping up with peers in physical activity. Previous history of use of asthma medication is integral since it may bring out the history of asthma symptoms improving on bronchodilator use, which supports asthma. On respiratory examination, the chest findings are often normal while some children may exhibit expiratory wheezing on auscultation especially during asthma exacerbations. Decreased breath sounds occurring more commonly on the right lower posterior right lobe, is consisted with regional hypoventilation as a result of airway obstruction. Rhonchi and crackles can also be appreciated as a result of excess mucus production and inflammatory exudates. In severe exacerbations there is extensive airway obstruction causing labored breathing, prolonged inspiratory and expiratory wheeze, poor air entry, suprasternal and intercostal retractions and nasal flaring. In extreme airflow limitation a child may present with a silent chest, with no wheezing heard

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

Cross-sectional study

3.2 Study Area.

The study was conducted at Moi Teaching and Referral Hospital outpatient clinic also known as sick child clinic. Moi Teaching and Referral Hospital is situated in Eldoret town, Uasin Gishu County, 300km west of Nairobi. Major catchment areas are Western Kenya and North rift regions. The pediatric outpatient clinic also known as sick child clinic has been housed separately from the general outpatient department. In the pediatric outpatient, there are about 4000 patients seen in a month, of whom approximately 200 children present with wheeze and or nocturnal cough. Among those who present with a wheeze and or nocturnal cough, based on clinical symptomatology, only 15 children have a diagnosis of asthma, 20 children have bronchiolitis, 161 have bronchospasms and 3 have a diagnosis of foreign body inhalation. The pediatric outpatient clinics are run by a multidisciplinary team consisting of a pediatrician, a medical officer, a nurse, clinical officer and other non-clinical staff members. It is subdivided into triage area, the records area, clinician's rooms, observation area and other staffrooms. In the **Triage area** the nurse carries out a quick assessment of every child, to prioritize the order in which the children shall be attended to by the clinicians, based on severity of illness. The key complains are also taken and noted down.

The records area: This is the second step after triage. Here the patient's particulars are collected and a file is opened with a unique hospital number for them. The patients who need emergency care are attended to first before this process is started.

Clinician's rooms: There are several rooms available for the clinicians to offer

services. It is usually a team consisting of a pediatrician, medical officers and clinical officers. The patients are directed to the rooms by the nurse at the waiting area which is between the triage area and the clinician's rooms. This is based on the availability of the clinician and the severity of the condition. From here they can either go to pharmacy, laboratory or observation room. **Observation area:** once the patient has been seen; they only go to the observation room if they require services such as rehydration, drug administration and observation. Patients who require emergency medical attention go directly to this room and are attended to and from here they are reviewed by the clinician to determine whether they can proceed home or to the inpatient wards for admission. Those requiring admission also wait here while the records and nursing team prepare to transfer them to the wards. **Staff rooms:** There are a few other rooms available for support services. These include; a staff room, a room for the nurse in charge and storage rooms. These are however not static and can be converted for different uses as required. In this set up asthma diagnosis is purely by use of clinical signs and symptoms, there are no available spirometer devices.

3.3 Study Populations.

All children aged 6-14 years, presenting with a wheeze and or nocturnal cough at MTRH sick child clinic.

3.4 Eligibility Criteria

3.4.1 Inclusion criteria.

Children aged 6 years to 14 years, presenting with wheeze and or a nocturnal cough in MTRH sick child clinic.

3.4.2 Exclusion criteria.

1. Children who are too sick to have spirometry done - these are children who were unconscious and unable to take instructions or those who required emergency resuscitation measures such as oxygen therapy.
2. Those who had received asthma medications such as short or long acting bronchodilator, steroids or Leukotriene inhibitors within a period of less than 12 hours on the day of the study were excluded. This is because the half-life of these drugs ranges from 4 to 12 hours and this could have interfered with our findings.

3.5. Sampling Procedure

Census was done to recruit participants aged between 6-14 years of age who presented with a wheeze and or nocturnal cough at MTRH over a period of 8months. From clinical records and experience during the months of March to June 2019 on average there were approximately 20 children aged 6 to 14 years, presenting with a wheeze and or nocturnal cough. In 8 months, we expected about 160 patients who fitted our eligibility criteria to be seen in MTRH.

3.5.3 Study period

The study was conducted over a period of 8 months duration from June 2019 to February 2020. The 8 months study period was justified to cover various seasons in the year together with their related triggers of childhood asthma; such as the cold and rainy season, warm season and the dry and dusty

3.5.4 Research instruments.

Data was collected using an interviewer administered questionnaire with subsections such as social demographic data and clinical characteristics of patients.

3.6 Study procedure.

MIR Spiro Lab III spirometer device was used.



Figure 3: MIR Spiro III spirometer device

Two research assistants were recruited, a medical officer and a clinical officer working in sick child clinic since this enabled them to have a better understanding on the details of the study e.g. the concept of spirometry upon training. Training of the research assistants about the study objectives and spirometry procedure was done. Staff at the sick child clinic were sensitized on the study. Following the normal patient flow from the triage area, patients who required emergency medical attention were

taken directly to the emergency room. The rest of the Patients were directed to the clinician's room. The clinician identified children presenting with a wheeze and or nocturnal cough, the research assistants or the PI confirmed the presence of a wheeze and nocturnal cough. First participant to be selected was the first child who met the eligibility criteria on the day of the study then every participant was picked. Each file was given a unique number to avoid duplication. Parents and guardians were asked to give consent and children aged 7 years and above were allowed to assent. The questionnaire was administered, spirometry performed and results were disseminated to the clinicians, parents and guardians. Patients were allowed to proceed with treatment. Participants were recruited for a period of 24 hours. Two MIR -Spiro lab III multifunction spirometer devices were available for the study, they were hired from the KAPTLD in which one would act as a backup in case of a break down. The principal investigator and the research assistants had been trained on the spirometry procedure. The devices met the equipment standards and requirements of American thoracic society (ATS).

3.6.1 Spirometry procedure.

The participants were explained to about the spirometry procedure; emphasis was put on the importance of taking a deep breath and blowing out forcefully for 6 seconds. Demographic data was recorded; the last time when a bronchodilator or Leukotriene antagonists were given was noted. The patient was in a standing or sitting position. A clean mouth piece was attached to the spirometer device, patient's nose clipped and he or she was instructed to breathe in fully then breath out forcefully, as the instructor verbally encouraged the patient. The procedure was repeated 3 times to obtain at least 2 highest values with minimal curve variability, which was in conformity with

standard international guidelines (ATS) in terms of quality. Salbutamol was given at 400ug from an MDI using a spacer with a mask or a mouth piece. Spirometry was performed after a period of 15 to 20 minute and >12% change in FEV1 from baseline was specific for asthma. Pre and post bronchodilator reversibility test was performed by the same person for consistency purposes. Children below 8 years used a spacer with a mask while those above 8 years used a mouth piece. However children above 8 years of age who could not follow instructions were allowed to use a spacer instead of a mouth piece. 10 spacers, 20 masks, 10 MDI and 200 mouth pieces were available for the study. Infection control and sterility was maintained by the use of disposable mouth piece, facemasks were disinfected and the spacer was cleaned after use.

