**Prevalence and predictors of residual sleep disordered breathing post adenotonsillectomy in children at selected hospitals in Nairobi**

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**MMED PAEDIATRICS AND CHILD HEALTH**

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A research proposal in partial fulfillment for the degree of Masters of Medicine in Paediatrics and Child Health, University of Nairobi.

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I wish to submit my research proposal for approval by your esteemed committee. I am currently a second-year student pursuing a Master’s Degree in Pediatrics and Child Health at the University of Nairobi, College of Health Sciences.

Yours Sincerely,

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# DECLARATION

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

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**ABBREVIATIONS**

A&T- Adenotonsillectomy

AAP- American Academy of Pediatrics

ATH- Adeno/tonsillar hypertrophy

ATS- American Thoracic Society

BIPAP- Bilevel positive airway pressure

BMI- Body mass index

CHAT- Childhood Adeno/tonsillectomy Trial

CI- Confidence interval

CPAP- Continuous positive airway pressure

CT- Computed topography

EEG- Electroencephalogram

ENT- Ear Nose and Throat

ERS- European Respiratory Society

MRI- Magnetic Resonance Imaging

NREM- Non rapid eye movement

NPPV- Noninvasive positive pressure ventilation

OSA- Obstructive sleep apnea

OSAS- Obstructive sleep apnea syndrome

POSAsT- Paediatric Obstructive Sleep Apnoea screening Tool

PSG- Polysomnography

PSQ- Paediatric Sleep Questionnaire

REM - Rapid eye movement

SDB- Sleep disordered breathing

YRS- Years

# DEFINITIONS

**Sleep disordered breathing -** A syndrome of upper airway obstruction during sleep characterized by snoring and/or increased respiratory effort that results from increased upper airway resistance and pharyngeal collapsibility[1].

**Residual sleep disordered breathing** - sleep disordered breathing symptoms that do not improve following surgical or non-surgical intervention. Can be detrimental.

**Obstructive sleep apnoea -** A disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction [2] that disrupts normal ventilation during sleep and normal sleep patterns. Obstructive hypoventilation during sleep is included in the above definition of OSA by the American Thoracic Society[3].

**Obstructive hypoventilation -** Snoring and abnormally elevated end expiratory carbon dioxide partial pressure in the absence of recognizable obstructive events[1].

**Polysomnography-** Polysomnography is a sleep study performed overnight while being continuously monitored by a credentialed technologist, is a comprehensive recording of the bio-physiological changes that occur during sleep. It is required to diagnose, exclude, or assess OSA severity in a definitive manner, since the history and physical examination findings are not sufficiently specific and is the gold standard for diagnosing OSA.[4]

**Apnea hypopnea index -** The apnea hypopnea index is the total number of apneas and hypopneas per hour of sleep. The AHI is most commonly calculated per hour of total sleep/REM sleep /non-REM sleep. [4]

**Apnea -** The cessation, or near cessation, of airflow lasting for at least 10 seconds in adults, in children the duration criteria is shorter than 10seconds[5]

**Hypopnea-** Airflow decrease ≥ 30% for ≥ 10 seconds and is associated with either ≥ 3% desaturation or an arousal. American Academy of Sleep Medicine, 2015

# ABSTRACT

Background: Sleep disordered breathing (SDB) is a spectrum disorder ranging from habitual snoring to obstructive sleep apnoea [6] in its severest form. If not treated, the consequences of SDB are severe including impaired growth, systemic or pulmonary hypertension, myocardial remodeling and neurocognitive impairment. The most common identifiable risk factor for SDB is enlarged tonsils and adenoids. Adenotonsillectomy results in improved secondary outcomes of behavior and quality of life. However, about 21 to 38 percent of children may not improve following surgery and may even require additional treatment modalities. Screening of children following treatment at 6 to 8 weeks is recommended to determine if there are residual symptoms of SDB so as to plan for further treatments including continuous positive airway pressure, tracheostomy or repeat A&T to prevent adverse outcomes.

**Objectives:**

To determine the prevalence of residual sleep disordered breathing in children 2-18years of age at the Kenyatta National hospital and the Nairobi Hospital and Coptic Hospital at 6 to 8 weeks post adenotonsillectomy.

**Methods:**

**Study design:** A hospital based prospective cohort study.

**Duration:** It will take a period of 6 months.

**Site:** Three hospitals in Kenya - The Kenyatta National Hospital, Nairobi Hospital and Coptic Hospital.

**Population**: Children 2 to 18 years. Inclusion criteria: All children undergoing adenotonsillectomy. Exclusion criteria: Those undergoing repeat surgeries, multisite surgeries or those whose caregivers do not have telephone numbers.

Sampling technique: Consecutive sampling in each hospital to reach the target sample size.

Clinical procedures: Enrollment will be done prior to surgery, following consent, a questionnaire will be administered to caregivers. It will contain sociodemographic characteristics, comorbidities and items from Paediatric sleep questionnaire (PSQ) and Paediatric obstructive sleep apnoea screening tool (POSAsT). A score of >33% on PSQ will denote presence of SDB at baseline. At about 6 to 8 post adenotonsillectomy we shall call the caregivers and administer the PSQ, a score of >33% will denote residual SDB.

**Data analysis:** Data will be exported to R (V3.4.3, R core team, 2017) for statistical analysis. Demographic and other patient characteristics will be summarized into percentages and means or medians. Prevalence will be presented as a percentage with 95% confidence interval. We will fit a marginal logistic regression model with an exchangeable working correlation and robust variance estimates using generalized estimating equations to determine if predictors are associated with residual SDB at 6 weeks.

Utility:Data on residual SDB in children in Africa is scarce. Determining the predictors of residual SDB will help us prioritize children at risk of developing residual symptoms to plan for timely follow up. Findings from this study will inform optimized management of residual SDB in both the public and private health sectors in Kenya. It may guide health system administrators on the need to set up facilities for evaluation of children with SDB in Kenyatta National Hospital such as a sleep laboratory.

# 1.BACKGROUND AND LITERATURE REVIEW

## 1.1Introduction

Sleep disordered breathing (SDB) is a syndrome of upper airway obstruction during sleep characterized by snoring and/or increased respiratory effort that result from increased upper airway resistance and pharyngeal collapsibility[1]. Pharyngeal collapsibility occurs when the pharyngeal dilators have a reduction in the tonic contraction during sleep. SDB occurs along a spectrum of severity, ranging from primary snoring on the mild end of the spectrum to obstructive sleep apnea[6] in its severest form[3, 7].

### Clinical entities of SDB

Children with SDB develop exaggerated upper airway resistance during sleep as compared with normal children and this could be due to increased airway compliance[8].This leads to decreased airflow ,increased negative pressure and increased CO2 which stimulates pharyngeal mechanoreceptors to augment pharyngeal dilator contractions. However, this response may not completely relieve the upper airway obstruction and hypoventilation ensues with a rise in PCO2 and a decrease in O2. The resulting clinical picture of increased work of breathing with snoring and SDB resulting in sleep disruption, hypoxia and hypercarbia.

Globally SDB affects 4-11% of children. Symptoms include excessive daytime sleepiness mostly seen in older children, inattention, learning problems, behavioral problems (hyperactivity, impulsivity, rebelliousness and aggression). Parents report of hearing their children snoring, having abnormal postures during sleep, mouth breathing, having episodes of apnoea during sleep and children appearing like they are not getting satisfactory sleep.

If not treated well, the consequences of SDB are severe including impaired growth with failure to thrive occurring in infants, systemic or pulmonary hypertension, and myocardial remodeling. OSA is associated with poor neurocognitive development and behavioral problems, including attention deficit disorder and poor school performance.

The most common identifiable risk factors for SDB are enlarged tonsils and adenoids, obesity, craniofacial abnormalities, neuromuscular factors and genetic abnormalities among others.

