QUALITY OF LIFE OF CHILDREN WITH CHRONIC COUGH AND OF THEIR PARENTS AT KENYATTA NATIONAL HOSPITAL

BY

DR ODHIAMBO JOY ROSE

H58/11276/2018

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF A MASTER OF MEDICINE DEGREE IN PAEDIATRICS AND CHILD HEALTH AT THE UNIVERSITY OF NAIROBI.

November 2021

DECLARATION

This dissertation is my original work, drafted under the guidance of my supervisors and has not been presented for the award of a degree in any other university. References of work done by others have been cited appropriately.

Signature………………… Date November 11th 2021

Dr Joy Rose Odhiambo (MBChB)
Senior House Officer
Department of Paediatrics and Child Health, University of Nairobi.

CERTIFICATE OF SUPERVISION

This dissertation has been submitted for examination with our approval as supervisors:

……………………………………………………………… 11.11.2021

Signed Date

Professor Elizabeth Maleche Obimbo (MBChB, Mmed, MPH, Fpulm)

Professor of Paediatrics and Respiratory Medicine, Paediatric Pulmonologist

Department of Paediatrics and Child Health, University of Nairobi

……………………………………………………………… 11.11.2021

Signed Date

Dr Paul Laigong (MBChB, Mmed, Fendoc)

Lecturer, Paediatric Endocrinologist,

Department of Paediatrics and Child Health, University of Nairobi

ABBREVIATIONS

CC-QoL:	Chronic Cough-specific QoL questionnaire for children
GER:	Gastroesophageal Reflux
IDI:	In depth Interview
IQR:	Interquartile range
KNH:	Kenyatta National Hospital
OR:	Odds ratio
PI:	Principal investigator
PCQOL:	Parent Proxy QOL Questionnaire for paediatric chronic cough
POPC:	Pediatric Outpatient Clinic
QoL:	Quality of Life
RA:	Research assistant
TB:	Tuberculosis
UON:	University of Nairobi
WHO:	World Health Organisation

ACKNOWLEDGEMENT

I am eternally grateful to God Almighty for without His grace and blessings; this study would not have been possible. I experienced your guidance day by day, and I will keep trusting you for my future.

The completion of this study could also not have been possible without the expertise and support of my supervisors, Prof Maleche Obimbo and Dr Paul Laigong. I wish to express my sincere gratitude to you for letting me fulfil my dreams of being a paediatrician. I am extremely grateful for your exemplary guidance and suggestions throughout my research.

I am forever indebted for your understanding, wisdom, patience and constant encouragement, and for pushing me even when I couldn’t believe in myself. It was an honor to be mentored by you.

Lastly, immeasurable gratitude goes to my statistician and research assistants for their dedication in ensuring this work was completed successfully.

DEDICATION

I dedicate this work to my husband, Billy Mella and my son, Tijani Mella. You two have been my constant source of inspiration and my greatest cheerleaders. *Billy*, this is from my heart; thank you for being my greatest pillar, my strength when I was weak, my calm when I was angry and my sanity when I went crazy during my research. You truly are the wind beneath my wings. *TJ*, my little human, my love, my life, my light…mummy did this for you.

And to my parents, who not only raised and nurtured me but also taxed themselves dearly over the years for my education and intellectual development. You have been my source of motivation during moments of despair and discouragement. You raised me to believe that everything was possible. I hope I have made you proud.

To my discussion mates- Let’s soar!!!

DEFINITION OF TERMS

Chronic cough: A cough that persists for four weeks or longer (American and Australian Pulmonology Societies)

Quality of life: An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment (World Health Organisation)

Degree to which an individual is healthy, comfortable and able to participate in or enjoy their day-to-day activities.

Children: Human beings below the age of 18 years

Caregiver: A person responsible for the care and wellbeing of children in all contexts (Kenya National Council for Children's Services, 2011)

Primary Caregiver: Person who has the greatest responsibility for the daily care and rearing of a child, examples include parents, other relatives in the family.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Background: Chronic cough is a common and frequently debilitating problem of childhood associated with high morbidity. It has been shown to negatively impact the quality of life (QoL) of both children and their caregivers. Recent development of chronic cough specific QoL tools has allowed for quantification of burden of cough on those affected. The impact of chronic cough on the QoL of Kenyan children and their parents has however not been studied, presenting a challenge in their holistic management.

Objective: To assess the quality of life of children with chronic cough and QoL of their parents and to determine the clinical and socio-demographic factors associated with QoL of those affected at Kenyatta National Hospital.

Methodology:

Study design: Hospital based cross sectional survey.

***Study site*:** Kenyatta National Hospital.

***Study population*:** 1. Parents of children who presented with a cough lasting longer than 4 weeks. 2. Children/Teenagers aged 7-17 years who presented with chronic cough at KNH.

***Study procedure*:**

i. Quantitative study: Consecutive sampling was used until a sample size of 135 was reached. A pretested questionnaire was used to collect socio-demographic and clinical data. A Parent-Proxy QoL Questionnaire for Paediatric Chronic Cough was used to assess the QoL of children and their parents. For older children/teenagers, a Child Chronic Cough QoL questionnaire was used to evaluate their QoL.

ii. Qualitative study: 15 in-depth interviews were carried out via convenience sampling to explore the perception of parents.

Data analysis and management:

Quantitative data analysis – Done using SPSS v21. QoL scores were analysed using median (IQR) and interpreted as poor QoL (median ≤ 3.5) or good QoL (median >3.5). Factors associated with QoL were summarised using frequencies and percentages and compared using Chi square test. Univariate and multivariable analysis and corresponding 95% confidence intervals were used to obtain odds ratios. P value of <0.01 was statistically significant.

For qualitative analysis, audio recordings were transcribed verbatim and content analysis used to arrive at themes and subthemes.

Results: Median age of the children was 1.1 years while that of their parents was 30 years. The overall QoL score of parents was poor with a median (IQR) of 1(1,2) and the overall QoL score of older children was poor with a median (IQR) of 2(1.5,2). Sociodemographic factors associated with extremely poor QoL included age of children ≤5years (OR 6.17, 95% CI 2.81-13.87), lower education level of parents (OR 3.64, 95% CI 1.03-12.20), monthly income (OR 7, 95% CI 2.11-21.30) and staying near a busy road (OR 2.86, 95% CI 1.19-7.42). Clinical factors included higher number of hospital consultation (OR 3.15. 95% CI 1.54-7.39) and HIV status of child (OR 8.25, 95% CI 1.43-89.77). After multivariable logistic analysis, predictors for extremely poor QoL included age of children ≤5 years (OR 11.38, 95% CI 3.85-33.64), lower education level of parent (OR 9.33, 95% CI 2.02-43.08), higher number of consultation (OR 5.32, 95% CI 2.68-24.73) and staying near a busy road (OR 3.23, 95% CI 1.19-8.75).

Conclusions: Parents of children with chronic cough have poor QoL. Older children with chronic cough have poor QoL. Predictors of extremely poor QoL included younger age of children, lower education of parents, higher number of hospital consultations and outdoor air pollution (staying near a busy road).

CHAPTER 1. INTRODUCTION

Cough is the most common reason for outpatient visits to a doctor(1). Cough can be classified based on duration of symptoms into acute, sub-acute and chronic. Acute cough may result when a foreign body such as pollen or an on-going or past viral infection irritates the respiratory tract of a child. Thus, most cases are self-limiting and can often resolve in less than four weeks with or without medical intervention (2). However, when cough is protracted and lasts ≥ 4 weeks, it is considered chronic. This definition is based on expert consensus as outlined in guidelines from American and Australian pulmonology societies(3). Chronic cough is often a strong indicator of an underlying health problem such as asthma, tuberculosis or protracted bacterial bronchitis (4). Idiopathic chronic cough is also a common aetiology (5).

The global epidemiology of chronic cough among children is well-described in literature to be about 2% to 10% in America and Europe, 1-28% in Asia, and 5.1-35% in Africa with symptoms such as anxiety and wheezing reported in many cases. Overall, children age <12 years are most at risk of chronic cough, and the difference in the occurrence of chronic cough by the gender of children and the socio-economic status or social behaviour of parents such as cigarette smoking have been reported. Moreover, environmental factors such as air pollution and dusty roads, and the clinical characteristics such as acute malnutrition can also influence the occurrence of cough directly or indirectly and in-turn dent the quality of life of children.

Even though the epidemiology of chronic cough, associated factors, and impact on the quality of life of children from the developed world and from southern Africa has been described sufficiently, scientific interest is marginal in the East Africa region, with the epidemiology of cough under-reported. In Kenya, scientific estimates on the prevalence of chronic cough in children is reported to be around 3-28%, varying between urban and underserved region and by the demographics of the population under study. However, even though considered to be a serious public health issue – going by the reports of health care workers and the community (6) – epidemiological data is limited to prevalence studies, which fail to demonstrate the impact of chronic cough on children comprehensively.

Chronic cough has thus been established as a common problem of childhood, and has been shown to negatively influence quality of life of children and their caregivers with increased health and societal economic costs. It has been shown to affect the child's quality of sleep and participation in activities, accounts for a significant number of school absenteeism and this causes them emotional distress.(7) Despite this burden, a study assessing quality of life of children who have a chronic cough has not been carried out locally.

In the same light, studies(8),(1) have confirmed a high burden of parental concern in children with chronic cough. These studies have described parental worries about disturbed sleep, discomfort, concerns regarding choking and fear that cough could cause permanent chest damage to the affected children. This burden to families is also reflected in the billions of dollars spent annually on over-the-counter drugs by caregivers in attempt to mitigate the effects of cough on their children. Despite the high prevalence of cough and the significant burden and negative impact on the QoL, there is relatively little research done to assess the impact of a child's cough on the quality of life of their parents locally.