3.7 Data Collection

Data was collected by the researcher together with research assistants. Questionnaires containing socio demographic data, clinical characteristics of the children presenting with a wheeze and or nocturnal cough were administered. Spirometry test was performed.

3.7.1 Data storage.

Data was checked for completeness and accuracy by the researcher and after cleaning it was keyed in and processed into Microsoft Access @ data base. Confidentiality was maintained by excluding identifiable information from keyed data sets. Password was utilized to prevent unauthorized access. Data backup was done in hard disks.

3.7.2 Data analysis.

Data was imported into STATA, coded, cleaned and analyzed. Descriptive statistics were done to explore and summarize the variables. For categorical variables such as sex, residence, type of house, allergens, clinical presentation, diagnosis, treatment among others were summarized through frequencies and proportions and reported in tables. For numeric variables like age and duration of illness, data was summarized in median, interquartile ranges and presented in tables. Chi square test was used to test for the association between abnormal spirometry findings and gender, residence, house floor, allergens, knowledge, and type of fuel. Mann Whitney U test was used to compare median age between those who had abnormal and normal spirometry findings. All statistical tests were performed at α level of significance of 0.05. The test statistics and corresponding P values were reported in tables.

3.9 Ethical consideration

Procedures performed in this study involving human beings were in line with the ethical standards. This study sought approval from Institutional Research and Ethics committee of Moi University/MTRH. Parents and guardians were allowed to consent for patients they accompanied, while assent was obtained for participants aged 7 years and above. There was equity in provision of health care to all patients whether enrolled to the study or not and the participants had the autonomy to exit the study at whatever level they wanted to without prejudice or bias. The data collected was confidential; hard copies were placed in a secure cabinet under lock and key, which remained with the primary investigator. Soft copies were Encrypted and placed in a password protected computer.

3.9. Dissemination of results

The results of the study will be disseminated through a written thesis and an oral defense in a forum that shall be convened by the school of medicine. The results will also be presented in national or international research meetings and published in peer reviewed journals.

CHAPTER FOUR

4.0 FINDINGS.

4.1 SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE STUDY PARTICIPANTS.

4.1.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS.

A total of 114 participants were recruited into the study, median age was 9.7 years, and male to female ratio was 1.1:1.

Details of other socio- demographic characteristics are shown in Table 1

Table 1: Socio-Demographic Characteristics (n=114)

Variable	Category	Frequency	Percentage (%)
Age categories	6 – 9 years	60	52.63
	10 – 14 years	54	47.37
Gender	Male	60	52.63
	Female	54	47.37
Informants Relationship with the child	Mother	73	64.04
	Father	29	25.44
	Relative	7	6.14
	Guardian	5	4.39
Type of residence	Rural	55	48.25
	Urban	59	51.75
County of residence	Uasin Gishu	91	79.82
	Nandi	13	11.40
	Elgeyo Marakwet	3	2.63
	Trans nzoia	3	2.63
	Kakamega.	2	1.75
	Others	2	1.75
Type of housing	Permanent	68	59.65
	Semi-permanent	46	40.35
Type of house floor	Cemented	90	78.95
	Earthen	24	21.05
Type of fuel	Charcoal	73	64.04
	Gas	69	60.53
	Firewood	66	57.89
	Kerosene	2	1.75
Exposure to allergens * Cigarettes smoke	Yes	23	20.18
	No	91	79.82
*Pets	Yes	69	60.53
	No	45	39.47

4.1.2 CLINICAL CHARACTERISTICS

Details of the participant's clinical characteristics are shown in Table 2.

Table 2: Clinical characteristics

Variable	Category	Frequency	Percentage (%)
Clinical presentation	Nocturnal Cough	21	18.42
	Wheeze	13	11.40
	Both	80	70.18
Family history of asthma	Yes	45	39.82
	No	69	60.18
Presence of concurrent illness in the current presentation * Allergic conjunctivitis, tonsillitis, Rheumatic fever.	Yes	8	7.02
	No	106	92.98
Admission in the last 6 months due to asthma related exacerbations	Yes	107	93.85
	No	7	6.25

* The duration of cough was Median (IQR) 5(3, 7) and that of wheeze was median (IQR) 4(3,7).

4.3. PROPORTION OF CHILDREN WITH ABNORMAL SPIROMETRY FINDINGS

Out of 114 participants study participants who presented with wheeze and or nocturnal cough, 28(24.6%) demonstrated FEV1 change of >12% (Positive Post Bronchodilator Reversibility test.)

Details are shown in Table 3.

Table 3a: Spirometry findings among the study participants (Pre Bronchodilator)

Category	Pre Bronchodilator n=114	
	Normal N(%)	Abnormal N(%)
FEV ₁ (Normal >70%)	82(71.9)	32(28.1)
FVC (Normal >80%)	87(76.3)	27(23.7)
FEV ₁ /FVC (Normal >85%)	39(34.2)	75(65.8)

Table 3b: Spirometry findings among the study participants. (Post Bronchodilator Reversibility Test)

Category	Post Bronchodilator n=75		FEV1 change > 12%
	Normal N(%)	Abnormal N(%)	
FEV1 (Normal > 70%)	50(66.7)	25(33.3)	28(24.6)
FVC (Normal>80%)	61(81.3)	14(18.7)	
FEV1/FVC (Normal>85%)	14(18.7)	61(81.3)	

4.4 FACTORS ASSOCIATED WITH ABNORMAL SPIROMETRY FINDINGS AMONG THE PARTICIPANTS.

At bivariate level male gender was significantly associated with abnormal spirometry findings at (p=0.022). Out of 60 male participants who participated in the study, 20(33.3%) were found to have abnormal spirometry findings, which was higher compared to that of female participants at 8(14.8%).

Details are shown in table 4.