The gold standard for diagnosis is polysomnography. Polysomnography reveals one or more obstructive apneas or hypopneas per hour of sleep (ie, an apnea hypopnea index >1 event per hour). In setups where this is unavailable, diagnosis is made from set of questionnaires such as the paediatric sleep questionnaire, night oximetry or sleep clinical record.

A stepwise treatment approach is usually implemented until complete resolution of SDB: Weight loss if the child is overweight or obese, nasal corticosteroids and/or oral montelukast, adenotonsillectomy, CPAP or NPPV (for nocturnal hypoventilation), craniofacial surgery and tracheostomy. Effective treatment leads to improved secondary outcomes of behavior, quality of life and polysomnography (PSG) findings.

A very important aspect of treatment involves the recognition and management of persistent SDB. Studies reveal that about 21 to 38 percent of children may not improve following surgery alone. Screening of children following treatment at 6 to 8 weeks is recommended to determine if there are persistent symptoms of SDB so as to plan for further treatments including continuous positive airway pressure, tracheostomy or repeat A&T to prevent adverse outcomes.

This study will enable us to identify the children who have residual sleep disordered breathing at 6 to 8 weeks post adenotonsillectomy and also the risk factors or predictors contributing to this. It will generate local evidence on the prevalence of residual SDB in our children and help us address this problem through designing of policies and guidelines and provision of treatment.

## 1.2 Literature review

## 1.21 Prevalence of SDB

The epidemiology of SDB in children from a meta-analysis, estimated prevalence of SDB as 4-11%, habitual snoring as reported by parents 7.45% and OSA 1-4%[9]. Based on cross sectional studies the prevalence of snoring ranged from 1 to 5%[10, 11]. One study done in 2012 by Marcus et al in which 350 articles from 1999 through 2011 were reviewed, established the prevalence of OSAS as 0 to 5.7%[12]. Epidemiological data on SDB in Africa is scarce yet SDB is common. The only data available from Nigeria found a prevalence of 28- 34% of snoring in children[13].

## 1.22 Causes of SDB or of upper airway obstruction

### Enlarged lymphoid tissue

Enlarged tonsils (palatine and lingual) and adenoids are the commonest cause of SDB in children. The lymphoid tissue grows from birth to 12 years of age[14]and the tonsils and adenoids grow faster compared to the facial bones. This predisposes the retropalatal area to having the smallest cross-sectional area within the pharyngeal airway as the tonsils and adenoids overlap predisposing children with adeno/tonsillar hypertrophy(ATH) to increased upper airway obstruction[14].

### Excessive other soft tissue

The prevalence of SDB in obese children is higher than in non-obese children, and this is particularly true for adolescents[15]. The fat pad and oropharynx become less round or more complex in shape and move closer in obese children with OSAS[16]. In many cases, obesity in addition to ADH causes SDB in an individual patient, and children with obesity are more likely to have residual SDB after A&T when compared to lean patients[17].

Children with any of the mucopolysaccharidoses and mucolipidoses who have significant accumulation of macromolecules in the tissues of the pharynx are more likely to have SDB[8].

### Race and prematurity

Premature children are found to be at higher risk of developing SDB compared with children who were born at term. In a study done by Rosen to look for associations of race and prematurity, African children were 4 to 6 times likely to have SDB as compared with Caucasian children[18].

### Abnormal bony cartilage development

Children with midfacial hypoplasia, retro or micrognathia, acutely angled skull base, narrow maxillary arch, nasal septal obstruction, macroglossia and soft tissue abnormalities are most commonly associated with SDB. These anomalies decrease the size of the upper airway predisposing the pharynx to collapse during sleep.

### Neuromuscular causes

Neuromuscular factors affect the size, shape, compliance, and coordination of the pharyngeal airway, which can have an important effect on the development of SDB. The most common example is found in children with trisomy 21 (Down syndrome), which is characterized by craniofacial anomalies and hypotonia. In one report, 81 percent of children with trisomy 21 had OSA or hypoventilation. This study used a daytime nap study, which may have underestimated the true incidence of OSA or hypoventilation[19, 20].

## 1.22 Diagnosis and Management of SDB

The European Respiratory Society (ERS) Scientific Committee made a document on the diagnosis and management of obstructive sleep disordered breathing in childhood in April 2012. [1] According to this document the management of SDB should follow a step wise approach starting with medical management and thereafter proceeding to surgical procedures if warranted[1].

Some of the modalities of treatment in those with SDB due to ATH include use of intranasal steroids, montelukast and adenotonsillectomy [17, 21-23].

The gold standard for diagnosing OSA is the PSG but where this is not feasible, the use of, questionnaires, nocturnal oximetry and sleep clinical records can be used.

## 1.23 Prevalence of residual SDB

Data on residual SDB in children in Africa is scarce, yet it may be common as documented in other studies done globally. A quick systematic search with the terms (snoring in children and sleep disordered breathing in children) through PubMed (NLM) 1983 to 2019 databases resulted in 421 and 237 studies respectively in which only one was in Africa, Cairo. The study was a special topic article reviewing current theories regarding the underlying pathophysiology of pediatric sleep apnea, summarizing standards for diagnosis and management[24]. One other study was found using the search term (prevalence of sleep disordered breathing in Africa) through PubMed (NLM) 1995 to 2019 databases was on the prevalence of snoring in primary school children carried out in Nigeria[13]. Out of 37 studies found by this search, only two were on children. The second study was in Egypt looking at the association between particulate matter exposure and sleep in children[25]. This demonstrates the scarcity of local evidence that would provide information on the prevalence of residual sleep disordered breathing in children in Kenya. From studies done globally prevalence of residual SDB ranges from 21-70% of children[17, 21, 23, 26]. This has been summarized on table 1.

**Table 1: Prevalence and predictors of residual SDB and residual OSA in the literature**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title, Country, Author, Year** | **Study population, Age, No. outcome measurement** | **Prevalence of residual SDB /OSA** | **Risk factors** |
| Predictors of sleep apnoea after surgery in children <3yrs  USA, Nath A et al 2013[22] | 70 children  post-op PSG (Random)  outcome -OSA by PSG | 70% (49/70) | Pre-op severity  Asthma  Allergic rhinitis |
| Risk factors of residual OSA after A&T in children  USA, Imanguli et al 2016[21] | 169 children  Outcome-OSA by PSG | 38% (64/169) | Toddlers 1-3yrs (27%)  Preschool 3-5yrs (33%)  Middle childhood 6-11yrs (29%)  Teenagers 12-18yrs (67%) \*  \*(p=0.03) |
| Adenotonsillectomy outcomes in treatment of OSA in children.  USA and Europe, Bhattacharjee R et al 2010[26] | 578 children  8/12 to 17yrs  Outcome -OSA by PSG ≈6/52 post op | 21.6% (125/578) | Age >7yrs  Obese children  Asthma  Pre-A&T AHI severity\*  \*p<0.05  Lower birth weight |
| Telephone screening to identify children at risk of persistent OSA post A&T.  USA, Schaeg LE et al 2016[23] | 85 children  2-17yrs  43 SDB clinically diagnosed  42 OSA, PSG based  Post op PSQ 6=8/52 | 10/43 (23%) residual SDB  18/42(42%) residual OSA | No risk factors identified |

## 1.24 Risk factors for residual SDB

### BMI score, asthma and pre-operative severity of SDB

Several factors are associated with long term persistence of SDB including pre-operative obstructive sleep apnea [6] severity[22]. A multicenter retrospective study by Bhattacharjee et al revealed that the factors most significantly associated with elevation of post-A&T AHI (residual OSAS) in order of influence were advancing age (>7 years); increasing BMI z-score; patients with asthma; and high severity of pre-A&T AHI. Subgroup analysis in obese and nonobese children revealed that the severity of OSAS and asthma did not exert a significant impact in obese children (p value 0.809), in contrast to the one identified in nonobese children (p value 0.006) [26].