CHAPTER 2. REVIEW OF LITERATURE

2.1 Prevalence of Chronic Cough in Children

In Africa, the prevalence of chronic cough on children has been reported to range from 5.1% and 35%, making it one of the commonest medical complications for children age 1-17 years. In South Africa, a population-based survey of the respiratory symptoms of 367 children from South-Central Durban by Nriagu et al. (9) reported prevalence of chronic cough to range from 33% to 35%. Frequently blocked-runny nose, chronic phlegm, and sinusitis were reported to afflict 44-50%, 31-32%, and 16-27% of children respectively. In Gaborone, Botswana, the prevalence of chronic cough is estimated to be 16.5%, peaking among children age 13-14 years (16.8%) and children attending private schools (10), while the prevalence in Nigeria has been reported to be significantly lower at 5.1% (11). In Kenya, the prevalence of asthma (a major cause of chronic cough) has been reported to range from 3% to 28.6%, even though its epidemiology has not been described sufficiently to date.

In America, Europe, and Australia, chronic cough is one of the commonest reasons for medical consultations of children (12) with prevalence estimates of between 2.0% and 20% reported. In the United Kingdom, a population-based prospective survey of 7670 children in Leicestershire reported the prevalence of chronic cough to be 10%, worsening at night in 25% of participants (13). Population-based studies in Seattle, America, and Italy have reported prevalence rates of 7.2% (14) and 2.0-3.9% (15) respectively, while Australia has reported the highest prevalence in the developed world at 20%. In Asia, Singh and colleagues reported a prevalence of 1.06 in India in 2002, while Pan et al. (16) found a prevalence of 21-28% as summarised in Table 1 below.

Table 1. Studies Evaluating the Prevalence of Chronic Cough in Children Globally

	Author & Year	**Country**	**Study subject age Sample Size**	**Study design/Setting**	**Prevalence of Chronic Cough (%)**
Africa	Nriagu et al. 1999	South Africa	Age 1-17 years N=367	Cross-sectional study Community	33-35
	Kiboneka et al. 2016	Botswana	6-14 years N= 924	Cross sectional study Schools	16.5
	Faniran et al. 1999	Nigeria	Age = 5-11 years N=1731	Cross sectional study Community	5.1
America	Carter et al. 2005	Seattle, USA	Age = 11-15 N=2397	Cross sectional study School	7.2
Europe	Jurca et al. 2017	United Kingdom	Age = 1-18 N= 7670	Population-based prospective cohort Community	10
	Dal Begro et al. 2019	Italy	Age = 1-15 years N=604	Cross-sectional telephone survey Community	4.3
Australia	Faniran et al. 1999	Australia	Age = 5-11 years N=1731	Cross sectional study Community	5.1
	Drescher et al. 2013	Australia	Age= 15 years N= 2397	Prospective cohort study Hospital	20
Asia	Pan et al. 2010	China	Age = 3-12 years N = 11,860	Cross sectional survey Community	21-28
	Singh et al. 2002	India	Age = 1-15 years N= 2275	Cross-sectional survey Community	1.06

2.2 Causes of Chronic Cough

The cough reflex is a critical air defence mechanism that involves an inspiratory phase of effort, followed by a compressive phase as the glottis closes, and an expulsive phase when the glottis opens (17). Cough is the body’s way of protecting the airways from foreign particles, mucus and microbes and is classified as acute or chronic based on its duration.

In children, chronic cough is described as a cough lasting more than four weeks and can be dry or wet. Its causation is diverse, with chronic infection of the airways reported to be one of the leading causes. According to Craven and Everard (4), impaired mucociliary clearance of (4)conducting airways leads to formation of a biofilm that supports growth of non-typable bacteria such as *Haemophilus influenza*, which out competes healthy microbiome. The development of chronic infections has also been linked with immunodeficiency in childhood. Other principle causes of chronic cough in children have been described previously by Bergamini et al. (18) as presented in Table 2 below. While prolonged non-specific cough can be self-limiting and easy to manage with antihistamines (19), idiopathic or specific chronic cough with complications of the trachea and lungs are associated with significant morbidity. From my experience, the common causes of chronic cough in children in an urban Kenyan setting include asthma, Pulmonary Tuberculosis, gastroesophageal reflux, recurrent aspiration, cardiac disease and less commonly interstitial lung disease, bronchiectasis and obliterative bronchiolitis.

Table 2. Pooled Prevalence of the Principle Causes of Chronic Cough among Children Globally (Adapted from Bergamini et al. 2017)

Country, Author, Year (ref) Age of children	**PBB**	**Asthma**	**UACS**	**GER**	**Bronchiectasis**	**Tracheo-malacia**	**Habitual psychogenic cough**	**Spontaneous resolution**	**Other**
New Zealand, Marchant 2006 (20) Mean age 2.6 years	40%	4%	3%	3%	6%	-	1%	22%	21%
USA, Asilsoy 2008 (21) Mean age 8.4 years	23%	25%	20%	5%	3%	-	4%	6%	3%
USA, Khoshoo 2009 (22) ditto(7.8 years average age)	-	13%	23%	28%	-	-	10%	-	25%
Australia, Chang 2012 (23) (4.5 years average age)	41%	15.8%	1.4%	2.3%	9%	6.1%	4.3%	13.9%	6.1%

PBB - Protracted bacterial bronchitis. UACS - Upper airway cough syndrome. GER - Gastro oesophageal reflux

2.3 Impact of Chronic Cough on the Psychological Wellbeing of Children and their Families

The relationship between chronic cough and the development of psychological problems has been reported in literature. While reviewing the adverse outcomes of children with chronic cough, Loan et al. (2) found that chronic cough induced affective states such as frustration and stress. Another cross-sectional study by Marchant and others on the burden of cough on families (1) had similar results. In the study, chronic cough had far-reaching consequences not only on affected children but also parents, with stress identified as the largest contributor to the emotional distress of parents. Because burden scores of parents reduced with cessation of coughing, Marchant and colleagues reiterated the need for improving the diagnosis and or proper management of chronic cough in children to lower the burden to families.

Prospective psychometry examination has also shown an association between cough and psychiatric and physical distress in children and their families. While evaluating change in symptoms of anxiety, depression, and stress at the University of Massachusetts Medical School, French et al. (24) reported a lower frequency of one or all of the three symptoms (anxiety, depression, and stress) with resolution of chronic cough. Another study by Vertigan et al. (25) found an association between voice disorders and chronic cough and proposed matching treatment to patient characteristics to improve outcomes, while McGaravy et al. (26) found 33% and 16% of patients with cough to be anxious and depressed respectively.

2.4 Impact of Chronic Cough on Quality of Life of Parents/ Caregivers

Despite cough being the most common symptom resulting in medical consultations, there is limited data on morbidity issues for parents/caregivers of children with chronic cough. The high burden of cough is reflected in the billions of dollars spent annually by caregivers on over the counter medications for cough treatment for their children (27) .

The health of children has been shown to influence the emotional and mental health of caregivers, with caregivers of children with persistent cough having a lower QoL than those of healthy children. In a mixed method study in Guangzhou China (28), caregivers' burden increased by between 2% to 52% whenever a child had a chronic cough. A majority demonstrated a mild to moderate burden (52%), with self-criticism found to be the most burdensome dimension among the caregivers studied. Loss of control, dependency, and sacrifice were other major contributors to burden, with the fear of the future of the affected children being the highest individually scored drivers for the burden of the studied population. According to the researchers, developing effective medical support systems for caregivers can stifle negative emotions and the “chaos” of care thus could improve outcomes for both the caregiver and the child.

A study by Fuller et al, described parental worries about disturbed sleep, discomfort, and fear that cough would cause permanent chest damage to their children (8). A similar study on British mothers of children with chronic cough by Conford et al (29), showed perception of the 'serious nature of the illness' as the most common reason why mothers consult a doctor over their child's cough. In the same study, concerns regarding choking, disturbed sleep, cough causing permanent chest damage, cot death and injury to the children were major sources of distress to mothers with children who had chronic cough. A pre-post follow-up study by Marchant *et al*. (30) using the DASS scale also reported similar findings in Queensland Australia in 2008. Data from Africa is however underreported.

2.5 Quality of Life

2.5.1 Defining Quality of Life in Children and their caregivers

According to the World Health Organisation (WHO), health refers to the state of complete physical, mental, and social well-being, and not merely the absence of a disease or infirmity. Quality of life measurement, may be subjective, but its definition is extrapolated from this definition of health. QoL of an individual tends to measure the level to which that individual is healthy, comfortable and able to participate in and enjoy their day-to-day activity. Subjective measures are often likely to best reveal the severity of illness from the perspective of those who matter (ie the patients and their families) and hence the importance of measuring the impact of symptoms on wellbeing should not be underestimated.

In literature, measuring the health related QoL of children and adults has been shown to provide vital information that aids physicians in understanding the burden of the disease and in evaluating the impact of health interventions. QoL questionnaires and or study tools are also increasingly being used in epidemiological studies as an outcome indicator (31).