Table 4: Factors associated with abnormal spirometry findings

Variable	Category			p-value
		Normal (n=86)	Abnormal (n=28)	
Gender	Male	40 (66.7%)	20 (33.3%)	0.022 ^c
	Female	46 (85.2%)	8 (14.8%)	
Age	Median (IQR)	9.3 (6.8, 11.4)	10.2 (7.4, 12.2)	0.156 ^m
Residence	Rural	42 (76.4%)	13 (23.6%)	0.825 ^c
	Urban	44 (74.6%)	15 (25.4%)	
Allergens				
Cigarette	Yes	69 (75.8%)	22 (24.2%)	0.849 ^c
	No	17 (73.9%)	6 (26.1%)	
Pets	Yes	53 (84.1%)	10 (15.9%)	0.595 ^c
	No	33 (64.7%)	18 (35.3%)	
Type of cooking fuel				
Charcoal	Yes	54(74.0%)	9 (22.0%)	0.628 ^c
	No	32 (78.0%)	19 (26.0%)	
Gas	Yes	49(71.0%)	8 (17.8%)	0.174 ^c
	No	37 (82.2%)	20 (29.0%)	
Firewood	Yes	53(80.3%)	15 (31.3%)	0.157 ^c
	No	33 (68.8%)	13 (19.7%)	
Nocturnal cough	Yes	77(76.2%)	24(23.8%)	0.732 ^f
	No	9 (69.2%)	4 (30.8%)	
Wheeze	Yes	68(73.1%)	3 (14.3%)	0.226 ^c
	No	18 (85.7%)	25 (26.9%)	
Family history	Yes	51(75.0%)	17 (25.0%)	0.947 ^c
	No	34(75.6%)	11 (24.4%)	
Admissions in the last six months	Yes	4 (57.1%)	3 (42.9%)	0.360 ^f
	No	82 (76.6%)	25 (23.4%)	
Family history	Yes	34(75.6%)	17 (25.0%)	0.947 ^c
	No	51 (75.0%)	11 (24.4%)	

^c Chi Square, ^m Mann Whitney U Test, ^f Fisher's Exact Test

CHAPTER FIVE

5.0 DISCUSSION

5.1 Socio- demographic characteristics.

There were more male participants compared to females with a male to female ratio of 1.1:1. This agreed with the findings of a study by Carolina in Lisbon who had male gender predominance (Constant et al., 2011). This can be explained by childhood asthma studies that have shown that there is gender disparity in the prevalence of childhood asthma. The prevalence is high in male gender in the prepubertal age compared to female gender and the reverse occurs after the pubertal age. This can further be explained by the existence of sex hormones specifically testosterone and estrogen that has been shown to play a role in the pathogenesis of childhood asthma. In terms of participant's place of residency, Majority of the participants were urban dwellers. The findings were close to MTRH study that had three quarters of the participants coming from an urban set up. This can be attributed to the fact that the two studies took place in a similar study set up. In regards to exposure to allergens such cigarette smoke, a quarter of the participants had been exposed to household cigarette smoke and this was closer to the findings of a study done in Uganda by Nantanda et al whereby an eighth of the participants were exposed to household cigarette smoke. This can be explained by similarities in leisure and socioeconomic activities in the two study set ups in that the two studies took place in East Africa, hence similar socio-cultural activities (Nantanda et al., 2013). Our findings were lower compared to the Lisbon study that had a higher percentage of the participants being exposed to household cigarette smoke at (37%)(Constant et al., 2011). This can be explained by the high prevalence of cigarette smoking in Europe from the WHO report 2019 which is at 28% compared to

Kenya, a developing country at 11.9%. The other probable explanation is the differences in leisure and socioeconomic activities in the two study set ups. Two thirds of the study participants came from households that were using charcoal for cooking as their source of fuel with the least being kerosene. The findings compared to a Kenyan case control study done in the year 1995. This could be explained by similar socioeconomic activities in the two study set ups (Mohamed., et al 1995). This was different from Nigeria study that had three quarters of the participants using kerosene. This can be explained by the fact that Nigeria being an oil producing county participants found it convenient to use kerosene for cooking due to its availability.(Kuti., et al 2017).

5.1.1 Clinical characteristics.

Two thirds of the participants presented with both wheeze and nocturnal cough, while a quarter of them presenting with nocturnal cough only. This was consistent with the findings of a study done in Lisbon (Constant et al., 2011). This is in tandem with childhood asthma studies and guidelines that have shown that wheeze and nocturnal cough is the most common symptomatology presentation for childhood asthma

In terms of family history of asthma, two fifth of the participants had a family history this was closer to findings of a Nigeria study whereby half of the participants had a family history of asthma (Kuti et al., 2017). This can be attributed to the fact that there is an association between childhood asthma with genetic factors such as familial history of asthma.

This study found that about 6% of the participants had been admitted due to asthma related exacerbations. This was closer to the findings of a longitudinal population study done in Netherlands whereby 8.3% of the participants had been hospitalized due

to asthma related exacerbations (Rasmussen et al., 2002). This was in contrast with a study in Nigeria whereby 50.28% of the children had been hospitalized due to asthma related exacerbations. This can be attributed to the fact that this study took place in a low social economic class which was an important predictor of suboptimal asthma control, leading to recurrent asthma symptoms and hospitalization since participants were unable to afford asthma medications.

5.2. Spirometry Findings among the participants.

Out of 114 participants who presented with wheeze and or nocturnal cough a quarter of them were found to have abnormal spirometry findings after short acting beta agonist's inhalation. This was consistent with cross-sectional study in Uk which found that 18% had a positive post bronchodilator (Schiffano et al, 2014). The other probable explanation is that the two studies recruited participants from a similar age group. This differed from another Uk study whereby only 9% of the participant demonstrated a positive post bronchodilator reversibility test (Murrey et al., 2017). This can be explained by differences in study methodology in that the Uk study was a population based prospective cohort study versus our study versus our study a hospital based cross-sectional study.

5.3 Factors associated with abnormal spirometry findings.

Of the variables assessed male gender was significantly associated with abnormal spirometry findings at ($p= 0.022$). This was in keeping with the findings of study done in United States (Jackson et al., 2018). This can be explained by asthma studies that have shown that boys tend to have a small airway diameter relative to lung volume hence they are prone asthma symptoms. The other probable explanation is that boys

are prone allergic inflammation due to elevated serum IGE levels. Our findings were in contrast with a Nigeria study which found no association between male gender and abnormal spirometry findings, (Chizalu et al., 2021). This can be explained by differences in study methodology in that the Nigerian study was a population based cross-sectional study versus our study a hospital based cross-sectional study that recruited participants who were already having asthma symptoms.

CHAPTER SIX.

6.0 CONCLUSION AND RECOMMEDATIONS.

6.1. Conclusion

1. Majority of the participants were aged between six to nine years of age. More than half resided in an urban set up and three quarters of them presented with wheeze and nocturnal cough.
2. Asthma was confirmed in a quarter of the participants who presented with wheeze and or nocturnal cough
3. Male gender was significantly associated with abnormal spirometry findings

6.2 Recommendations

1. Spirometry should be done for all children presenting with wheeze and or nocturnal cough, (considered to have asthma) since not all participants were found to have abnormal spirometry findings.