### Nocturnal enuresis and rhinitis before surgery

Another study on the treatment outcomes following A&T 6 through 36 months post-surgery, established that residual pediatric OSA was significantly associated with enuresis and rhinitis before surgery[27]. In as much as enuresis in itself is not a cause of SDB, its presence is positively correlated with severity of obstructive SDB[1].

### Males

Adolescent males are at increased risk of recurrence compared to females [1]. Testosterone induces changes in upper airway morphology during adolescence and this is in contrast to the equal risk noted between the genders in prepubertal children [28].

### Comorbidities

Comorbidities such as neurological, craniofacial and developmental abnormalities presumably because in these cases a substantial part of the SDB is caused by craniofacial and/or neuromuscular factors or pharyngeal instability and not simply enlarged tonsils and adenoids[29]. Imanguli and Seckin found a higher prevalence of residual OSA (44%) in patients with neurodevelopmental disorders than patients without comorbidities (33%) (*P* < .05)[21].

### Age

Age is a contributing factor to residual disease, studies suggest those <3 years and >7 years to be at increased risk[21, 26]. As mentioned earlier, teenagers may especially develop re-emergence of symptoms of OSA months or years after A&T due to growth spurt, hormonal influence, regrowth of adenoid/tonsillar tissue or changes in body shape due to puberty.

## 1.10 Evaluation of patients post adenotonsillectomy

The issue of residual SDB necessitates for screening of persistent SDB symptoms following surgery. The American Academy of Pediatrics (AAP) and European Respiratory Society (ERS) recommend screening for residual SDB at 6-8 weeks after A&T. All children should be followed up at 6 to 8 weeks after surgery to ensure that the symptoms or signs of OSA have abated[12]. PSGs are recommended postoperatively for follow up[3]. Repeat PSGs are also indicated for those with craniofacial or neurologic abnormalities[30].

The post-operative evaluation determines persistence of symptoms in order to plan for further treatment. Those with residual SDB may require repeat A&T, while others will require use of positive airway pressure- CPAP(continuous positive airway pressure) and BIPAP(bilevel positive airway pressure)and if need be tracheostomies[1].

The initial evaluation post A&T can be carried out in-person in the office, as a telephone follow up and as a post-operative PSG[31]. A telephone call is practical as loss to follow up may occur due to distance and improvement of symptoms post A&T may discourage the use of in-office evaluation.

## 1.10 Why the Pediatric Sleep Questionnaire (PSQ)?

The post-op PSG is fraught with major obstacles as it is expensive, quite technical and not readily available even in high resource settings[32]. This has led to less diagnosis (<10%) using PSG and has brought about the reliance on questionnaires which are more readily available[33].

Several questionnaires have been used including the Brouillette Score, OSA 18, Sleep-Related Breathing Disorder Scale (SRBD Scale) and Sleep Disorders Inventory for Students. Several disadvantages include high sensitivity with low specificity, low (40%) sensitivity and numerous questions (40 questions) respectively making them impractical for routine use[34].

A subset of 22 questions from the SRBD Scale makes up Chervin’s Pediatric Sleep Questionnaire (PSQ)[2]( It is attached on part C of appendix 3). This is a validated questionnaire which was first established in Michigan, USA between 1996 and 1998 in children 2 to 18 years. It was found to be a valid and reliable instrument that can be used to diagnose SDB in clinical research when polysomnography is unavailable. A score of ≥8/22(33%) has a sensitivity of 85% and specificity of 87% in diagnosing SDB[35].

The use of PSQ for screening would be effective, cheap and would identify children at increased risk of residual symptoms[33]. It has been used to determine prevalence of SDB in various populations without correlating with overnight PSG findings[31]. In evaluation of risk of OSA, the PSQ led to significant identification compared to earlier evaluations where no questionnaire was used at all with a p value of, p<0.001[36, 37].

Telephone screening with the PSQ 6 to 8 weeks post A&T has been carried out to find out the persistent symptoms of OSA and SDB in children[23]. In this study among 85 children 2 to 18 years of age, 43 had clinically diagnosed SDB while 42 had OSA diagnosed based on the PSG studies. At about 6 to 8 weeks post A&T, the parents and guardians received phone calls based on the PSQ, 10 out of the 43 (23%) had residual SDB while 18 out of the 42 (42%) had residual OSA. This study concluded that telephone calls could be used as follow up measures to detect children who required further evaluation and treatment[23].

In our setting where there are limited resources and PSG is unavailable, the PSQ would be a useful tool for prediction of residual of SDB and of checking improvement of symptoms after A&T with a sensitivity of 78% and specificity of 72%[2].

## 1.11 Why the Paediatric obstructive sleep apnoea screening tool?(POSAT)[33]

This is a validated questionnaire that was developed by Karen Spruyt and David Gozal in 2012. It has been validated in children aged 3 to 9years in Canada, USA and Israel [38]. It was found to provide a valid and a simple approach for identifying children at risk of more severe OSA. The screening tool consists of 6 questions which are answered on a hierarchical Likert scale answered as never, rarely, occasionally, frequently and almost always (Appendix 3 part D). A cumulative score of ≥ 2.72 is indicative of the high risk of OSA. The predictive value for mild OSA using it is low (20-62%), though is highly sensitive 83% and moderately specific 64% for the diagnosis of moderate and severe OSA. It can therefore discriminate children with greater urgency for evaluation and timely treatment prior to surgery. In our study, this screening tool will enable us to classify the severity of SDB as one of the priori risks for residual SDB. The questionnaire is attached in appendix 4.

Cumulative score of all the questions:

A= B= C= and so forth.

# 2.STUDY JUSTIFICATION

SDB is common and it significantly impacts on the morbidity of children globally. It results in decreased quality of life and can lead to life threatening complications. Early identification of children with residual SDB is important to prevent morbidities associated with the disease as it is treatable using non-surgical and surgical interventions. There is lack of evidence on the prevalence of SDB In Kenya.

Generating evidence and insight on children will help us address this problem. If study findings suggest that the burden for residual SDB is high, it would help health facility administrators and program implementers plan for additional interventions such as CPAP or design policies and guidelines to provide treatment.

Determining the predictors of residual SDB will help health workers prioritize children at risk for timely follow up.

# 3.STUDY OBJECTIVES

## Broad objective

To determine the prevalence and predictors of residual sleep disordered breathing post adenotonsillectomy.

## Specific objectives

1. To determine the proportion of children who develop residual sleep disordered breathing at 6 to 8 weeks post adenotonsillectomy.
2. To determine the pre-operative predictors of residual SDB 6 to 8 weeks post adenotonsillectomy.

# 4.METHODS

## 4.1 Study design:

This will be a hospital based prospective cohort study. Children who are between the ages of 2 to 18 years and are undergoing A&T in the three hospitals - Kenyatta National Hospital, The Nairobi Hospital and Coptic Hospital (letters for permission to carry out study in these hospitals are attached in Appendix 4) will be identified prior to performance of surgery. They will then be followed up with a telephone call at 6 to 8 weeks post-operatively to determine how many of them still have residual symptoms of SDB.

## 4.2 Study duration:

This study will be conducted over a period of 6 months following approval from the ethics committee. (Appendix 7 shows the timelines from the development of the proposal.)