2.5.2 Evaluating Quality of Life of Children with Chronic Cough and their Parents

Health related quality of life can be assessed through parental reports and among older children, through interviewing the child or adolescent. The following are among the recommended tools for evaluating QoL of patients with chronic cough:

a) Parent-Proxy Quality of Life Questionnaire for Paediatric Chronic Cough (PC-QOL)

The Parent-Proxy Quality of Life Questionnaire for Paediatric Chronic Cough (PC-QOL) is the most extensively studied and commonly used tool for the evaluation of QoL of children with chronic cough from the parent's perspective and the parent's own quality of life, and was developed by Peter A Newcombe et al (32) . It was designed to assess the *impact of the child's cough on the parent* as well as the *perception of the parent on their child's quality of life*. It is used for parents with children who present with chronic cough. This 27-item questionnaire is designed to assess the level of frequency of parental feelings (15 items) and worry (12 items) related to their child's cough. The first 15 items address the impact of chronic cough on the quality of life of the parents, and the last 12 questions address the perception of the parent on the quality of life of their child. The items in this tool can be reliably divided into 3 domains of functioning: psychological, physical, social, in line with the WHO definition of health as illustrated in the table below:

Table 3. Summary of content of the Parent Proxy Quality of Life Tool (32)

Domain	**Number of questions per domain**	**Selected questions Min-Max (each question) 1-7** *During the past week, how often:*	**Median (IQR) For each question**	**Overall median (IQR) For each domain**
Physical	11	-did you have sleepless nights because of your child's cough? -did you feel tired or exhausted because of your child's cough?		
Social	5	-did your child's cough interfere with your job or work around the house?		
Psychological	11	-did you feel frightened when your child experienced cough? -did you feel helpless because of your child's cough?		
All Domains	**27**			

Median value 3.5 used i.e. X>3.5- High QoL X ≤3.5 -Low QoL

This questionnaire uses a 7-point Likert type scale for each question to assess QoL. For example, during the past week how often did you have sleepless nights because of your child's cough? A response of 1 stands for 'all the time' reflecting a higher frequency of worry concerns hence a lower QoL, and a response of 7 represents 'none of the time' reflecting a lower frequency and fewer worry concerns hence a greater QoL. A median value of 3.5 is used as a cut off whereby a value less than or equal to 3.5 is classified as low QoL and a value of greater than 3.5 is classified as a high QoL.

The PCQoL was validated by comparing it with other measures of cough severity (subjective cough scores, objective cough counts) and generic QoL tools (PedsQL, SF12) across two-time frames in children with chronic cough. It demonstrated high levels of both internal consistency and test-retest reliability. In a validation survey by Newcombe et al. (33), the PC-QoL demonstrated a high internal consistency with a Cronbach α of 0.84 reported. The test-retest reliability was modest interclass correlation (ICC=0.66), while a strong correlation between PC-QoL and Visual Analogue Scale (VAS) scores demonstrated a high reliability. PCQoL scores were found to be sensitive to change over time, following a clinical intervention, and they mirrored the changes in other subjective and objective cough severity measures. Hartnick et al. (34) also found the PC-QoL ideal for longitudinal analysis of chronic cough. These findings endorse the PCQoL as a cough specific QoL measure that is reliable, valid, sensitive, and specific tool designed to identify and locate areas of concern of parents of children with chronic cough. The clinical utility of the PCQoL is also apparent as an outcome measure for evaluating interventions in research involving children with chronic cough. It can help clinicians determine whether the intervention done to these children has a positive impact on both physical and psychological functioning over time.

b) Chronic Cough-Specific QoL (CC-QoL) Questionnaire for Children

Chronic Cough-Specific QoL (CC-QoL) questionnaire is a I6-item research tool recommended for assessing QoL *from the perspective of the child*. It was designed by Peter A Newcombe et al to assess the impact of chronic cough across multiple dimension of the wellbeing of older children and adolescents (7-17years) (35). The tool is in line with the WHO’s definition of health, as it encompasses a review of the Physical (physical consequences of cough), Social (the response of others to the cough) and Psychological (the reactions/emotional response to pain) domains of children with chronic cough as presented in *Table 4* below. The tool can also monitor change in health status after an intervention such as treatment and has been ascertained to be a reliable, valid, sensitive, and specific tool for assessing chronic cough.

Table 4. Summary of Content of the Chronic Cough Specific Quality of Life Tool for Children. (36)

Domain	**Number of questions per domain**	**Selected questions Min-Max (each question) =1-7** *In the past 1 week, how often did your cough*	**Median (IQR) For each question**	**Overall median (IQR) For each domain**
Physical	7	-make you feel tired -wake you during night	49	
Social	3	-disturb others -annoy others	21	
Psychological	6	-make you feel frustrated -annoy you in the past week	42	
All Domains	**16**			

- **Median value 3.5 used i.e. X>3.5-High QoL X ≤3.5- Poor QOL**

The scoring system of the CCQoL uses ‘past week’ recall items on a 7-point Likert type scale (1=all the time, 7=none of the time) with high scores reflecting a higher QOL. It uses the same principles as the parent tool (PCQoL) where each question is scored between 1-7 and a median value of 3.5 is used as a cut off for low vs high QoL.

In 2016, the statistical properties of the CC-QoL was evaluated and reported by Newcombe and colleagues (35) in a survey of 130 children aged 8-12 years and its results were compared to the cough diary scores of children, the Spence Children's Anxiety Scale (SCAS), and the 4th version of the Pediatric QoL Inventory (PedsQL4.0). In the study, CC-QoL demonstrated an excellent internal consistency with the Cronbach alpha rate of 0.94. Construct and criterion validity were established to be significant for all subscales (psychological, physical, and social) and the sensitivity and specificity scores of the CC-QoL found to be excellent and positively correlated with SCAS and PedsQL scores. Even though a confirmatory cohort study was recommended to assess its suitability for evaluating changes in outcome, it exceeded recommended standards.

c) The Leicester Cough Questionnaire (LCQ)

Like the CC-QoL tool, the Leicester Cough Questionnaire (LCQ) is another recommended tool for evaluating quality of life of a patient with chronic cough. It evaluates 47 items using a seven-point Likert response scale and covers three domains of health (physical, psychological, and social). Internal consistency of the LCQ has been established scientifically and its Cronbach α score reported to range between 0.79 and 0.89. The reliability of the LCQ has also been determined using the test-retest method and reported to range between 0.88 and 0.96, which attests excellent reliability. To hasten data collection in population and clinical setting without compromising quality, a short 19-item version has been developed (5).

d) The Chronic Cough Impact Questionnaire (CCIQ)

The Chronic Cough Impact Questionnaire (CCIQ) tool for evaluating QoL of adult patients with chronic cough is globally accepted. Like the CC-QoL and LCQ, CCIQ evaluates the impact of chronic cough on QoL using self-administered questions (25 items) scored via a 5-point Likert scale. In literature, the CCIQ has been reported to be a valid tool for evaluating the burden of chronic cough on subjective well-being of patients. In a study by Biardini et al. (36), the CCIQ demonstrated good reliability with interclass correlation coefficient (ICC) of 0.67-0.88 reported. However, because the CCIQ is predominantly for assessing adult patients with chronic cough, it has questions that may not be appropriate for children, such as whether cough affects their work life. Chang et al in 2006 in a study titled 'Cough: Are children really different to adults?', noted that adult QoL tools could not be used to assess the QoL of children.(37)

2.5.3 Factors Affecting Quality of Life of Children with Chronic Cough

a) Clinical Factors

Severe acute malnutrition has been identified as a risk factor for chronic cough as it predisposes the affected child to diseases such as TB. In combination they adversely affect the quality of life of affected children. While evaluating the link between severe malnutrition and the risk of infection, Jones and Barkley (38) found a strong positive association between malnutrition and infection. Obesity has also been shown to play a major role in development and progression of many respiratory illnesses that cause chronic cough such as asthma and GER. Further studies on the same have recommended that weight loss may form part of management of chronic cough to improve their quality of life (39).Children admitted in hospital are at risk of nosocomial infections of the respiratory tract, which when poorly managed, can recur many times and predispose children to chronic cough, significant morbidity and mortality (40). When children have a chronic cough, it usually raises parental concern and anxiety. Therefore, attempts to mitigate this usually leads to an increased number of medical consultations and purchase of medication so as to improve their overall quality of life (1).

b) Socio Demographic Factors

Referring to the global statistics in *Table 3* above, children from Africa (South Africa, Kenya, and Botswana) and China seem to be most at risk of chronic cough in population and health care settings with several factors associated with its development. An evaluation of 65 female and 45 male patients with a median cough duration of four years by Kelsall et al. (41) demonstrated a link between gender and chronic cough. In the study, cough reflex was more sensitive in females than males, with the number of explosive cough sounds per hour found to be statistically significantly higher among females than males. In another study by Gui et al. (42) on evaluating the gender differences in respiratory sensations of 26 female and 27 male participants in 2014, females were more likely to cough than males, while Serah et al. found a significant gender difference in coughing in Europe with a female predilection (43).

According to Jurca et al. (13), age differences in the prevalence of cough exist, with the prevalence of cough dropping as children grow older up to 12 years but reverses at 14 years, with chronic attacks reported mostly at night in this age group. In China, Pan et al. (44) found that younger age was associated with a higher risk of chronic cough statistically in 2010, while younger Aboriginal children in Australia were more at risk of contracting protracted bacterial bronchitis and wet cough in a 2019 population study by Faniran et al. (11). In the studies by Pan and Faniran, air population was also associated with a higher risk of chronic cough among residents of overpopulated cities in China with unsealed roads in Australia.

In literature, a strong association between the smoking status of parents and the quality of life of children has been demonstrated. In a cross sectional survey of children whose mothers were current smokers or smoked during pregnancy in the United Kingdom, Pattenden et al. (45) demonstrated a strong link between parental smoking during postnatal and prenatal period and development of nocturnal cough, bronchitis, asthma, and wheeze which have been shown to negatively affect quality of life. According to Charlton (46), the risk of chronic cough is higher among young children exposed to cigarette smoke, and is dependent on the level of exposure. In the 1982 cross sectional study in North England, frequent coughs were reported in 42% of children who had one parent as a smoker. However, when both parents were smokers, prevalence of chronic cough increased to 48%, and was higher in girls (52%).

The socioeconomic status of parents, which includes a low occupational class and a low level of education have also been linked with a high risk of chronic cough. In a study by Ellison-Loschmann et al. (47), a low economic class increased the odds of bronchitis in children by 1.8 times. When parents had a low education level, the odds of coughing increased to 2.8 times with the risk of atopy and asthma also reported to increase significantly.