REFERENCES

- Akhiwu, H. O., Mustafa, O. A., Abdulwahab, B. J., & Ibrahim, M. (2017). Epidemiology of Pediatric Asthma in a Nigerian Population. *Journal of Health Research and Reviews*, (October), 89–95.
- Akinbami, L. J., & Schoendorf, K. C. (2002). Trends in childhood asthma: prevalence, health care utilization, and mortality. *Pediatrics*.
- Alavaikko, S., Jaakkola, M. S., Tjäderhane, L., & Jaakkola, J. J. (2011). Asthma and caries: a systematic review and meta-analysis. *American journal of epidemiology*, 174(6), 631-641.
- Anon. (2015). Guidelines for the Diagnosis and Management of Asthma January 2015. *National Heart, Lung, and Blood Institute*, 3(January). Retrieved from <https://www.nhlbi.nih.gov/files/docs/resources/lung/NHLBAC-Asthma-WG-Report.pdf>
- Asher, M. I., Keil, U., Anderson, H. R., Beasley, R., Crane, J., Martinez, F., ... Stewart, A. W. (1995). International Study of Asthma and Allergies in Childhood (ISAAC): rationale and methods. *European Respiratory Journal*, 8(3), 483–491.
- Ayuk, A. C., Uwaezuoke, S. N., Ndukwu, C. I., Ndu, I. K., Iloh, K. K., & Okoli, C. V. (2017). Spirometry in Asthma Care: A Review of the Trends and Challenges in Pediatric Practice. *Clinical Medicine Insights. Pediatrics*, 11, 1179556517720675.
- Bacharier, L. B., Boner, A., Carlsen, K. H., Eigenmann, P. A., Frischer, T., Götz, M., ... Wolthers, O. D. (2008). Diagnosis and treatment of asthma in childhood: A PRACTALL consensus report. *Allergy: European Journal of Allergy and Clinical Immunology*, 63(1), 5–34.
- Barbato, A., Turato, G., Baraldo, S., Bazzan, E., Calabrese, F., Panizzolo, C., ... Fabbri, L. M. (2006). Epithelial damage and angiogenesis in the airways of children with asthma. *American Journal of Respiratory and Critical Care Medicine*, 174(9), 975–981.
- Barreiro, T. J., & Perillo, I. (2004). An approach to interpreting spirometry. *American Family Physician*, 69(5), 1107–1116.
- Becker, A. B., & Abrams, E. M. (2017). Asthma guidelines: the Global Initiative for Asthma in relation to national guidelines. *Current Opinion in Allergy and Clinical Immunology*, 17(2), 99–103.
- Berry, M. A., Hargadon, B., Shelley, M., Parker, D., Shaw, D. E., Green, R. H., ... & Pavord, I. D. (2006). Evidence of a role of tumor necrosis factor α in refractory asthma. *New England Journal of Medicine*, 354(7), 697-708.

- Berry, M. A., Hargadon, B., Shelley, M., Parker, D., Shaw, D. E., Green, R. H., ... & Pavord, I. D. (2006). Evidence of a role of tumor necrosis factor α in refractory asthma. *New England Journal of Medicine*, *354*(7), 697-708.
- Brand, P. L. P., Baraldi, E., Bisgaard, H., Boner, A. L., Castro-Rodriguez, J. A., Custovic, A., ... Everard, M. L. (2008). Definition, assessment and treatment of wheezing disorders in preschool children: an evidence-based approach. *European Respiratory Journal*, *32*(4), 1096–1110.
- Braun, L. (2015). Race, ethnicity and lung function: a brief history. *Canadian journal of respiratory therapy: CJRT= Revue canadienne de la therapie respiratoire: RCTR*, *51*(4), 99.
- Constant, C., Sampaio, I., Negreiro, F., Aguiar, P., Silva, A. M., Salgueiro, M., & Bandeira, T. (2011). Respiratory disease screening in school-aged children using portable spirometry, *87*(2), 123–130.
- Debley, J., Filbrun, A. G., & Subbarao, P. (2011). Clinical Applications of Pediatric Pulmonary Function Testing: Lung Function in Recurrent Wheezing and Asthma. *Pediatric Allergy, Immunology, and Pulmonology*, *24*(2), 69–76.
- Diamant, Z., Boot, J. D., & Virchow, J. C. (2007). Summing up 100 years of asthma. *Respiratory medicine*, *101*(3), 378-388.
- Enright, P. (2008). is it feasible and beneficial to asthma patients? Spirometry and Asthma Management in Children and Adults in General Practice Need for Spirometry “ When presented with interpreted spirometry results , GPs usually make the appropriate diagnostic and treat, (June).
- Esamai, F., Ayaya, S., & Nyandiko, W. (2002). *Prevalence of asthma, allergic rhinitis and dermatitis in primary school children in Uasin Gishu District, Kenya. East African medical journal* (Vol. 79).
- FitzGerald, J. M., Spier, S., & Ernst, P. (1996). Evidence-based asthma guidelines. *Chest*, *110*(6), 1382–1383.
- Giner, J., González-mangado, N., Ortega, F., & Maestu, P. (2013). Recommendations of SEPAR Spirometry , *49*(9), 388–401.
- Green, R. J. (2011). Pediatric Asthma in Southern Africa. *The Open Allergy Journal*, *4*, 8–15.
- Guilbert, T. W., Morgan, W. J., Zeiger, R. S., Bacharier, L. B., Boehmer, S. J., Krawiec, M., ... Mauger, D. T. (2004). Atopic characteristics of children with recurrent wheezing at high risk for the development of childhood asthma. *Journal of Allergy and Clinical Immunology*, *114*(6), 1282–1287.
- Jackson, J. H., Pillai, D., Barnawi, Z., Gatti, M., Naime, S., & Pillai, D. K. (2018). The Relationship between the Asthma Control Test (ACT) and Spirometry in Assessment of Asthma Control.