## 4.3 Study site

The study will be conducted at the Kenyatta National Hospital ENT clinic and wards. This hospital is a national referral hospital with approximately 20 children undergoing A&T every week. Some of the children here may have symptoms of severe SDB either due to health seeking behavior, financial constraints and late interventions. It would be imperative to also include children seen in private facilities as their risk factors may differ from those at the Kenyatta Hospital. Therefore, we will also include private facilities in Nairobi, specifically, The Nairobi Hospital and Coptic Hospital, to enable comparison of risk factors for children in both public and private facilities. These children from these private facilities will be recruited through the Nairobi Ear Nose and Throat clinic. This is a busy practice of an association of ENT specialists, who undertake approximately 10 A&Ts weekly. Once patients needing surgical interventions are identified, they book the procedures to be done in various hospitals with operating rooms. The children in these facilities will be followed up from the ward a day prior to the operation or on the day of surgery if it is being done as a day procedure.

## 4.4Study population:

Children aged 2 years to 18 years with clinician diagnosed adenoid/tonsillar hypertrophy scheduled for adenotonsillectomy for obstructed SDB.

**Inclusion criteria:**

Otherwise healthy children who are aged between 2-18yrs of age undergoing A&T for SDB at KNH, Nairobi hospital and Coptic hospital. Those with comorbidities such as craniofacial anomalies (CFA), Down syndrome or cerebral palsy in addition to SDB undergoing A&T at these health facilities will also be included. In addition, children whose parents give consent and those above 8 years who give age appropriate assent, will be included.

**Exclusion criteria:**

Children with cardiovascular abnormalities, tracheostomies or concurrent procedures to address multisite obstruction such as palate, nasal and tongue surgery will be excluded. Those undergoing revision of surgery after prior A&T will also be excluded. Those who have no telephone numbers will be excluded.

## 4.5 Sampling technique

We will recruit the patients in the ENT wards or clinics pre-operatively once the decision for surgery has been made. Consecutive sampling will be employed until the desired sample size is reached. After eligible participants are enrolled, the caregivers will be approached to obtain study consent. For children above 8 years there will be an assent document that will be provided after the legal guardian consents to the study.

## 4.6 Data collection

We will collect data using a structured, validated questionnaire and standard case report forms (CRFs) (Appendix 3) which we will administer to the care givers pre-operatively within the health facility and 6 to 8 weeks post-operatively through telephonic survey. The CRFs will include socio-demographics and items from the validated Pediatric Sleep Questionnaire.

## 4.7 Data management and analysis

Questionnaires will be coded, entered and managed in SPSS database. Data will be exported to R (V3.4.3, R core team, 2017) for statistical analysis. Demographic and other patients’ characteristics will be summarized into percentages and means or medians.

Prevalence will be presented as a percentage with 95% CI. We will fit a marginal logistic regression model with an exchangeable working correlation and robust variance estimates using generalized estimating equations to determine if predictors are associated with residual SDB at 6 to 8 weeks.

## 4.8 Sample size determination

We will estimate the required sample size using the following:

n= ==121

Where:

* **n** is the required sample size
* **z** is the standard normal at 95% confidence interval = 1.96
* **p** is estimated prevalence of outcome of interest within the population of interest in our case the prevalence of residual SDB was taken as 23% according to the Schaeg study[23].(look at table 1)
* **d** is the precision set at 7.5% .

## 4.9 Study procedures

### STUDY PROCEDURE FLOW CHART

1.

Ethical approval

2.

Invitation to the study and assessment of participant eligibility.

3.

Consent and age appropriate assent, and study enrollment.

4.

Administration of the standard case report forms (CRFs) including items from the PSQ tool. Socio-demographic characteristics will be captured in CRFs pre-operatively.

5.

Telephonic surveys comprising the PSQ items will be administered to caregivers at 6 weeks post -operatively

## 4. 10 outcomes:

The main outcome of this study is the prevalence of residual sleep disordered breathing in Kenyan children.

### Dependent variable

The occurrence of residual sleep disordered breathing after A&T.

### Independent variables

Some of the known risk factors of recurrence studied such as presence of asthma[22], allergic rhinitis[26], enuresis[27], genetic conditions leading to craniofacial anomalies and neuromuscular disorders[19, 29].

Other independent variables will include age, birth weight, gender and BMI for age z-score[21, 26].

## 4.11 Data dissemination

The overall study findings will be availed to the staff working within the pediatric and ENT wards, KNH staff, the Nairobi Hospital and the Coptic Hospital staff working in the pediatric wards with the overall aim of improving evaluation and management of patients with SDB post-operatively. The study findings will also be presented to the University of Nairobi Department of Pediatrics and Child Health staff and residents as a fulfillment of the requirements of the Masters programme. Data will also be presented at conferences both locally and internationally; and submitted for publication in a peer reviewed journal.

# 5. Ethical considerations

Permission for the study will be sought from the department of Pediatrics and Child health. Ethical approval will be sought from the KNH/UON Ethics and Research Committee (ERC). Permission will be sought from the three hospital administrations where the study will be conducted. Copies of the data collection tool, the consent form as well as any subsequent modifications to either document will be presented to the KNH/UON ERC prior to commencement of the study. Once approval is obtained, study data will be collected and analyzed while patient confidentiality is maintained. Personal identifiers will not be captured or disseminated in any format.

The purpose of the study will be carefully explained to the parents/legal guardians of potential study participants identified prior to surgery and written consent obtained prior to commencing the study. The filled data collection forms will be stored by the principal investigator in a locked cabinet with only the principal investigator having access. Data will be entered into a computerized data base and coded. Access passwords will only be given to the principle investigator and statistician.

This is a non-invasive study with no risks of bodily harm, with minimal involvement of the study participants and their guardians beyond giving consent and answering a questionnaire in the study. There is a small risk of causing emotional upset by administering a questionnaire to a care giver who is anxiously awaiting surgery for their child.

Participation in the study will be voluntary. Parents/guardians may refuse their children to be enrolled in the study without prejudice. Children above 8 years of age will give age appropriate assent. It will also be made clear to the study participants that consent to participate in the study can be terminated at any time.

# 6. Study strengths and limitations

### Strengths

The strengths include the novel use of the PSQ (validated questionnaire) in the Kenyan context. All children who have residual SDB surveyed telephonically using PSQ will benefit from further assessment in a timely manner. This study will foster multidisciplinary collaboration between the Pediatrics and ENT departments.

### Limitations

The main limitation is the unavailability of PSG thus restricting us to reporting on a clinical diagnosis of SDB. The other limitation is recall bias during the administration of the questionnaire to parents or guardians. The PSQ has not been validated against the PSG at 6 weeks post adenontonsillectomy.

# 

# 7. Timelines

The following is a proposed time-frame of the study process:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Activity Period | MAY  2019 | JUN  2019 | JUL  2019 | AUG  2019 | SEP  2019 | OCT  2019 | NOV  2019 | DEC  2019 | | JAN  2020 | FEB  2020 | MAR  2020 | APR  2020 | MAY  2020 | JUN  2020 | JUL  2020 | AUG  2020 |
| Proposal Development |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |
| Ethical approval |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |
| Data Collection |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |
| Data Analysis |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |
| Manuscript preparation |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |
| Dissemination |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |

# 8. Study budget

|  |  |  |  |
| --- | --- | --- | --- |
| **ITEM** | **UNIT** | **UNIT COST (KES)** | **TOTAL (KES)** |
| **KNH ERC application fee** | **1** | **2,000** | **2,000** |
| **Research assistant** | **1\*120** | **500** | **60,000** |
| **Stationery (consents)** | **120** | **70** | **8,400** |
| **Stationery baseline and 6 weeks (CRFs)** | **240** | **70** | **16,800** |
| **Telephone calls** | **120** | **120** | **14,400** |
| **Total** |  |  | **101,600** |

## Budget justification

The major expense in the budget is the salary of one part-time research assistant. One research

assistant will be required on a part time basis to assist me on the data collection and on making the follow up phone calls. This study has many sites and we shall coordinate in such a way that as I collect data at Kenyatta hospital, they can move to Nairobi and Coptic hospital or vice versa. The assistant will take 60 hours to administer questionnaires to 60 parents or guardians each taking 30 minutes[35]; 60 hours to make 30 minute phone calls to 60 parents or guardians ; and will also spend about 30 minutes on transit from one hospital to another per day. This results in about 135 hours of employment time assuming 15 hours are spent in transit for the study period. In view of the lengthy periods the assistant spends with the patients it was appropriate that 500KES per encounter would suffice to cater for the costs. Taking the total which is 60,000 KES divided by the 135 hours would be equivalent to a rate of 445KES per hour which is a fair rate for a clerk in Kenya. Application fees for ethics submission is a requirement in Kenya. Quoting the major mobile phone providers, the range of per minute billing is approximately 2 -4 KES. Using the maximum tariff (4KES per minute), we require about 20 to 30minutes to administer a questionnaire over the phone, for the longest call it would take 120 KES per call. We estimate 70KES for stationery for items such as printing consent forms at baseline, case report forms for baseline and at 6 to 8 weeks.