2.6 Conceptual Framework

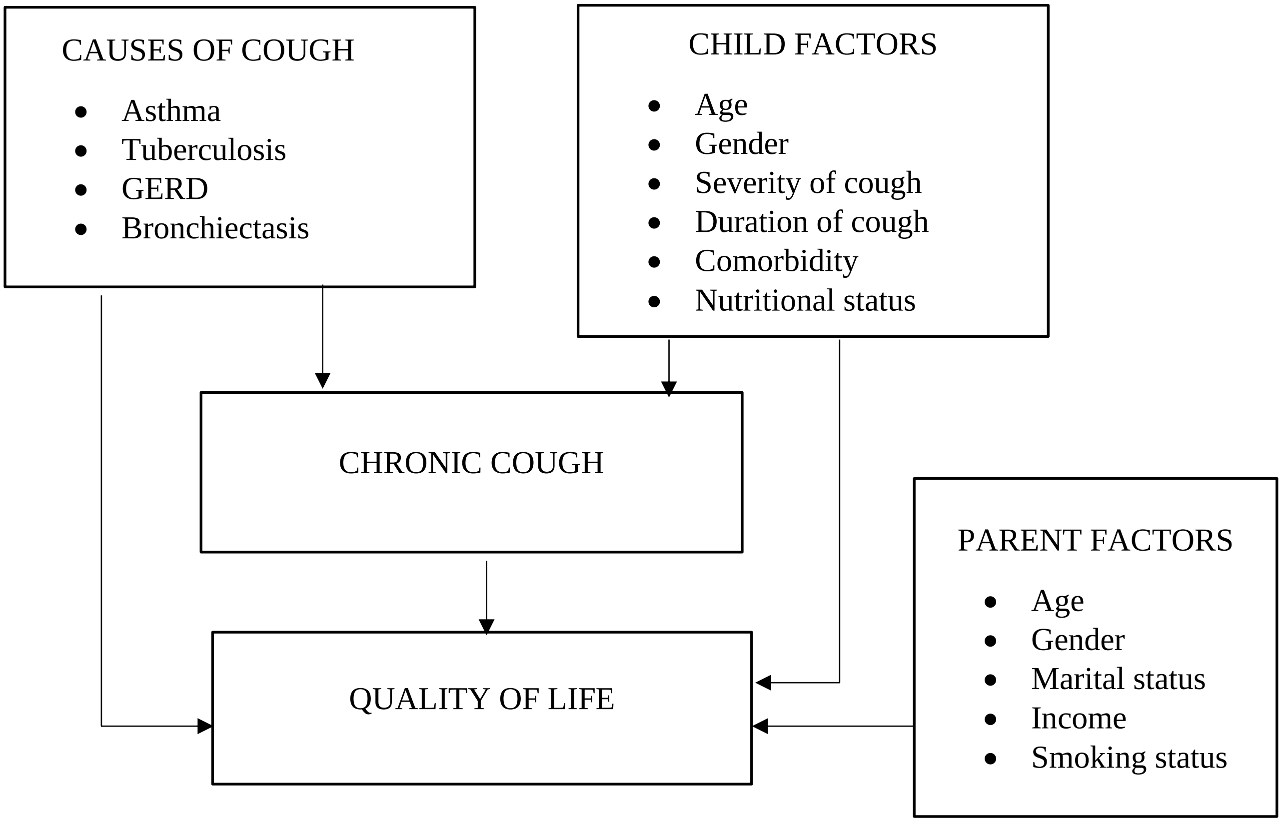

Figure 1. Conceptual framework showing the relationship between sociodemographic and clinical factors of children with chronic cough, and sociodemographic factors of their parents and their overall quality of life

2.7 Study Justification and Utility

Chronic cough afflicts millions of children globally. It is reported to be the most common reason for outpatient visits to a physician in areas where data is available such as the US (27) and Australia (48). Studies from the western world report a high burden of stress, frustration, and depression among affected children and their families due to chronic cough as it adversely affects their quality of life(49). However, conclusions from these studies may not apply to different regions of the world due to differences in diagnoses, lifestyle, climate, economic status, and customs.

There is a growing interest in assessing the quality of life of patients as understanding how a disease affects the general wellbeing of an individual can improve their outcome and reduce morbidity. According to the United Nations Convention on the Rights of the child, every child has the right to survival, to develop to the fullest and to participate fully in family, cultural and social life. It is therefore important to understand how chronic cough affects the quality of life of children in our setup.

Young children are however often unable to verbally express themselves adequately, it is therefore standard practice for parents to be the proxy assessors of their young child's medical condition. A parent's (proxy) perception of QoL and symptom level is a primary determinant of healthcare utilisation in young children.

The Parent Proxy Quality of Life questionnaire for Pediatric Chronic Cough (PC-QOL) and the Chronic Cough-Specific QoL (CC-QoL) questionnaire were developed by a group of Australian researchers to assess the impact of chronic cough on the QoL of those affected. They are relatively easy to use and have been shown to accurately measure the impact of chronic cough on the QoL of children and their caregivers and are correlated to severity of disease.

Although recognised as a major cause of morbidity in children, there is a paucity of research done to understand the impact of chronic cough on quality of life in the African setting. This study intends to offer insights on the impact of chronic cough on the quality of life among Kenyan children and their families. The information gathered may be useful in improving service delivery to those affected, and hence their overall wellbeing.

CHAPTER 3. RESEARCH QUESTION AND STUDY OBJECTIVES

3.1 Research Questions

- What is the quality of life of children presenting with chronic cough at Kenyatta National Hospital, and what is the quality of life of their parents?
- Which clinical and socio-demographic factors are associated with quality of life of children with chronic cough and that of their parents at Kenyatta National Hospital?

3.2 Study Objectives

3.2.1 Overall Objective

To assess the quality of life of children with chronic cough at Kenyatta National Hospital and the quality of life of their parents, and to determine factors that are associated with quality of life of these children and their parents.

3.2.2 Specific Objectives

Primary Objective

1. To assess the quality of life of parents with children presenting with chronic cough at Kenyatta National Hospital using the Parent-Proxy Quality of Life Questionnaire for Pediatric Cough (PC-QOL).

Secondary Objectives

2. To assess the quality of life of children/teenagers aged 7-17 years presenting with chronic cough at Kenyatta National Hospital using the Chronic Cough-Specific QoL Questionnaire for Children (CC-QoL).

3. To determine the clinical and socio-demographic factors that are associated with quality of life among children presenting with chronic cough and their parents at Kenyatta National Hospital.

CHAPTER 4. METHODOLOGY

4.1 Study Design

This was a hospital based cross sectional survey done in two phases. Phase one was a quantitative and phase two was a qualitative arm.

4.2 Study Site and Setting

This study was carried out in various departments at Kenyatta National Hospital (KNH), the teaching hospital of the University of Nairobi and the largest referral hospital in Kenya. It is located in Upper Hill, approximately 3.5kilometres from the central business district of Nairobi, the capital city of Kenya. KNH is at the apex of Kenya's health delivery system (level 6) and is mandated to provide specialised tertiary health services for adults and children in Kenya and the region. However, it also provides general health services to the population of Nairobi and its environs and receives referrals from all 47 counties in Kenya.

Services for children aged <13 years: The paediatric department in the hospital offers both inpatient and outpatient services. The inpatient unit is organised into four general wards and admits approximately 14000 patients annually. Each ward has consultant paediatricians of various specialities, among whom are two qualified Paediatrics Pulmonologists. Other personnel attending to the children include paediatric registrars, medical officer interns, clinical officer interns, nurses, nutritionists, and physiotherapists. These wards cater to children less than 13 years. The paediatric outpatient unit has a general paediatric outpatient clinic (POPC) that runs once weekly. Children under 13 years with various chronic respiratory diseases such as asthma are attended to here. A TB clinic also runs daily and attends to children of all ages who are on treatment for Tuberculosis. A paediatric pulmonology clinic has also been recently set up in the hospital to cater for children with chronic lung diseases. It runs every Thursday and is headed by the pulmonology consultant and qualified nurses. The hospital also has a paediatric neurology clinic which runs once weekly. Herein are children with cerebral palsy who often have chronic cough due to swallowing incoordination. An Ear, Nose and Throat (ENT) clinic is also run daily and caters to children who often present with chronic cough among other illnesses.

Services for teenagers aged 13-17 years: Children older than 13 years with chronic respiratory illnesses are attended to in the adult chest clinic, adolescent asthma clinic, TB clinic, HIV clinic, ENT clinic and the adult emergency unit for their outpatient needs. For their inpatient services, they are admitted in the adolescent/adult general medical wards, the adolescent/adult chest ward and the ENT wards and managed by qualified consultants, residents and nurses.

4.3 PHASE ONE: Quantitative Phase

4.3.1 Study Population

We included children and teenagers aged 17 years or below who presented with chronic cough to the study hospital and their parents.

4.3.2 Inclusion criteria:

-Child must have had a chronic cough defined as cough lasting longer than 4 weeks

-*Parent/caregiver interview:* we included a parent or primary caregiver of children presenting with chronic cough who lived with the child. If a non-parent (primary caregiver), they should have lived with the child for at least two months and be the primary person responsible for the child's care. (We aimed to enrol parents, but in our setting a child may often be accompanied to the hospital by someone who is not their parent but is actually their primary caregiver.)

- *Child/teenager interview:* we included a child or teenager aged 7-17 years who had had a cough lasting longer than 4 weeks.
- Have given informed consent (parent/primary caregiver) and assent (children ages 7-17 years) to participate in the study.

4.3.3 Exclusion criteria:

- Parent/ primary caregiver who has a chronic mental illness and unable to respond reliably to the questionnaire.