- Kuti, B. P., Omole, K. O., & Kuti, D. K. (2017). Factors associated with childhood asthma control in a resource-poor center. *Journal of family medicine and primary care*, 6(2), 222.
- Lamb, A. K., Ervice, J., & Peters, J. (2015). Reducing the Burden of Childhood Asthma : From Practice to Policy by WHEN ASTHMA MANAGEMENT ISN ' T ENOUGH ;, 137–151.
- Looijmans-Van den Akker, I., van Luijn, K., & Verheij, T. (2016). Overdiagnosis of asthma in children in primary care: a retrospective analysis. *British journal of general practice*, 66(644), e152-e157.
- Makino, S., & Sagara, H. (2010). Evolution of asthma concept and effect of current asthma management guidelines. *Allergy, Asthma & Immunology Research*, 2(3), 172-176.
- Medjo, B., Atanaskovic-Markovic, M., Nikolic, D., Spasojevic-Dimitrijeva, B., Ivanovski, P., & Djukic, S. (2013). Association between pet-keeping and asthma in school children. *Pediatrics International: Official Journal of the Japan Pediatric Society*, 55(2), 133–137.
- Mohamed, N., Ng, L., Odhiambo, J., & Nyamwaya, J. (1995). Home environment and asthma in Kenyan schoolchildren : a case-control study, *i*, 74–78.
- Murray, C., Foden, P., Lowe, L., Durrington, H., Custovic, A., & Simpson, A. (2017). Diagnosis of asthma in symptomatic children based on measures of lung function: an analysis of data from a population-based birth cohort study. *The Lancet Child and Adolescent Health*, 1(2), 114–123.
- Nantanda, R., Tumwine, J. K., Ndeezi, G., & Ostergaard, M. S. (2013). Asthma and pneumonia among children less than five years with acute respiratory symptoms in Mulago Hospital, Uganda: evidence of under-diagnosis of asthma. *PLoS One*, 8(11), e81562.
- Nwosu, N. I., Chukwuka, C. J., Onyedum, C. C., Odilinye, H. C., Niewedim, P. I., & Ayuk, A. C. (2016). Current pattern of spirometry utilisation in a sub-Saharan African country. *African Journal of Respiratory Medicine*, 12(1), 15–20.
- Palmqvist, M., Cui, Z.-H., Sjöstrand, M., Lindén, A., & Lötvall, J. (2001). Reduced late asthmatic response by repeated low-dose allergen exposure. *European Respiratory Journal*, 17(5), 872 LP-880.
- Patil, P. M., & Chavan, M. (2017). Study on to assess pulmonary function test changes in asthmatic child using spirometry and its diagnostic and prognostic value, 4(3), 762–768.
- Pauwels, R. A., Buist, A. S., Calverley, P. M. A., Jenkins, C. R., & Hurd, S. S. (2001). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. *American Journal of Respiratory and Critical Care Medicine*, 163(5), 1256–1276.

PHCmanual2010 _ Wellness _ Health Sciences. (n.d.).

Prajapati, R., Shrestha, B., Dhungel, S., Devkota, K. C., Pramanik, T., & Roychowdhury, P. (2010). ``Spirometric evaluation of pulmonary function tests in clinically. *Nepal Medical College Journal*, 12(December 2009), 45–47.

Rasmussen, F., Taylor, D. R., Flannery, E. M., Cowan, J. O., Greene, J. M., Herbison, G. P., & Sears, M. R. (2002). Risk factors for hospital admission for asthma from childhood to young adulthood: a longitudinal population study. *The Journal of Allergy and Clinical Immunology*, 110(2), 220–227.

Simba, J., Marete, I., Waihenya, R., Kombe, Y., Mwangi, A., Mburugu, P., ... Simba, J. (2018). Knowledge and perceptions on childhood asthma among care-takers of children with asthma at a National Referral Hospital in Western Kenya : a descriptive study, 18(4), 965–971.

Ulrik, C. S., Backer, V., Dirksen, A., Pedersen, M., & Koch, C. (1995). Extrinsic and intrinsic asthma from childhood to adult age: a 10-yr follow-up. *Respiratory Medicine*, 89(8), 547–554.

APPENDICES

SPIROMETRY FINDINGS AMONG CHILDREN PRESENTING WITH A WHEEZE AND OR NOCTURNAL COUGH AT MOI TEACHING AND REFERRAL ELDORET KENYA.

Appendix 1: Consent Form - (ENGLISH).

Name of Principal Investigator(s): Dr. Mwendu Mutunga

Supervisors: Prof. Constance Tenge

Dr. Irene Marete

Moi University, Eldoret School of Medicine

This form has been designed to be read and filled by the guardians or parents of the participants of this study

This Informed Consent Form has two parts:

- Information Sheet – to provide an explanation of the study and its purpose.
- Certificate of Consent – to append your signature if you agree to your child's participation.

Part I: Information Sheet

Introduction:

You are being requested to allow your child to be included as a participant in this study. The information given below will provide a brief explanation about the study scope and purpose. Questions and clarifications are welcome. In the event you agree for your child to participate in this study, a copy of the signed form will be issued to you.

Participation in this study is voluntary and will not alter the quality of services offered to you. You are free to drop out of the study at any time during the study or after and one is free to request for any information given to be destroyed and hence not to be used in the study. In case there is any new pertinent information regarding the study and its effect to you, you shall be notified.

Purpose of the study:

The purpose of the study is to determine the Spirometry findings among children presenting with a wheeze and or a nocturnal cough in MTRH sick child clinic.

Type of Research Project/Intervention:

There will be a questionnaire administered to you and a subsequent Spirometry test performed.

Why has my child been identified to Participate in this study?

Your child has been selected since he or she has presented with a wheeze and or a nocturnal cough.

How long will the study last.

You will be in the study only during the time of our interaction.

What will happen to my child and I during the study?

During this study, you will be asked questions and your child will be examined and Spirometry performed.

We are requesting for your participation to help us learn more about the use of Spirometry in the diagnosis of childhood asthma.

The questions asked shall be regarding your child and the family social economic factors. There is also a section on the clinical presentation and the environmental characteristics of your home. These questions are private and shall be asked in a private environment. Information gathered shall be kept confidential and your identity will not be written on any of the forms nor revealed.

There are no risks or side effects to participating in the study.

Benefits to taking part in the study

- a) The possible benefits to you from this study are the free spirometry exams.
- b) There are no financial benefits or gifts offered on participation.
- c) The possible benefits to the society may include the achievement of proper asthma control due to the improved diagnosis and monitoring of childhood asthma with the routine use of the Spirometry tests.

Contacts:

In case of any question or clarifications please contact – Dr.Mwende Mutunga – 0726860876 – principal investigator.

OR Supervisors – Prof. Constance Tenge and Dr. Irene Marete.

You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects.

Privacy and confidentiality of information:

All reasonable efforts will be made to keep your protected information (private and confidential). Protected Information is the form of information that is, or has been, collected or maintained and can be linked back to you. Using or sharing (“disclosure”) of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission (“authorization”) for the uses and disclosures of your personal information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, Dr. Mwende Mutunga and her study team may share the results of your information provided in the questionnaire. These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

- The National Bioethics. Committee
- The Institutional Research and Ethics Committee,
- The supervisors of this study.