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# 10. APPENDICES

## APPENDIX1: Consent explanation and certificate of consent

**UNIVERSITY OF NAIROBI KENYATTA NATIONAL HOSPITAL**

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**Informed Consent form for Parent and Guardian**

This informed consent form is for parents and guardians of children of ages 2-18 years who have a diagnosis of sleep disordered breathing (SDB) and are undergoing adenotonsillectomy at the satellite clinic in Kenyatta National Hospital or The Nairobi Hospital and Coptic Hospital who we are inviting to participate in research on prevalence and preoperative predictors of residual SDB.

**Project Title**: **Prevalence and predictors of residual sleep disordered breathing post adenotonsillectomy in children at Kenyatta National Hospital and The Nairobi and Coptic Hospital**

**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the research with you)**
* **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form**

**PART I: Information Sheet**

**Introduction**

I am Dr. Sylvia Mwathi, a postgraduate student pursuing a Masters degree in Paediatrics and Child Health at the University of Nairobi. We are conducting a study on treatment of children with sleep disordered breathing. I am going to give you information and invite you to have your child participate in this research. Before you decide you can talk with anyone you feel comfortable with. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them from me, the study doctor.

**Purpose**

Children who undergo adenotonsillectomy get improvement in breathing and behavior. However not all of them will remain well after surgery. The adenoids and tonsils may regrow. Some may have other medical problems that may put them at risk of having the breathing problems re-occur. This study will identify the proportion of children who develop recurrence of symptoms and the risk factors that are involved. It will then guide the medical and surgical team to plan for further evaluation and treatment of affected children.

**Participant selection**

I am inviting any parent/guardian with a child who has been diagnosed with snoring, sleep discorded breathing, adenotonsillar hypertrophy and is about to undergo adenotonsillectomy within Kenyatta National Hospital, The Nairobi Hospital and Coptic Hospital to participate in this research. Those from the private facilities will be recruited through the Nairobi Ear Nose and Throat clinic. You and your child are requested to participate in the study because your child meets the qualification to be included in my study.

**Voluntary Participation**

Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this hospital will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the hospital will continue.

**Procedures and Protocol**

After obtaining permission from the committee concerned with ethics at the Kenyatta National Hospital, you will be asked for written permission to allow your child to be used in the research. All the time respecting you and your child’s privacy. Any information that identifies your child will not be availed to people not allowed to see that information. This will not affect you and your child. Your child will receive the medical attention required. You will not be asked for anything more other than giving us permission to administer a questionnaire by signing the certificate of consent. After 6 weeks of having the surgery you will also receive a phone call and we shall ask you questions about symptoms that your child might still have after surgery. This will enable us to determine whether or not your child has developed recurrence.

At the end of the study, the information obtained will help the medical team taking care of children who have undergone adenotonsillectomy be more aware about the risk of recurrence following surgery and to ensure that timely follow up is done.

**Risks**

Participation in this study will not put your child in danger. There is a risk of giving the principal investigator the parent/guardian phone number. We shall sign a confidentiality agreement that this will not be used for any other purposes apart from the study.

**Discomforts**

We may take a bit of your time in order to give you enough information for you and your child so that you may make an informed decision concerning your participation in the study. Some questions may be sensitive to older children.

**Benefits and** **Reimbursements**

There will be no financial benefits to you or your child for participating in this study. However, the results of this study will give more information concerning treatment of SDB among children in both the public and private hospitals and help our doctors treat them more effectively.

**Confidentiality**

The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except members of the research team and the KNH/UON ethics committee.

**Right to Refuse or Withdraw**

You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child's treatment at this hospital in any way. You and your child will still have all the benefits that you would otherwise have at this hospital. You may stop your child from participating in the research at any time that you wish without either you or your child losing any of your rights as a patient here. Neither your treatment nor your child's treatment at this hospital will be affected in any way.

**Who to Contact?**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Principal Investigator: Dr. Sylvia Mwathi on the cell phone number 0724373827, or Chairman of the KNH/UON Ethics and Research committee on Tel: 2726300, Ext: 44102

This proposal has been reviewed and approved by the Kenyatta National Hospital/UON-Ethics and Research Committee, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the Kenyatta National Hospital/UON-Ethics and Research Committee, contact Chairperson on Tel: 2726300, Ext: 44102.

**PART II: Certificate of Consent**

Certificate of Consent

I have been invited to participate in the antibiotics for fever episodes in cancer research.I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Parent or Guardian\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent or Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_/\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_

*If illiterate*

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of parent/guardian

Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

Privacy and confidentiality will be maintained at all points during the study

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

 A copy of this informed consent form has been provided to the participant.

Print Name of Researcher/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher /person taking the consent \_\_\_\_\_\_\_\_Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_

An Informed Assent Form will be completed. For further clarification kindly contact:

Principal Investigator:

**Dr Sylvia Mwathi**,**Tel 0724373827,**

**Master of Medicine (Paediatrics), University of Nairobi**

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## APPENDIX 2: Kielelezo kwa wazazi na idhini kushiriki katika utafiti



**UNIVERSITY OF NAIROBI KENYATTA NATIONAL HOSPITAL**

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**(254-020) 2726300 Ext 44355 Website:** [**http://erc.uonbi.ac.ke**](http://erc.uonbi.ac.ke/) **Telegrams: MEDSUP, Nairobi**

**Maelezo na hati ya kibali**

Fomu hii ya idhini ya ruhusa ni kwa wazazi na walezi wa watoto wenye umri wa miaka 2-18 ambao wana ugonjwa wa kung’orota na shida ya pumu wanpolala usiku katika Hospitali ya Taifa ya Kenyatta na hospitali za ubinafsi kupitia madaktari wa kliniki ya Nairobi ENT , ambao tunawakaribisha kushiriki katika utafiti kuhusu kiwango cha maambukizi na utabiri wa sababu za urudiaji wa usingizi zisizo na taratibu kinga baada ya upasuaji wa findo katika watoto.