-Absence of parent/primary caregiver to give consent.

4.4 Sample Size Calculation

This was based on the primary objective to determine QoL of parents with children presenting with chronic cough at KNH. It was computed using the formula to determine prevalence of outcome of interest as follows:

Formula: (Fisher, 1981): $n = \frac{Z^2 x p(1-p)}{d^2}$

Parameters:

n: Desired sample size

P: Estimated prevalence of poor quality of life

Z^2: Normal variate for alpha representing the likelihood of a true population parameter lying outside the confidence interval. The confidence interval was set at 95% and the significant level at <0.05.

d: Precision

Estimate of prevalence (p) was adopted from a study carried out in Australia on indigenous children in a rural setting by Lovie-Toon et al. (50). They evaluated 85 children aged <18-years who had chronic cough, and found that 11.4% had poor quality of life. Precision was set at 5% (0.05) and the normal variate set at 1.96 to achieve 95% confidence interval. Sample size (n) was calculated as follows:

$$n = \frac{1.96^2 x 0.114(1-0.114)}{0.05^2} = 133$$

We would then enrol a minimum of 133 parent-child pairs to respond to the primary objective of the study.

4.5 Case definitions

i. Chronic cough - defined as a cough lasting longer than 4 weeks in children (American and Australian Pulmonology Societies).

ii. Parent QoL- was defined by assessing the impact of the child's cough on the parent/caregiver as well as the parental/caregiver's perception of their child's QoL using the Parent-Proxy Quality of Life Questionnaire for Paediatric Chronic Cough (PC-QOL). This was assessed from 27 questions of the questionnaire, each of which had a Likert score range of 1-7, where lower scores indicated more concerns/worries hence a lower quality of life and higher scores indicated fewer concerns/worries hence a higher quality of life. A median value of 3.5 was used as a cut off such that any value less or equal to 3.5 depicted a low QoL and any value higher than 3.5 depicted a high QoL.

iii. Child/teenager's health related QoL- was defined by assessing the impact of the child's cough on the physical, psychological and social aspects of their daily life. For younger children, this was assessed as a proxy from the parent's perspective using the Parent-Proxy Quality of Life Questionnaire for Paediatric Chronic Cough (PC-QOL). For older children aged >7 years, this was assessed using the Chronic Cough-Specific QoL (CC-QoL) Questionnaire for Children. This 16-question tool has a Likert score range of 1-7, where lower scores indicate more concerns/worries and higher scores indicate fewer concerns/worries. Similar to the parent’s tool, a median value of 3.5 was used as a cut off such that any value less or equal to 3.5 depicted a low QoL and any value higher than 3.5 depicted a high QoL.

Iv. Factors impacting QoL

-Socio-demographic factors of interest for child/teenager included: age, gender, level of education (current class), source of fuel for cooking, main source of fuel.

-Socio-demographic factors of interest for parents include: age, gender, marital status, level of education, household income, employment.

-Clinical factors of interest for child/teenager: duration of cough, severity of cough, cause of cough, HIV, nutritional status and number of consultations.

4.6 Study Tools

a) A case record form

The case record form in *Appendix 1* was used to record relevant socio-demographic characteristics of the child/ teenager and their parent, and medical data of the child

b) Parent-Proxy Quality of Life Questionnaire for Paediatric Chronic Cough (PC-QOL)

The PC-QoL questionnaire (*Appendix 2)* was the main data collection tool. This 27-item questionnaire was used to evaluate the impact of a child's cough on the parent/caregiver as well as the parental/caregiver's perception of their child's QOL. The questions capture the frequency and worry about aspects of the child's and family's functioning as related to the chronic cough of the child. The items in the PC-QoL are divided into 3 domains of physical, social and psychological concerns, as well as the total measure of quality of life (table 5).

Table 5. Summary of content of the Parent Proxy Quality of Life Tool (29)

Domain	**Number of questions per domain**	**Example** *During the past week, how often:*	**Median (IQR) For each question**	**Overall median (IQR) For each domain**
Physical	11	-did you have sleepless nights because of your child's cough? -did you feel tired or exhausted because of your child's cough?		
Social	5	-did your child's cough interfere with your job or work around the house?		
Psychological	11	-did you feel frightened when your child experienced cough? -did you feel helpless because of your child's cough?		
All Domains	**27**			

c) Chronic Cough-Specific QoL (CC-QoL) Questionnaire for Children

The CC-QoL questionnaire was used to interview children age 7 – 17 years, and assess their QoL in physical, social and psychological domains (table 6). Sixteen questions were asked to evaluate the impact of chronic cough on the quality of life of the affected children.

Table 6. Summary of the Chronic Cough Specific Quality of Life Tool for Children (32)

Domain	**Number of questions per domain**	**Example** *In the past 1 week, how often did your cough*	**Median (IQR) For each question**	**Overall median (IQR) For each domain**
Physical	7	-make you feel tired -wake you during night		
Social	3	-disturb others -annoy others		
Psychological	6	-make you feel frustrated -annoy you in the past week		
All Domains	**16**			

4.7 Study Procedures

4.7.1 Screening, recruitment and enrolment to the study

Having received approval from the ethics committee, we identified potential study subjects by perusing through files/ records on various clinic days before commencement of the clinic or in the admitting ward. We were also informed of potential study subjects by clinicians in various departments in the hospital. The principal investigator (PI) together with trained research assistants (RA) then screened eligible clients based on the child's / teenager’s presence of cough that has lasted longer than 4weeks. We then used a consecutive sampling method whereby the parents / teenagers who satisfied our eligibility criteria were recruited until our sample size was achieved. An interview was then conducted in a private and quiet room in the clinic or wards.

i. Interview of parent:

The PI /research assistant approached the parent, introduced ourselves and explained the purpose of the study. The parent was allowed to ask questions for clarification which were answered satisfactorily and was then allowed to provide a voluntary informed consent. The consent provided details on the purpose of the study, the study procedure to be followed and potential advantages and risks of taking part in the study. Those who consented were included in the study. Data on sociodemographic characteristics of the child and parent such as age, gender, household income, main fuel used, marital status and level of education were collected using a structured pretested questionnaire in Appendix 1. It also captured data on the clinical factors such as the child's severity of cough, medical diagnosis and nutritional status. The *Parent-Proxy Quality of Life Questionnaire for Paediatric Chronic Cough (PC-QOL)* in Appendix 2 was then used to evaluate the QOL of the parents and their perspective on the QOL of their children who have chronic cough. This tool was read verbatim to the parents and all grey areas clarified to improve accuracy on data collection. The interview took approximately 20 to 30 minutes.

ii. Interview of older children/teenagers:

The PI /research assistant approached the teenager and their parent, introduced themselves and explained the purpose of the study. They were then allowed to ask questions for clarification which were answered satisfactorily and were then allowed to provide a voluntary informed assent and consent from the teenager and parents respectively. The assent / consent provided details on the purpose of the study, the study procedure to be followed and potential advantages and risks of taking part in the study. Those who assented / consented were included in the study. Data on sociodemographic characteristics of the teenager and parent such as age, gender, household income, main fuel used, marital status and level of education were collected using a structured pretested questionnaire in Appendix 1. It also captured data on the clinical factors such as the teenager's severity of cough, medical diagnosis and nutritional status. The *Chronic Cough-Specific QoL (CC-QoL) Questionnaire for Children* in Appendix 3 was then used to evaluate the QOL of the older child/ teenager who had chronic cough as their parents filled the parent tool. These tools were read verbatim and all grey areas clarified to improve accuracy on data collection. The interview took approximately 20 to 30 minutes.

Figure 2 below summarizes the study procedure.