The study results will be retained in your research record for at least six years after the study is completed. At that time, the research information not already in your medical record will be disposed by incineration. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your Personal Information does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr. Mwende Mutunga in writing and let her know that you are withdrawing your permission. The postal address is P. O. BOX 4606, ELDORET. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You will receive a copy of this form after it is signed.

Part II: Consent of Subject:

I have read or have heard what has been read to me pertaining the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions i have at this time. I have been told of the potential risks, discomforts. I freely volunteer to take part in this study.

_____	_____	_____
Participant's parent	Signature of parent or Guardian	Date & Time

_____	_____	_____
Name of Representative/Witness	Relationship to Subject	Date and Time

_____	_____	_____
Name of person Obtaining Consent	Signature of person Obtaining Consent	Date and Time

_____	_____	_____
Printed name of Investigator	Signature of Investigator	Date and time

Appendix 2: Ascent Form - (KISWAHILI)

FOMU YA IDHINI:

KICHWA: SPIROMETRY FINDINGS AMONG CHILDREN PRESENTING WITH A WHEEZE AND OR NOCTURNAL COUGH AT MOI TEACHING AND REFERRAL HOSPITAL ELDORET KENYA.

MTAFITI MKUU: Dr. Getrude Mwendu Mutunga

WASIMAMIZI: Prof. Constance Tenge

Dr. Irene Marete

Moi University, School of Medicine, Eldoret

Fomu hii imetayarishwa kwa nia ya kusomwa na kujazwa na wazazi au wasimamizi wa watoto wanaohusika katika utafiti huu.

Fomu hii ina sehemu mbili:

- Sehemu ya maelezo.
- Sehemu ya makubaliano na sahihi.

Sehemu 1: maelezo:

Unaombwa kutoa ruhusa kwa mtoto wako kuhusika katika utafiti huu. Maelezo yafuatayo yataweza kufafanua minaaajili ya utafiti huu. Unaruhusiwa kuuliza swali au maelezo zaidi kwa ufafanuzi zaidi. Iwapo utakubali kuhusishwa katika utafiti huu utakabidhiwa na nakala ya fomu hii. Kuhusishwa kwa mtoto wako katika utafiti huu ni kwa hiari. Unaweza kusitisha kuhusishwa katika utafiti huu kwa wakati wowote. Huduma ya afya unayopata haitabadilishwa kwa vyovyote vile.

Ikiwa kutakuwa na ugunduzi wowote unaoweza kukufaidi au kukudhuru katika utafiti huu, basi tutawasiliana nawe kukufahamisha.

Madhumuni ya utafiti huu: ni kuweza kugundua uwepo wa ugonjwa wa aina ya asthma unao sababisha kufungana kwa mapafu ukitumia kifaa cha spirometer.

Aina ya utafiti

Ni aina ya kipimo cha pumzi kwa mapafu kinacho tambulika kama spirometry kwa watoto wanao onekana sick child clinic wakiwa na sauti ya korota na kikohozi cha usiku.

Sababu ya kuchagulia kwa mtoto wako:

Mtoto wako amechaguliwa kwa sababu ako katika umri wa miaka sita mpakakumi na minne na akonakikohozi cha usiku pamoja na sauti inayojulikana kama korota.

Utafiti huu utaendeshwa kwa muda ambao mtoto wako atakua akifanyiwa kipimo cha spirometry. Mtoto wako atahesabika katika utafiti huu kwa leo tu

Katika muda huu, utaulizwaa maswali na mtoto kufanyiwa kipimo cha spirometry.

Maswali hayo yatahusisha sehemu ya makaazi, mapato yako ya kifedha kwa mwezi.

Maswali haya ni ya siri na yataulizwa katika chumba kilicho tengwa kuwezesha usiri huu kudumishwa. Habari zote zutakazopatikana katika utafiti huu hazitafichua jina au chochote kinachoweza kufanya wewe au mtoto huyu kutambulike kwa njia yoyote.

Hakutakuwa na faida ya moja kwa moja ya kushiriki katika utafiti huu bali na matokeo ya kipimo hicho cha spirometry. Kushiriki katika utafiti huu ni kwa hiari na una uhuru wa kusitisha kushiriki kwa utafiti huu kwa wakati wowote na kuondoka.

Hakuna hatari yoyote katika kuhusika kwa utafiti huu. Weka sahihi au alama yoyote ya kuonyesha kwamba umekubali kuhusika katika utafiti huu.

Manufaa ya kuhusishwa katika utafiti huu:

- Kipimo cha bure cha spirometry.
- Hakuna malipo yoyote.
- Jamii yetu kwa jumla itaaidika kutokana na habari itakayopatikana katika utafiti huu.

Mawasiliano:

Ikiwa ungependa kuwasiliana na mtafiti mkuu au wasimamizi wake, wasiliana nao kupitia sime nambari zao zikiwa:

Dr. Mwende Mutunga – 0726860876 – mtafiti mkuu OR wasimamizi –Prof .Constance Tenge pamoja naye Dr. Irene Marete

Unaweza kuwasiliana na shirika la Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008 ambalo linatetea na kuhakikisha haki za mhusika yeyote katika utafiti huu hazijadhulumiwa.

Usiri wa habari zinazopokelewa:

Habari zozote utakazotoa katika utafiti huu zitawekwa kwa usiri mkubwa. Habari zote zutakazopatikana katika utafiti huu hazitafichua jina au chochote kinachoweza kufanya wewe au mtoto huyu kutambulike kwa njia yoyote. Habari hiyo itaweza tu kutolewa kwa wasimamizi, shirika la IREC.

Kutolewa kwa habari hiyo itafuata sheria iliyowekwa na National privacy guidelines. Kuweka sahihi katika fomu hii inatukabidhi ruhusa kutumia habari unazotupatia kwa jinsi tuluoieleza hapa.

Ugunduzi wa utafiti huu, utawekwa kwa muda wa miaka sita. Baada ya muda huu, habari hiyo itawezwa kuchomwa kwa usiri. Habari iliyo katika maktaba ya hospitali inayohusu matibabu na ugonjwa wa mtoto zitaendelea kuwekwa katika maktaba hiyo, kwa muda usiojulikana.

Ikiwa utaamua kujitoa katika utafiti huu, tafadhali wasiliana na mtafiti mkuu Dr. Mwende Mutunga kwa sanduku la posta 4606 Eldoret. Tutasitisha kuchukua habari zaidi kwako. Habari utakayokuwa umetupatia itatumika kwenye utafiti huu.

Huduma ya matibabu kwa mtoto wako haitasitishwa ama kubadilishwa hata usipohusika katika utafiti huu.