**Jina la mradi**:. KIWANGO CHA MAAMBUKIZI NA UTABIRI WA SABABU ZA URUDIAJI WA USINGIZI ZISIZO NA TARATIBU KINGA KWA WATOTO WENYE UMRI WA 2-18 WANAOHUDUMIWA KATIKA HOSIPITALI YA KITAIFA YA KENYATTA NA NAIROBI HOSPITAL NA COPTIC HOSPITAL

Fomu hii ya idhini kushiriki ina sehemu mbili:

• Karatasi ya Taarifa (kushiriki habari kuhusu utafiti na wewe)

• Hati ya Ruhusa (kwa ishara ikiwa unakubali kushiriki)

Utapewa nakala ya Fomu ya Idhini Kushiriki na Karatasi ya taarifa

SEHEMU YA I: Karatasi ya Taarifa

**Utangulizi**

Mimi ni Dk. Sylvia Mwathi, mwanafunzi ambaye anafuatilia shahada ya uzamili ( yaani masters degree)katika Afya ya Watoto kutoka Chuo Kikuu cha Nairobi. Tunafanya utafiti juu ya kiwango cha maambukizi na utabiri wa sababu za urudiaji wa usingizi zisizo na taratibu kinga kwa watoto wenye umri wa 2-18 wanaohudumiwa katika hosipitali ya kitaifa ya kenyatta na hospitali za kibinafsi kupitia kliniki ya Nairobi ENT.Nitakupa taarifa na kukualika wewe na mtoto wako ashiriki katika utafiti huu. Kabla ya kuamua unaweza kuzungumza na mtu yeyote ambaye umemzoea na kumwamini. Kunaweza kuwa na maneno ambayo huyaelewi. Tafadhali nieleze wakati tunapitia taarifa hii ili nichukue muda wa kukuelezea. Ikiwa una maswali baadaye, unaweza kuniuliza mimi kama daktari wa utafiti.

**Kusudi**

Watoto wenye ugonjwa wa usingizi zisizo na taratibu kinga huwa wanatibiwa kwa njia tofauti tofauti mojayapo ikiwa upasuaji wa findo. Upasuaji wa findo huwa inaboresha hali ya kupumua nay a kitabia. Hata hivyo sio watoto wote watabaki sawa baada ya upasuaji. Watoto wengine watarudiwa na dalili za ugonjwa kwa sababu ya findo kukua. Wengine wana magonjwa mengine yanayoweka watoto hao kwa hatari ya kushindwa kupumua au kurudi kung’orota baadaye.

Shida hii inaporudi inaweza kuwafanya watoto hawa kuathirika roho na mapafu na kuongezeka kwa hali hii mbaya kwa weza hata kusababisha kifo isipotibiwa kwa haraka. Kutambua urudiaji wa ugonjwa ni muhimu ndio tuanzishe matibabu mapema kuzuia hatari. Watoto hawa watahitaji kufanyiwa upasuaji tena au kuwekewa pumzi au kupata matibabu mengine. Ni muhimu kuanzisha matiababu mapema.

Utafiti huu utatambulisha uwiano wa watoto wanaoendeleza kupata urudiaji wa dalili za usingizi zisizo na utaratibu kinga na sababu zinazohusika na urudiaji huu. Maelezo kutoka kwa utafiti yanaweza kutumika baadaye kufahamisha madaktari watoto wanaostahili kufuatiliwa zaidi ,kupanga tathmini baada ya matibabu ili kutibu wale walioathirika. Kwa hivyo tutaweza kuboresha matibabu yetu katika kutibu ugonjwa huu.

**Uchaguzi wa washiriki**

Ninakaribisha mzazi / mlezi yeyote aliye na mtoto ambaye ana ugonjwa wa usingizi zisizo na taratibu kinga na atafanyiwa upasuaji wa findo katika Hospitali ya Taifa ya Kenyatta au hospitali kibinafsi ya Nairobi na Coptic kupitia kliniki ya Nairobi ENT kushiriki katika utafiti huu. Wewe na mtoto wako mnaombwa kushiriki katika utafiti kwa sababu mtoto wako amefikia vigezo vya kuingizwa katika utafiti huu.

**Kushiriki kwa hiari**

 Uamuzi wako wa kuwa na mtoto wako kushiriki katika utafiti huu ni kikamilifu kwa hiari. Ni chaguo lako wako kama mtoto wako atashiriki au la. Ikiwa unachagua kutokubali, huduma zote ambazo wewe na mtoto wako mnapokea katika hospitali hii zitaendelea na hakuna kitu kitakachobadilika. Unaweza pia kuchagua kubadilisha mawazo yako baadaye na kuacha kushiriki, hata kama ulikubaliana hapo awali, na huduma ambazo wewe na / au mtoto wako anapata katika hospitali zitaendelea.

**Taratibu na Itifaki**

Baada ya kupata ruhusa kutoka kwa kamati inayohusika na maadili katika Hospitali ya kitaifa ya Kenyatta,tutatafuta watoto wanaofuzu kukuwa kwa utafiti wetu. Tutaomba ruhusa kutoka wazazi /walezi wao na wakipeana idhini tutawauliza maswali kupitia dodoso. Maswali ni rahisi na yatajibiwa kwa muda usiozidi dakika thelathini. Tutachukua nambari za simu za wazazi/walezi ndio tuweze kuwasiliana nao baada ya upasuaji .Mzazi/mlezi ataweza kujisomea maswali mwenyewe ama mimi kama mtafiti nitaweza kumsomea. Tutafanya hivi kwa njia ya kuheshimu faragha ya mtoto wako, ili taarifa yoyote ambayo itamtambulisha mtoto wako haitatumiwa na watu ambao hawaruhusiwi kuona habari hiyo. Hii haitaathiri kwa njia yoyote huduma ya matibabu ambayo wewe na mtoto wako utapokea katika hospitali hii. Baada ya wiki sita utapigiwa simu na kuulizwa maswali tena kutambua kama mtoto amepona ama amerudiwa na ugonjwa. ikiwa shida yoyote itapatikana ,basi utaelekezwa vile mtoto atapata matibabu mengine.

Mwishoni mwa utafiti huo, habari zilizopatikana zitasaidia timu ya matibabu kutunza watoto wenye ugonjwa wa usingizi usio na taratibu kinga

**Hatari**

Kushiriki katika utafiti huu hakutamtia mtoto wako hatari yeyote. Kuna hatari ys kumpa mtafiti nambari yako ya simu, ilhali tutakupatia fomu ya kukuhakikishia kwamba hatutaitumia nambari hiyo, ila tu, kwa utafiti wetu.

**Usumbufu**

Tunaweza kuchukua muda wako ili kukupa taarifa za kutosha kwako na mtoto wako ili uweze kufanya uamuzi sahihi juu ya ushiriki wako katika utafiti.

**Faida**

Hakutakuwa na faida za kifedha kwako au mtoto wako kwa kushiriki katika utafiti huu. Hata hivyo matokeo ya utafiti huu utatoa habari zaidi kuhusu matibabu ya homa kati ya watoto walio na kansa katika KNH na kusaidia madaktari wetu kutibu maradhi haya vyema zaidi.

**Usiri**

Taarifa ambayo tunakusanya kutoka kwa mradi huu wa utafiti itahifadhiwa kwa siri. Habari zinazomtambulisha mtoto wako ambazo zitakusanywa kutoka kwa utafiti zitaondolewa na hakuna mtu isipokuwa watafiti ndio wataweza kuiona. Maelezo yoyote kuhusu mtoto wako yatakuwa na nambari yake badala ya jina lake. Watafiti tu ndio watajua nambari yake ni nini na tutaibana habari hiyo. Haitashirikiwa au kupewa mtu yeyote isipokuwa wanachama wa timu ya utafiti na kamati ya maadili ya UON / KNH.

**Haki ya kukataa au Kuondoka utafitini**

Hautalazimishwa kukubali mtoto wako kushiriki katika utafiti huu ikiwa hutaki kufanya hivyo na kukataa kumruhusu mtoto wako kushiriki hakutaathiri matibabu yako au matibabu ya mtoto wako katika hospitali hii kwa namna yoyote. Wewe na mtoto wako mtakuwa na faida zote ambazo mngekuwa nazo katika hospitali hii. Unaweza kumzuia mtoto wako kushiriki katika utafiti wakati wowote unavyotamani bila wewe au mtoto wako kupoteza haki yoyote kama mgonjwa hapa. Wala matibabu yako ama matibabu ya mtoto wako katika hospitali hii yataathirika kwa njia yoyote.