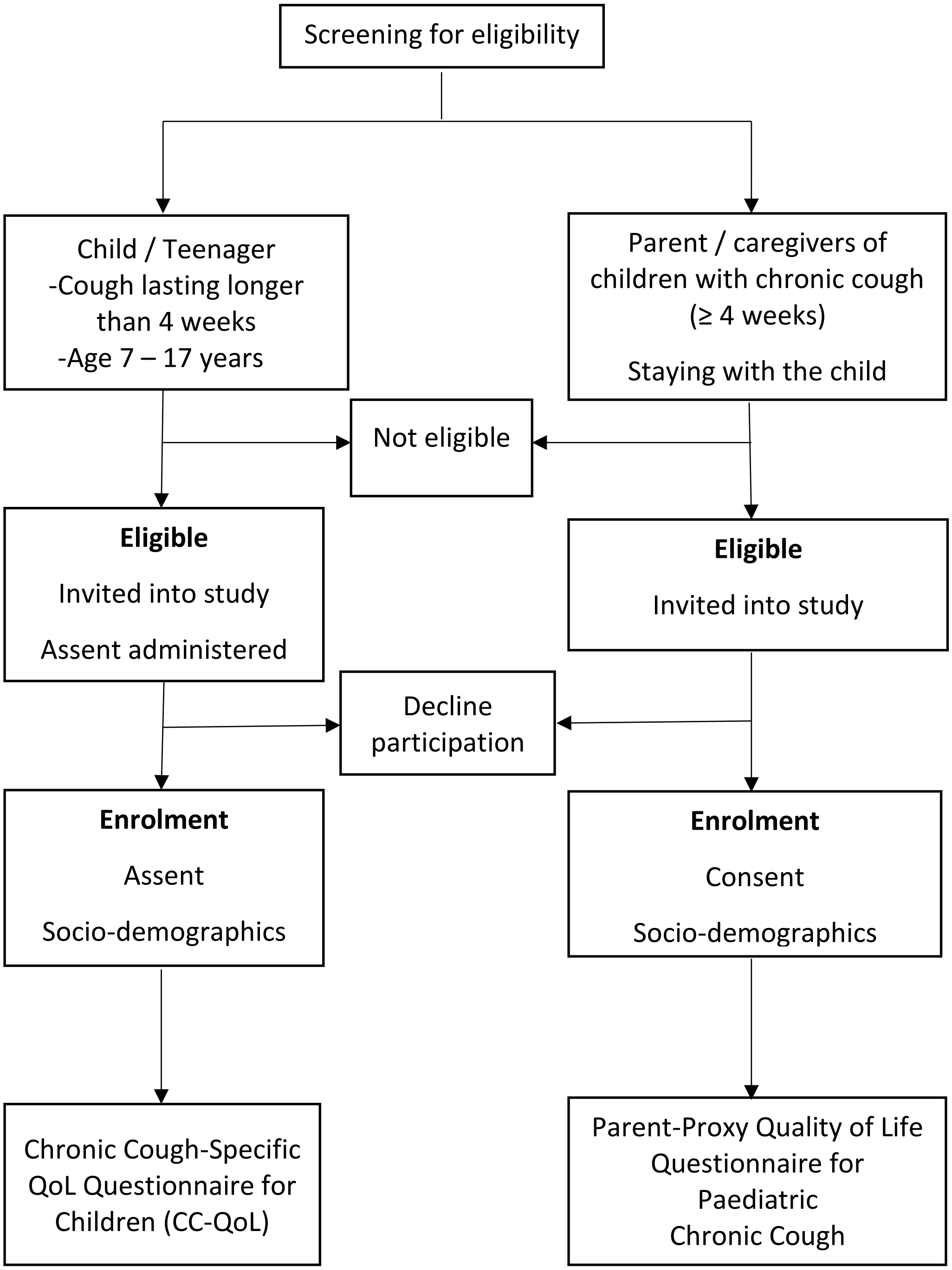

Figure 2. Flow chart demonstrating the sampling strategy and procedure for the study

4.8 PHASE TWO: Qualitative Phase

4.8.1 In-depth Interviews for Parents

Parents whose children have chronic cough and were currently hospitalized were selected for the in-depth interviews (IDI). This convenience sampling was be favourable in view of COVID-19. The study participants were informed briefly about the purpose of the study and a written informed consent obtained. Data was collected by the PI and qualified qualitative research assistants. The data was collected using an IDI guide (*Appendix 4*) in a private space within KNH during the day. We used face to face interviews which lasted approximately 30 minutes each. The note taker documented summarized responses of the discussion as well as other important observations such as participants' mood and body language. We recruited study subjects until we reached a point of information saturation.

Stage 1: **Scene setting and ground rules**: The research team welcomed the participant as they arrived for the IDI. Once settled, the PI formally started the IDI by introducing herself, stating the research topic and the purpose of the study. The PI then explained to the participant that they were invited to give their own opinions and that there were no right or wrong answers. The PI then requested the participant for the session to be recorded, explaining that the recording would be kept confidential and would only be used for the study purposes. The research assistant then switched on the voice recorder.

Stage 2: **Opening topic**: The PI engaged the participant by introducing the topic and inquired about the participant's perceptions on how their daily life has been affected (quality of life) while caring for children with chronic cough.

Stage 3: **Discussion:** The participant was involved in detailed discussion of their experiences and views on their quality of life. They were also be asked on what factors they felt have contributed to their perceived quality of life as pertains to caring for children with chronic cough and whether they had any coping strategies.

Stage 4: **Ending the discussion**: The PI ended the discussion by thanking the participant for their participation.

4.9 Measures To Minimize Risk of COVID-19 Exposure During My Study

In the course of my study, I took the following infection prevention and control measures to minimize risk of COVID-19 exposure to myself, my research assistants and the study participants:

Principal investigator and research assistants:

1. We used appropriate Personal Protective Equipment as recommended by MOH infection prevention and control guidelines when conducting the face-to-face interviews.
    - N95 masks and 3-ply face masks were be worn at all times
    - Surgical gloves were used and disposed appropriately as per IPC guidelines
    - Dust coats and face shields were worn at all times
2. We were screened daily for COVID-19 exposure and symptoms using daily temperature checks. We only continued with the face-to-face interviews when we were symptom free and had had no known exposure to COVID-19.
3. Alcohol based hand sanitizers and hand washing were used before and after contact with the participants.
4. Physical distance of minimum 1.5 metres was maintained between us and the participant.
5. We had been trained on the appropriate cleaning and Infection control procedures necessary to mitigate COVID-19 spread at our study site.

Study participants:

1. All participants had their temperature taken using a non-contact thermometer. Those found to have fever (>38 degrees Celsius), difficulty in breathing or recent exposure to COVID-19 would be directed for COVID-19 testing.
2. Alcohol based hand sanitizers and hand washing were availed to them.
3. They were advised to put on a 3-ply face mask during the face-to-face interview.
4. They were advised to maintain social distancing of at least 1.5 meters during the sessions.

4.10 Data Management and Analysis

4.10.1 Study variables

i. Dependent

The dependent variable was the quality of life of children with chronic cough and their parents. The overall quality of life and sub-domains (psychological, physical, and social) were evaluated and summarised as QOL scores whereby the higher the score, the higher the quality of life i.e. Low QoL $X \leq 3.5$ High QoL $X > 3.5$

ii. Predictor Variables (Factors associated with QoL)

Sociodemographic characteristics such as age and gender and clinical data such as nutritional status and causes of chronic cough were intermediate variables as in *Table 7*.

Table 7 Objectives and Variables in the study

Objective	**Variable (s)**
Objective 1. Quality of life of parents with children presenting with chronic cough	Quality of life (Physical domain, social domain and psychological domain)
Objective 2. Quality of life of children/teenagers aged 7-17 years presenting with chronic cough	Quality of life (Physical domain, social domain and psychological domain)
Objective 3. To determine the clinical and socio-demographic factors that are associated with high verses low quality of life.	**Sociodemographic Factors** (Gender, education, marital status, household income, smoking status, main source of fuel) **Clinical factors** (Severity of Chronic cough, cause of cough, number of health visits, nutritional status, HIV status)

4.10.2 Quantitative Data Analysis

Data was extracted from data collection tools, uploaded in an SPSS worksheet, and cleaned following the guidelines of Van Den Broeck et al.(51). Records were screened for typing errors, outliers, and incomplete data and records with missing data deleted from the worksheet. Statistical testing was done as follows: The demographic characteristics of children and parents and household characteristics were summarized as medians with interquartile range if continuous and frequencies with percentages if categorical, and presented in a table. Objective 1 and 2 were analysed by computing the median (IQR) scores for social, psychological, and physical quality of life domains and overall quality of life and scores interpreted as either poor (median ≤3.5) and good (median >3.5). Poor scored were recategorized as either being extremely poor (median ≤1) or poor (median >1). For objective 3, the Chi square test or Fisher's test (if the frequency of any cell was <5) was used for comparative analyses with odds ratios with 95% confidence levels interpreted as the measure of association. A P value <0.05 was considered statistically significant. Logistic regression was used for multivariable analysis to control for confounding.

4.10.3 Qualitative Data Analysis

Audio recordings from IDIs were transcribed verbatim and content analysis conducted -guided by the thematic approach of Albers Michael (52). The findings were aggregated, coded progressively, and line-by-line reads done to identify central themes. Then, the central themes were revised to identify sub-themes, reports abstracted to findings, and the findings presented in form of direct quotations from the responses of participants.

Study tools were filed and locked in cabinets for safe storage. Digital databases were developed using Microsoft Access and password protected to limit access. Before analysis and or dissemination, data was de-identified for confidentiality. As the custodian of data, the PI not only handled data management responsibilities, but also oversaw disapproval and approval of data access in liaison with the KNH/UoN Ethics team.

4.11 Ethical Considerations

The proposal and all data collection tools were submitted to the KNH/UoN Ethics and Review committee for evaluation. The study commenced only after formal approval from the committee. Belmont Principles (53) were used to ensure justice to participants and respect of their autonomy.

Autonomy- Study participants were explained to fully the risks and benefits involved in the study together with the study procedures. They were then asked to voluntarily choose whether or not to participate, and those who agreed were given an informed consent/assent form to sign.

Confidentiality of gathered information – personal identifiers such as names of children or parents were not captured on data collection tools. The personal identifiers were recorded only on consent forms, which will not be shared with third parties without formal authorisation by the KNH/UoN ethics committee. Instead, serial study numbers were used to identify study participants. Interviews were scheduled in a confidential area of KNH. After use, files were locked in cupboards and databases were password protected.

Beneficence- insights into impact of chronic cough on QOL of the patients will provide information aiming to improve their overall quality of life.

Justice- each participant had a fair chance of selection into the study.

Non-maleficence- Caution was taken not to cause physical or psychological harm to subjects in the course of the study.