Sehemu 2: makubaliano:

Mimi nimeweza kusoma na kuelewa sehemu ya maelezo ya utafiti huu. mtafiti mkuu au msaidizi wake amenieleza kinaga ubaga na kujibu maswali yangu yote. Nimeelezwa manufaa na hatari zitakazokuwa katika utafiti huu. Nimejitolea kwa hiari kuhusishwa katika utafiti huu.

_____	_____	_____
Jina ya mzazi au msimamizi wake	Uhusiano na mtoto	Sahihi. Tarehe na saa
_____	_____	_____
Jina la mzazi au msimamizi wa mzazi wa mtoto	Sahihi	Tarehe na saa:
_____	_____	_____
Jina la anayechukua idhini Saa	Sahihi yake	Tarehe na
_____	_____	_____
Mtafiti mkuu Saa	Sahihi yake	Tarehe na

Appendix 3: Assent Form (>7 years)**SPIROMETRY FINDINGS AMONG CHILDREN PRESENTING WITH A WHEEZE AND OR NOCTURNAL COUGH AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET KENYA.**

Client Code..... Age

Health FacilityName of Interviewer

Dear Respondent,

This research study is being carried out to determine the spirometry findings among children presenting with a wheeze and or nocturnal cough in Moi Teaching and Referral hospital Kenya

Based on the above information i am kindly requesting for your participation in this research by giving information needed. You are free to withdraw from the study at any time. However, am urging you to take part to the end in order to make this study a success. There shall be no material gain to you from this research. The study intends to engage you purely through answering the questionnaire. There shall be no any physical or chemical harm transferred to you considering role in this study shall remain purely the answering of questions.

For any further clarifications concerning this study, you are free to contact the researcher, Dr Getrude Mwende Mutunga Tel.0726860876. If you have concerns about human rights, ethics and welfare issues you may contact the Institutional Research and Ethics Committee(IREC) University Ethics Review Committee, P.O. Box 3-30100, Eldoret Kenya, Tel+254 787723677 Email: irec@mtrh.or.ke

I hereby confirm to have read/been told what the study entails. I have understood the objectives and as the eventual participation in this study, it is by choice and not coercion. I have also understood that I am free to withdraw from the study any time I feel like and that my withdrawal will not affect my right to access to information and health services in the Sub-County Health Facilities.

Yes, I will be in this research study. do this.

No, I don't want to do this.

Individual Participant's Signature

Date

 Parent/Guardian/Relative/Caretaker

 Date

Appendix 4:Fomu Ya Idhini/Lililopo (> 7years)**KICHWA: SPIROMETRY FINDINGS AMONG CHILDREN PRESENTING WITH A WHEEZE AND OR NOCTURNAL COUGH AT MOI TEACHING AND REFERRAL HOSPITAL ELDORET KENYA****Kanuni ya Mteja.....****Umri.....****Kituo cha Afya.....**

Ndugu kujibu,

Utafiti huu unaendeshwa na Dk Getrude Mwendu Mutunga, mwanafunzi wa Chuo Kikuu cha Moi kutafuta Shahada ya Uzamili katika Tiba. **Madhumuni ya utafiti huu: ni kuweza kugundua uwepo wa ugonjwa wa aina ya Asthma unao sababisha kufungana kwa mapafu ukitumia kifaa cha Spirometer.**

Aina ya utafiti

Ni aina ya kipimo cha pumzi kwa mapafu kinacho tambulika kama spirometry kwa watoto wanao onekana sick child clinic wakiwa na sauti ya korota na kikohozi cha usiku.

Kulingana na taarifa hii naomba ushiriki wako katika utafiti huu kwa kutoa taarifa zinazohitajika. Wewe uko huru kujiondoa kutoka kwenye utafiti huu wakati wowote. Hakutakuwa na faida au vifaa kwako wewe kutokana na utafiti huu. Hakutakuwa na madhara ya kimwili au kemikali ambayo yatahamishwa na wewe.

Kwa ufafanuzi wowote zaidi kuhusu utafiti huu, wewe uko huru kuwasiliana na mtafiti, Dk Getrude Mwendu Mutunga.0726860876. Kama una wasiwasi juu ya haki za binadamu, maadili na masuala ya ustawi unaweza kuwasiliana na Taasisi za utafiti na Kamati ya Maadili (IREC), Chuo Kikuu Maadili Kamati ya Uchunguzi, S.L. Posta 3-30100, Eldoret Kenya, Simu + 254 787723677 pepe: irec@mtrh.or.ke Mimi nadhibitisha kuwa nimesoma / nimeambiwa ni nini utafiti huu unahusu. Nimeelewa malengo na kwamba kushiriki ni kwa hiari yangu wala si kwa kulazimishwa. Mimi pia nimeelewa kwamba niko huru kujiondoa kutoka kwenye utafiti huu wakati wowote Najisikia kama kwamba kujiondoa kwangu itakuwa si kuathiri haki yangu ya kupata habari na huduma za afya katika kata hii ndogo.

 Ndiyo, mimi itakuwa katika utafiti huu. **Hapana, mimi sitaki****kufanya hivyo.**

Sahihi ya Mshiriki Binafsi

Tarehe

Mzazi/Mlezi/Jamaa/_____
Tarehe

Appendix 5: Questionnaire**INSTRUCTIONS FOR USE:**

- Fill in responses in the columns on the right.
- Special instructions written in italics:

Interviewee number:	
Date of interview:	
Time of interview:	
Interviewers name and signature:	

1. RESPONDENTS RELATIONSHIP TO CHILD:Father Mother Guardian Relative

If others please specify _____

PATIENT CHARACTERISTICS**SOCIO-DEMOGRAPHIC DATA:**

2. Date of Birth: _____

3. Gender: a. Male b. Female

4. Residence: County _____ Sub-County _____

Ward _____ Village _____.

5. Type of residence: (*tick appropriately*). Rural setup urban setup.

6. Type of housing.

 Permanent semi- permanent

7. What are the social economic activities taking place in your residential area?

8. Is your child in school?

Yes No

9. If no what is the highest level of education attained?

a. Preschool b. Primary c. Secondary

10. What are the reasons for not attending school? _____

 Current illness others.

If others please specify _____

RISKFACORS FOR DEVELOPMENT OF ASTHMA.