**Nani wa Kuwasiliana**

Ikiwa una maswali yoyote unaweza kuuliza sasa au baadaye, hata baada ya utafiti kuanza. Ikiwa unataka kuuliza maswali baadaye, unaweza kuwasiliana na wafuatao: Mtafiti Mkuu: Dk.Sylvia Mwathi kwenye namba ya simu ya mkononi 0724373827au Mwenyekiti wa kamati ya KNH / UON ya Maadili na Utafiti juu kwa nambari ya simu: 2726300, Ext: 44102

Pendekezo hili limepitiwa na kupitishwa na Kamati ya Taifa ya Kenyatta / UON-Maadili na Utafiti, ambayo ni kamati ambayo kazi yake ni kuhakikisha kuwa washiriki wa utafiti wanalindwa dhidi ya madhara. Ikiwa unataka kupata habari zaidi kuhusu Kenyatta National Hospital / UON-Maadili na Kamati ya Utafiti, unaweza wasiliana na Mwenyekiti kwenye nambari ya simu: 2726300, Ext: 44102.

**SEHEMU YA II: Hati ya Ruhusa**

**Hati ya Ruhusa**

Nimealikwa kushiriki katika utafiti kuhusu vipindi vya homa katika watoto wanaougua saratani. Nimesoma taarifa iliyotangulia, au nimesomewa. Nimekuwa na fursa ya kuuliza maswali kuhusu utafiti huu na maswali yoyote niliyoyauliza yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari kwa mtoto wangu kushiriki kama mshiriki katika utafiti huu.

Jina la Mshiriki\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Jina la Mzazi au Mlezi \_\_\_\_\_\_\_

Saini ya Mzazi au Mlezi \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tarehe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Siku / mwezi / mwaka

**Kwa wasio na elimu**

Nimeona usomaji sahihi wa fomu ya idhini kwa mzazi wa mshiriki aliye na uwezo, na mtu huyo amepata fursa ya kuuliza maswali. Ninathibitisha kwamba mtu huyo ametoa ridhaa kwa uhuru.

Jina la shahidi\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NA chapisha kidole cha mzazi / mlezi

Saini ya shahidi \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tarehe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

                Siku / mwezi / mwaka

**Taarifa ya mtafiti / mtu kuchukua idhini**

Nimesoma kwa usahihi karatasi ya habari kwa mzazi wa mshiriki aliye na uwezo, na kwa uwezo wangu wote kuhakikisha kuwa mtu anaelewa kuwa zifuatazo zitafanywa:

Faragha na siri zitasimamiwa wakati wote wa utafiti

Ninathibitisha kwamba mzazi alipewa fursa ya kuuliza maswali kuhusu utafiti, na maswali yote yaliyoulizwa na mzazi yamejibiwa kwa usahihi na kwa uwezo wangu wote. Ninathibitisha kwamba mtu huyo hakulazimishwa kutoa idhini, na ridhaa imetolewa kwa uhuru na kwa hiari.

Nakala ya fomu hii imetolewa kwa mshiriki.

Jina la Mtafiti \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Saini ya Mtafiti \_\_\_\_\_\_\_\_\_\_

Tarehe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

                 Siku / mwezi / mwaka

Fomu ya idhini ya watoto itapeanwa.. Kwa ufafanuzi zaidi tafadhali wasiliana:

Mtafiti Mkuu:

Dk Sylvia Mwathi

Sanduku la Posta 13010, 00200

Nairobi, Kenya

Simu 0724373827

Taasisi zilizoshirikishwa:

CHUO KIKUU CHA NAIROBI

COLLEGE OF HEALTH SCIENCES

S.L.P 19676 KODI 00202

Telegrams; varsity

(254-020) 2726300 Ext 44355

KNH / UON-ERC

Barua pepe; uonknh\_erc@uonbi.ac.ke

Tovuti: http://erc.uonbi.ac.ke

HOSPITALI YA KITAIFA YA KENYATTA

S.L.P 20723 KODI 00202

Simu; 2726300-9

Faksi 725272

Telegrams: MEDSUP, Nairobi

## APPENDIX 3: Questionnaire

**THE PREVALENCE AND PREDICTORS OF SLEEP DISORDERED BREATHING POST ADENOTONSILLECTOMY IN CHILDREN 2 TO 18 YEARS**

**DATE OF DATA COLLECTION \_\_\_/\_\_\_\_\_/\_\_\_\_\_\_**

**A .Socio-Demographics**

Subject identification\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_/\_\_/\_\_

Age \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of birth\_\_/\_\_/\_\_ birth weight \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg

Sex M\_\_\_ F\_\_\_\_

Weight \_\_\_\_kg

Height \_\_\_\_\_cm BMI\_\_\_\_\_\_\_\_\_\_\_

Caregiver characteristics

Age \_\_\_ DOB\_\_/\_\_/\_\_

TELEPHONE NUMBERS 1)\_\_\_\_\_\_\_\_\_\_2)\_\_\_\_\_\_\_\_\_\_\_\_3)\_\_\_\_\_\_\_\_\_\_\_\_\_

Employed \_\_\_\_\_\_ Self-Employed \_\_\_\_\_\_ Unemployed\_\_\_\_\_\_\_\_\_

Wealth quintile –monthly earning \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kes\_\_\_

Insurance scheme NHIF \_\_\_ or NONE\_\_\_\_ or EMPLOYER\_\_\_\_\_\_OTHER\_\_\_\_\_

Smoking yes\_\_\_\_ no\_\_\_\_

Place of residence\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**B.Comorbidities**

Is your child known to have asthma? YES \_\_\_NO\_\_\_

Has he/she had wheezing in the last 3 months? YES\_\_\_NO\_\_\_

Has he/she been on any of the following medications in the past 3 months

* 1. Salbutamol inhaler (eg Ventolin) YES\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_\_
  2. Inhaled corticosteroid (eg budecort..)YES\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_
  3. Ventolin syrup YES\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_\_\_\_
  4. Oral steroid (prednisolone) YES\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_
  5. Nebulization YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  6. Antihistamine YES\_\_\_\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is your child known to have allergic rhinitis YES\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has he/she had the following symptoms in the last three months ?

1. Persistent sneezing YES\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Persistent itching or rubbing of the nose YES\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_
3. Rhinorhoea and nasal obstruction lasting longer than two weeks YES\_\_\_\_\_\_NO\_\_\_\_

Examination findings

1. Prominent inferior turbinates \_\_\_\_\_\_\_ RIGHT \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_LEFT \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Allergic dorsal nasal crease YES\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Allergic shiners YES\_\_\_\_\_\_\_\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has he / she used steroid nasal sprays or drops in the last three months YES\_\_\_\_\_NO\_\_\_\_\_\_\_\_\_\_

Does your child use antacids(Gaviscon) or proton pump inhibitors? YES\_\_\_NO\_\_\_\_

If yes, which one?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Why was it prescribed? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is your child exposed to cigarette smoke from any of the household members? YES\_\_\_NO\_\_\_

On examination is child found to have any craniofacial anomaly

Down syndrome\_\_\_\_cleft palate\_\_\_\_\_micro/retrognathia\_\_\_\_\_narrow maxillary arch\_\_\_\_

Nasoseptal obstruction\_\_\_\_\_\_\_\_\_\_ other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**C. PAEDIATRIC SLEEP QUESTIONNAIRE: SLEEP DISORDERED BREATHING SUB- SCALE (PSQ-SRDB)(Chervin, #33)**