CHAPTER 5. RESULTS

5.1 Recruitment of study participants

We screened and found one hundred and fifty (150) eligible parent-child pairs of whom 135 parent-child pairs were willing to participate, gave written consent and were enrolled. The children were of median age 1.5 years (IQR), and 97 (71.9 %) of children were aged below 7 years (suitable for parent only to respond to the QoL tool), while 38 (28.1%) were older than 7 years (suitable for both child and parent to each respond to the QoL tool) as shown in Figure 3 below:

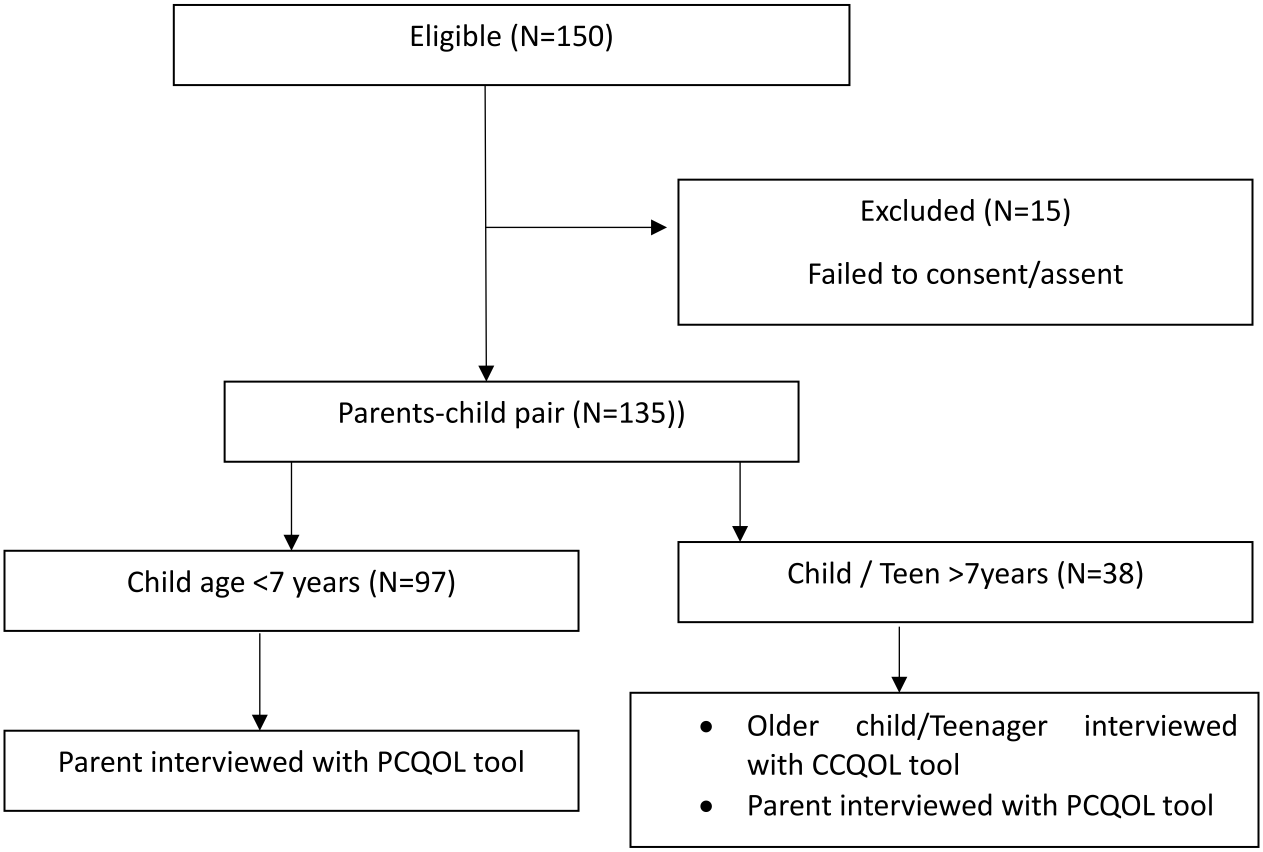

Figure 3. Recruitment flow chart of study participants

5.2 Sociodemographic characteristics of children and parents

Sociodemographic characteristics of children and parents are presented in table 8 below. Most children were aged less than 5 years (68.9%), with a median age of eighteen months. Most were female (54.1%), and had not started school (63.0%). Most parents were older than 25 years (53.3%), female (99.3%), married (86.7%), and had a secondary or higher level of education (85.2%). The average monthly income for a majority was 5000-10000 Kenyan shillings (35.6%). The household density for a majority was ≥5 (72.6%). Most households used biomass as the main source of fuel (65.2%) and were residing close to a busy road (83.0%).

Table 8. Demographic characteristics of parents and children (N=135)

Variable	**Detail**	**Frequency (%)**
Child		
Age	0-5 years	93 (68.9)
	6-14 years	42 (31.1)
Gender	Female	73 (54.1)
	Male	62 (45.2)
Education	Not started	85 (63.0)
	Kindergarten	10 (7.4)
	Primary	40 (29.6)
Parent and household characteristics		
Age	<25	63 (46.7)
	≥25	72 (53.3)
Gender	Female	134 (99.3)
	Male	1 (0.7)
Education	Primary or lower	20 (14.8)
	Secondary or higher	115 (85.2)
Marital status	Not married	18 (13.3)
	Married	117 (86.7)
Monthly income (KShs)	<5000	33 (24.4)
	5000-10,000	48 (35.6)
	>10,000	18 (13.3)
	Not comfortable disclosing	36 (26.7)
Household density (persons/room)	<5	37 (27.4)
	≥5	98 (72.6)
Main source of fuel	Clean fuel (gas)	47 (34.8)
	Biomass	88 (65.2)
Live near a busy road	Yes	112 (83.0)
	No	23 (17.0)

5.3 Clinical characteristics of children

Most of the children (77%) were admitted in the wards at the time of the study, while only twenty three percent (23%) were found in the outpatient clinics. On the severity of cough, most children had cough lasting longer than 8 weeks (56.3%) and coughed throughout the day (55.6%). Approximately sixty seven percent of parents had consulted various doctors ≥5 consultations in a year over the cough of the child. Most of the children had good nutritional status (51.1%) with only 26.7% being stunted and 13.3% being underweight. In the clinical diagnosis, the commonest respiratory cause of chronic cough in the children was recurrent infective pneumonia at 32.6% followed by asthma at 16.3% while pulmonary TB and bronchiectasis accounted for 11.1% and 8.1% of cases respectively. Twenty three percent (23%) of the children had GERD, 21.5% of them had cardiac disease and 10.3% of then were HIV positive. These findings are in table 9 below:

Table 9. Clinical characteristics of children (N = 135)

Variable	**Detail**	**Frequency (%)**
Duration of cough	<8 weeks	76 (56.3)
	≥8 weeks	59 (43.7)
Timing of cough	Throughout the day	75 (55.6)
	Only night and evening	60 (44.4)
Consultations in a year	<5	45 (33.3)
	≥5	90 (66.7)
Nutritional status	Wasted	12 (8.9)
	Underweight	18 (13.3)
	Stunted	36 (26.7)
	Normal	69 (51.1)
Clinical diagnosis	Respiratory	
	a) Infectious	
	Recurrent infective pneumonia	44 (32.6)
	Pulmonary Tuberculosis	15 (11.1)
	b) Non infectious	
	Asthma	22 (16.3)
	Adenotonsillar hypertrophy	16 (11.9)
	Bronchiectasis	11 (8.1)
	Gastrointestinal tract	
	Gastroesophageal reflux disease	31 (23.0)
	Recurrent aspiration pneumonia	19 (14.1)
	Other/comorbidity	
	Cardiac disease	29 (21.5)
	Rickets	20 (14.8)
	HIV	14 (10.3)

5.4 Quality of life of parents of children with chronic cough

Table 10 below shows median values and IQR for responses of the 27 questions relating to burden of chronic cough from the parent's perspective. The median quality of life score for the psychological, physical, and social domain of parents were 1 [1, 2], 1 [1, 2], and 1 [1, 1] respectively. Using a median cut-off value of 3.5 for good quality of life, all parents reported poor quality of life scores across all the domains. The overall quality of life score for parents was poor as shown be a median (IQR) of 1[1, 2]. Questions that caused the greatest concern have a lower score as shown. The items with the greatest burden were feelings of frustration, upset, anxiety, helplessness, stress, having sleepless nights, and feeling sorry for the child. The items that bothered the parents most were choking, child not sleeping well, cough indicating a serious illness, child not being able to breath and whether the child would be able to lead a normal life. (Table 10).

Table 10. Parent QoL -Parent proxy cough tool (PCQOL) (N = 135)

Domain	**Question: During the past week, how often/were you worried: (Min-Max = 1-7)**	**Median [IQR]**	**Overall median (IQR)**
Psycho-logical	Did you feel frightened when your child experienced cough?	*2 [1, 2]	1 [1, 2]
	Did you feel frustrated because of your child's cough?	1 [1, 2]	
	Did you feel upset because of your child's cough?	1 [1, 2]	
	Did you feel anxious about your child's cough	1 [1, 2]	
	Did you feel helpless because of your child's cough?	1 [1, 2]	
	Did you feel stressed about your child's cough?	1 [1, 2]	
	*Did you feel sad about your child's cough?	2 [1, 2]	
	*Did you feel scared because of your child's cough?	1 [1, 2]	
	*Did you feel being overprotective because of your child's cough?	2 [1, 2]	
	Did you feel powerless because of your child's cough?	1 [1, 2]	
	Did you feel sorry for your child because of your child's cough?	1 [1, 2]	

Domain	**Question: During the past week, how often/were you worried: (Min-Max = 1-7)**	**Median [IQR]**	**Overall median (IQR)**
Physical	Did you have sleepless nights because of your child's cough?	1 [1, 2]	1 [1, 2]
	*Were you awakened during the night because of your child's cough?	2 [1, 2]	
	*Did you feel tired or exhausted because of your child's cough?	2 [1, 2]	
	*Over the medications your child takes and the side effects of them?	2 [1, 2]	
	*About the cause of your child's cough?	2 [1, 3]	
	About your child's cough indicating a serious illness?	1 [1, 2]	
	About your child chocking when coughing?	1 [1, 2]	
	About your child not being able to breathe again after coughing?	1 [1, 2]	
	About your child feeling tired because of the cough?	1 [1, 2]	
	About your child not sleeping well because of the cough?	1 [1, 2]	
	*About the cough causing damage to your child's chest or lungs?	1 [1, 2]	
Social	Did your child's cough interfere with your job or work around house?	1 [1, 2]	1 [1, 1]
	About child's performance of normal activities including feeding/schooling?	1 [1, 1]	
	About your child being able to lead a normal life?	1 [1, 2]	
	*About leaving your child with others because of his/her cough?	2 [1, 2]	
	About the effects of your child's cough on him/her?	1 [1, 2]	
Overall			**1[1, 2]**

Median value of 3.5 used as cut-off. i.e., X>3.5=Good QoL and X≤3.5 Poor QoL

*Scored better (higher median)

5.5 Quality of life of older children with chronic cough

The median quality of life score for the psychological, physical, and social domains of children were 2 [1, 2], 2 [1, 2], and 2 [2, 3] respectively. Assuming a median cut-off value of 3.5 for good quality of life, all children reported poor quality of life scores for all domains. The overall median quality of life score for children was 2 [1.5, 2], showing poor overall QoL for older children with chronic cough (Table 11).