11. What kind of floor do you have in your houses?
- a. Cemented
- b. Earthen Floor
- c. If others please specify _____
12. Have you been exposed to cigarette smoke within your house? Yes
13. Have you been exposed to allergens such as?
- a. Pollen grains Yes No
- b. Animal Dander Yes No
- c. Mould Yes No
- d. Dusty Rooms Yes No
- e. Perfumes And Air Fresheners Yes No
- f. Cold Air Yes No
- g. If others please specify _____
14. If yes for how long have you been exposed to any of the above allergens?
- 1 Month Months
15. Do you have any knowledge on Asthma control?
- Yes No
16. If yes specify _____
17. What type of fuel do you use for cooking?
- Charcoal Gas Fire Wood Kerosine Others
18. Are there Relatives with Similar Illness? _____
- Yes No
19. Are there pets in your Household? _____ Yes No

CLINICAL EXAMINATIONS**20. Assessment of an acute exacerbation of asthma.**

- a. Respiratory rate _____
- b. Breathlessness
- Yes No
- c. Talking.
- i. Sentences. Yes No
- ii. Phases. Wo
- d. Agitation. Yes No
- e. Drowsy or confused. Yes
- f. Use of accessory muscles.
- Wheeze Yes No

21. Classification of asthma severity.

Frequency of symptoms.

- a. Less than once a week. Yes No
- b. More than once a week but less than once a day. Yes
- c. Daily. Yes

22. Severity of exacerbations?

- a. Brief Yes No
- b. Affecting sleep and activity.

- c. Frequency.
 Twice a month or less. Yes No
 More than twice a month Yes No
 More than once a week.
- d. Nocturnal symptoms. Yes No

23. During this visit what brought the child to the hospital this time? Cough
 wheeze

If yes what is the duration of wheeze? _____

If Yes What Was the Duration of nocturnal cough? _____

What is the diagnosis?

24. Any other Concurrent chronic illness? Yes No

If yes

Specify _____

25. Any known congenital anomalies: _____

26. Have you been admitted in the last 6 months? Yes

If yes what were the reasons.

- a. Cough.
 b. Wheezing.
 c. Nocturnal cough + wheeze.
 d. Eczema
 e. Others

27. Any Current treatment for this complains?

- a. Inhaled short acting beta agonists (salbutamol)
 b. Inhaled long acting beta agonists (formoterol)
 c. Corticosteroid (budesonide)
 d. Oral steroids (prednisolone)
 e. Oral beta agonists(salbutamol)
 f. Antibiotics
 e .Oral montelukarst
 g .Others

(select as appropriate)

28. SPIROMETRY FINDINGS

WHAT WAS THE FORCED VITAL CAPACITY	
FORCED EXPIRATORY VOLUME IN THE FIRST SECOND in (%)	
RATIO OF FORCED EXPIRATORY VOLUME IN THE FIRST SECOND TO FORCED VITAL CAPACITY	
FORCED EXPIRATORY VOLUME CHANGE AFTER 200UG OR 2 PUFFS OF BRONCHODILATOR (SALBUTAMOL VIA INHALATION)	

Appendix 6: Budget

ITEMS	QUANTITY	UNIT COST	TOTAL
LAPTOP	1	50,000	50,000
PRINTER \$ PHOTOCOPIER	1	10,000	10,000
STATIONERY	-	10,000	10,000
BIOSTASTICIAN	1	20,000	20,000
INTERNET \$COMMUCATION	-	10,000	10,000
PUBLICATION	-	30,000	30,000
RESEARCH ASSISTANTS	-2	30,000	60,000
SPIROMETER	2	100,000	200,000
MASKS ,MDI, SPACERS ,MOUTHPIECE, TRAINING	-	60,000	60,000
MISCELENIIOUS		50000	50,000
GRAND TOTAL	-	500,000	500,000

Appendix 7: WORK PLAN

ACTIVITY	START	COMPLETE
PROPOSAL DEVELOPMENT	FEBRUARY 2018	JUNE 2018
DEPARTMENT PRESENTATION	JULY 2018	AUGUST 2018
IREC APPROVAL	SEPTEMBER 2018	DECEMBER 2018
DATA COLLECTION	JUNE 2019	FEBRUARY 2020
DATA ANALYSIS	MARCH 2020	APRIL 2020
THESIS WRITING	MAY 2020	JULY 2020
MOCK DEFENCE	AUGUST 2020	SEPTEMBER 2020
SCHOOL DEFENCE	MARCH 2021	JULY 2021

Appendix 8: IREC Approvals



MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 334711/2/3

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

Reference IREC/2018/232
Approval Number: 0003169

Dr. Getrude Mwende Mutunga,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Mwende,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"Spirometry Findings among Children Presenting with a Wheeze and or Nocturnal Cough at Moi Teaching and Referral Hospital, Eldoret, Kenya."

We note that you are seeking to make an amendment as follows:-

1. To change the sample size from 384 to a census study.

The amendment has been approved on 16th September, 2019 according to SOP's of IREC. You are therefore permitted to continue with your research.

You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely

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

cc: CEO - MTRH Dean - SPH Dean - SOM
Principal - CHS Dean - SOD Dean - SON



MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 334711/2/3
16th September, 2019





MU/MTRH-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)
 MOI TEACHING AND REFERRAL HOSPITAL
 P.O. BOX 3
 ELDORET
 Tel: 33471/2/3
 Reference: IREC/2018/232
Approval Number: 0003169



MOI UNIVERSITY
 COLLEGE OF HEALTH SCIENCES
 P.O. BOX 4606
 ELDORET
 6th December, 2018

Dr. Getrude Mwende Mutunga,
 Moi University,
 School of Medicine
 P.O. Box 4606-30100,
ELDORET-KENYA.



Dear Dr. Mwende,

RE: FORMAL APPROVAL

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

"Spirometry Findings among Children Presenting with a Wheeze and or Nocturnal Cough at Moi Teaching and Referral Hospital, Eldoret Kenya".

Your proposal has been granted a Formal Approval Number: **FAN: IREC 3169** on 6th December, 2018. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; hence will expire on 5th December, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date. You will be required to submit progress report(s) on application for continuation, at the end of the study and any other times as may be recommended by the Committee.

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

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

Appendix 9: Hospital Approval (MTRH)



MOI TEACHING AND REFERRAL HOSPITAL

Telephone : (+254)053-2033471/2/3/4
 Mobile: 722-201277/0722-209795/0734-600461/0734-683361
 Fax: 053-2061749
 Email: ceo@mtrh.go.ke/directorsoffice@mtrh@gmail.com

Nandi Road
 P.O. Box 3 – 30100
 ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

20th December, 2018

Dr. Getrude Mwende Mutunga,
 Moi University,
 School of Medicine,
 P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Spirometry Findings among Children Presenting with a Wheeze and or Nocturnal Cough at Moi Teaching and Referral Hospital, Eldoret, Kenya".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

for [Signature] 20/12/18

DR. WILSON K. ARUASA, MBS
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

cc - Senior Director, (CS)
 - Director of Nursing Services (DNS)
 - HOD, HRISM

All correspondence should be addressed to the Chief Executive Officer

Visit our Website: www.mtrh.go.ke

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