ANSWER BY ENCIRCLING Y -YES, N -NO, DK –DON’T KNOW

**1.WHILE SLEEPING DOES YOUR CHILD…**

A2-snore more than half the time……………………………………………………………Y N DK

A3-always snore……………………………………………………………………………………..Y N DK

A4-snore badly………………………………………………………………………………………..Y N DK

A5-Have heavy or loud breathing…………………………………………………………….Y N DK

A6- has trouble breathing or struggle to breathe …………………………………..Y N DK

**2.HAVE YOU EVER:**

A7-SEEN YOUR CHILD STOP BREATHING DURING THE NIGHT?..................Y N DK

**3.DOES YOUR CHILD…**

A24- Tend to breathe through the mouth during the day?.........................Y N DK

A25-tend to have a dry mouth on waking up in the morning?....................Y N DK

A32- for children above 4yrs; occasionally wet the bed?............................Y N DK

**4.DOES YOUR CHILD…**

B1- wake up feeling unrefreshed in the morning?.....................................Y N DK

B2- have a problem with sleepiness during the day?................................Y N DK

**5.HAS A TEACHER OR OTHER SUPERVISOR COMMENTED**

**THAT YOUR CHILD APPEARS SLEEPY DURING THE DAY? B4....................** Y N DK

**6.IS IT HARD TO WAKE YOUR CHILD UP IN THE MORNING? B6**..............Y N DK

**7.DOES YOUR CHILD WAKE UP WITH HEADACHES IN THE MORNING? B7.................Y N DK**

**8.DID YOUR CHILD STOP GROWING AT A NORMAL RATE AT ANY TIME SINCE BIRTH? B9.Y N DK**

**9. IS YOUR CHILD OVERWEIGHT? B22...............................................................**Y N DK

**10.THIS CHILD OFTEN:**

C3-Does not seem to listen when spoken to directly?................................Y N DK

C5- has difficulty organizing task and activity?...........................................Y N DK

C8- is easily distracted by extraneous stimuli?..........................................Y N DK

C10- fidgets with hands or feet or squirms in seat?...................................Y N DK

C14-is on the go or often acts as if driven by a motor?..............................Y N DK

C18- interrupts or intrudes on others eg. butts into conversation or game..Y N DK

**D. PAEDIATRIC OBSTRUCTIVE SLEEP APNOEA SCREENING TOOL (POSAT)[33]**

For the following questions, use:

“never” -0 (zero)

“rarely”- 1 (once per week)

“occasionally”- 2(twice per week)

“frequently”- 3 (3 to 4 times per week)

“almost always”- 4 (>4 times per week)

Apart from the 5th question, respond as:

Mild quiet =0

Medium loud=1

Loud=2

Very loud=3

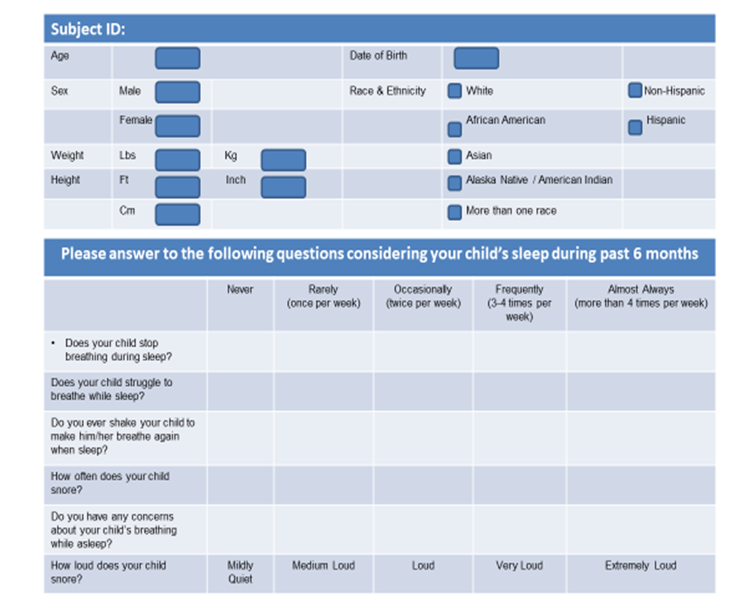
Extremely loud=4

For the preceding 6 months’ timeframe;

1. Do you shake your child to breathe? \_\_\_\_\_\_\_
2. Have you witnessed an apnoea during sleep? \_\_\_\_\_\_\_\_
3. Does your child struggle breathing while asleep? \_\_\_\_\_\_\_\_
4. Do you have concerns about your child breathing while asleep? \_\_\_\_\_\_
5. How loud does your child snore? \_\_\_\_\_\_\_\_\_\_
6. Does your child snore while asleep? \_\_\_\_\_\_\_\_\_\_\_

## Appendix 4: SPRUYT AND GOZAL’S POSAT QUESTIONNAIRE

## Figure 1



## APPENDIX 5: Letters requesting for support and sample support letters for The Nairobi Hospital and Coptic Hospital

Sylvia Mwathi

P.O BOX 13010-00200

NAIROBI

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The Nairobi Hospital

+254703082000

hosp@nbihosp.org

Argwings Kodhek Rd

Nairobi, Kenya

June 25, 2019

To the CEO,

Dear Sir,

RE: REQUEST TO CONDUCT A STUDY AT THE NAIROBI HOSPITAL

My name is Sylvia Mwathi, a 2nd year student at the University of Nairobi pursuing a Masters in Medicine in Pediatrics and Child health.

I will be conducting a study looking at prevalence and risk factors for recurrence of sleep disordered breathing after adenotonsillectomy.

In this regard, I will be following up children who undergo adenotonsillectomy at the Nairobi hospital to see how many develop the recurrence. The children I will recruit are only those undergoing procedures through the Nairobi ENT Clinic.

One of my supervisors, Professor Isaac Muthure is aware that I am writing this letter in this regard, I have full permission from him to recruit these patients.

Once I get your permission and the approval of the ethics committee, I will start collecting data.

The tentative data collection period is 6 months and I will begin any time from June 2019.

Kindly consider my request, the utility of this study is that I will share my findings with your staff and this will improve patient care in your facility.

Yours faithfully

Dr Sylvia Mwathi

Sylvia Mwathi

P.O BOX 13010-00200

NAIROBI

[viathi89.sm@gmail.com](mailto:viathi89.sm@gmail.com)

Coptic Hospital

+254732341241/0202724737

P/O BOX 21570-00505

Nairobi, Kenya

June 25, 2019

To the CEO,

Dear Sir/Madam

RE: REQUEST TO CONDUCT A STUDY AT THE COPTIC HOSPITAL

My name is Sylvia Mwathi, a 2nd year student at the University of Nairobi pursuing a Masters in Medicine in Pediatrics and Child health.

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Yours faithfully

Dr Sylvia Mwathi

The Nairobi Hospital

+254 703082000; [hosp@nbihosp.org](mailto:hosp@nbihosp.org); Argwings Kodhek Road

Nairobi, Kenya

Sylvia Mwathi

P.O BOX 13010-00200

Nairobi

[viathi89.sm@gmail.com](mailto:viathi89.sm@gmail.com)

June 25, 2019

Dear Sylvia,

RE: LETTER OF SUPPORT

This is a follow up response to your earlier request to conduct a study on the Prevalence and predictors of residual sleep disordered breathing (SDB) in children 2 to 17years of age 6 weeks post adenotonsillectomy.

We are pleased to write in support of you conducting a study at the Nairobi Hospital. We are interested in this project because the findings will be relevant to our clinical practice, specifically in optimizing our algorithms in the management of sleep disordered breathing.

Depending on the study findings, our hospital would be interested in implementing recommended approaches to optimize quality healthcare for children with SDB.

It is in this regard that we hold no reservation in supporting your application for this call.

Yours sincerely,

Signed

Print name

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+254 732341241/0202724737

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Nairobi, Kenya

Sylvia Mwathi

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Nairobi

[viathi89.sm@gmail.com](mailto:viathi89.sm@gmail.com)

June 25, 2019

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Signed

Print name