Table 11: Child/teenager interview – Child chronic cough tool (CCQOL) (N=38)

Domain	**Question: During the past week, how often/were you worried: (Min-Max = 1-7)**	**Median [IQR]**	**Overall Median (IQR)**
Psychological	You hate your cough	1 [1, 2]	2 [1, 2]
	Coughing annoys you in the past week	2 [2, 2]	
	Your cough make you feel frustrated	1 [1, 2]	
	You annoyed by your cough during activities	2 [1, 2]	
	Coughing up phlegm/ mucus annoy you	2.5 [1, 3]	
	You feel uncomfortable because of cough	1 [1, 2]	
Physical	Your chest or stomach pains bother you	2 [2, 3]	2 [1, 2]
	Your cough makes you feel tired	2 [2, 2]	
	You troubled sleeping at night because of cough	2 [1.25, 2]	
	Your cough wakes you at night	2 [2, 2]	
	You have trouble getting to sleep because of cough	2 [2, 2]	
	You find it difficult to do things because of cough	2 [2, 2]	
	Your chest feels bad	2 [2, 2]	
Social	Your cough disturbs others	2 [1, 2]	2 [2, 3]
	Your cough annoys others	2 [1, 2.75]	
	You feel frustrated because you couldn't keep up with others	2 [1, 2]	
Overall			**2 [1.5, 2]**

Median value of 3.5 used as cut-off. i.e., X>3.5=Good QoL and X≤3.5 Poor QoL

5.6 Sociodemographic and household factors associated with quality of life

Since our overall median score reflected a poor quality of life, we analyzed and categorized the score into two: extremely poor QOL for those who scored 1 and poor QOL for those who scored greater than 1. The age and education of children; education and monthly income of parents; and environmental pollution(residing near a busy road) were associated with the quality of life of parents before controlling for confounding (table 12).Parents of children aged less than 5 years had 6.17 greater odds (95% CI=2.81-13.67) of having extremely poor quality of life compared to those with children aged greater than 6 years and this was statistically significant p<0.01.Parents who had pre-schoolers were 8.30-fold (95% CI= 0.47-18.58) more likely to have extremely poor quality of life (p<0.01) compared to those with primary school children .Poorly educated parents (primary of lower) were 3.64-fold (95% CI=1.03-12.20) more likely to have extremely poor quality of life (p=0.043) compared to those well-educated (secondary school or higher). Households with lower monthly income of <KSh5000 and <KSh10000 had 3.5-7-fold greater odds of having extremely poor quality of life respectively compared to those with monthly income of >Kshs 10000, and this was statistically significant as the confidence interval did not involve the null value of 1 p=0.041, p=<0.001, Families residing close to a busy road had 2.86-fold greater odds (95% CI=1.19-7.42), p=0.021 of extremely poor quality of life compared to those not residing near a busy road. The gender of children, age of parents, and household density of were not associated with the quality of life of parents significantly.

Table 12. Sociodemographic and household factors associated with QoL (N=135)

Variable	**Details**	**Extremely poor QoL (N=87)**	**Poor QoL (N=48)**	**OR (95% CI)**	**P value**
Age of child	0-5 years	72 (77.4)	21 (22.6)	**6.17 (2.81-13.67)**	**<0.01**
	6+ years	15 (35.7)	27 (64.3)	Reference	
Gender of child	Female	43 (58.9)	30 (41.1)	0.58 (0.28-1.20)	0.144
	Male	44 (71.0)	18 (29.0)	Reference	
Education of child	Preschool	68 (80.0)	17 (20.0)	**8.30 (0.47-18.58)**	**<0.01** 0.150
	Kindergarten	6 (60.0)	4 (40.0)	3.11 (0.84-10.89)	
	Primary	13 (32.5)	27 (67.5)	Reference	
Age of parent	<30 years	40 (63.5)	23 (36.5)	Reference	0.828
	30+ years	47 (65.3)	25 (34.7)	1.08 (0.52-2.21)	
Education of parent	Primary or lower	17 (85.0)	3 (15.0)	**3.64 (1.03-12.20)**	**0.043**
	Secondary or higher	70 (60.9)	45 (39.1)	Reference	
Monthly income	<5,000	19 (57.6)	14 (42.5)	**3.52 (1.99-11.27)**	**0.041** **<0.01**
	5,000-10,000	35 (72.9)	13 (27.1)	**7.00 (2.11-21.30)**	
	>10,000	5 (27.5)	13 (72.2)	Reference	
Presence of busy road	Yes	77 (68.8)	35 (31.3)	**2.86 (1.19-7.42)**	**0.021**
	No	10 (43.5)	13 (56.5)	Reference	
Household density	≤5	65 (65.7)	34 (34.3)	Reference	0.625
	>5	22 (61.1)	14 (38.9)	0.82 (0.37-1.77)	

5.7 Clinical factors associated with quality of life

The number of consultations per year and the HIV status of children were associated with quality of life of parents before controlling for confounding (Table 13). Attending five or more consultations per year was associated with a 3.15-fold (95% CI=1.54-7.39) increase in the odds of having extremely poor quality of life. Having a HIV positive child increased the odds of having extremely poor quality of life 8.25-fold (95% CI=1.43-89.77) in the population studied (P=0.018). The duration of cough, timing of cough, and the number of coughs per hour of children were not associated with the quality of life of the parents studied statistically.

Table 13. Clinical factors associated with Quality of Life (N=135)

Variable	**Details**	**Extremely poor QoL (N=87)**	**Poor QoL (N=48)**	**OR (95% CI)**	**P value**
Duration of cough	<8 weeks	78 (63.4)	45 (36.6)	Reference	0.537
	≥8weeks	9 (75.0)	3 (25.0)	1.73 (0.48-6.16)	
Timing of cough	Only at night and early morning	41 (68.3)	19 (31.7)	Reference	0.398
	Throughout the day	46 (61.3)	29 (38.7)	0.73 (0.36-1.50)	
Coughs per hour	<5 coughs	55 (63.2)	32 (36.8)	Reference	0.688
	5+ coughs	32 (66.7)	16 (33.3)	1.16 (0.54-2.49)	
Consultations in a year	<5	28 (62.2)	17 (37.8)	Reference	**0.003**
	≥5	59 (65.6)	31 (34.4)	3.15 (1.54-7.39)	
Child HIV status	Positive	13 (92.9)	1 (7.1)	8.25 (1.43-89.77)	**0.018**
	Negative	74 (61.2)	47 (38.8)	Reference	

5.8 Multivariable analysis

Factors that showed significant association with QoL during univariate analysis were then considered for inclusion in adjusted analyses. After controlling for confounding, the age of children, education of parents, staying near a busy road (pollution) and a higher number of consultations per year were found to be the predictors for extremely poor quality of life in the population studied (Table 14). Parents of younger children (aged <5years) had 11.38-fold greater odds (95% CI=3.849-33.641) of having extremely poor quality of life compared to those with older children and this was statistically significant, p=<0.01. Having a low level of education (primary or lower) increased the adjusted odds for extremely poor quality of life 9.331-fold (95% CI=2.021-43.08), p=0.004, while residing close to a busy road increased the adjusted odds for having extremely poor quality of life 3.23-fold (9% CI=1.192-8.753), p=0.021. Attending five or more consultations per year increased adjusted odds for having extremely poor quality of life 5.32-fold (95% CI=2.68-24.73), p=0.04. Monthly income and the HIV status of children were not predictors for quality of life in this population.

Table 14. Multivariable analysis – Factors associated with Parent Quality of Life

Variable	**Details**	**Adjusted OR (95% CI)**	**P value**
Age of children	0-5 years	11.38 (3.85-33.64)	**<0.001**
	6-14 years	Reference	
Education of parent	Primary or lower	9.33 (2.021-43.08)	**0.004**
	Secondary or higher	Reference	
Monthly Income	<5,000	0.446 (0.136-1.465)	0.183
	5,000-10,000	2.329 (0.826-6.565)	0.110
	>10,000	Reference	
Presence of busy road	Yes	3.230 (1.192-8.753)	**0.021**
	No	Reference	
Child's HIV status	Positive	4.28 (0.94-68.73)	0.674
	Negative	Reference	
Consultations in a year	<5	Reference	**0.04**
	≥5	5.32 (2.68-24.73)	

5.9 Parent Perspectives on Quality of Life – In Depth Interviews

We conducted in-depth interviews (IDIs) with 15 parents of children who had chronic cough to understand their perspectives on their quality of life and the children's quality of life. Nearly all the parents had children aged below 5 years who were hospitalized at the time of the interviews. The parents gave varied descriptions of the nature of cough that the child had; in some instances, some children had a dry cough, others had a productive cough and others had an irritating cough that resulted in vomiting while others developed difficulty in breathing following the cough. A few of the parents were aware that the children had an underlying condition that was the cause of the chronic cough as they mentioned being informed by healthcare providers about GERD, heart condition, and aspiration pneumonia. Notably, the subject of the caregivers' quality of life elicited painful emotions from the participants sometimes even to the point of crying during the session. Interviews were recorded and transcribed verbatim and content analysis was conducted to arrive at themes as summarized in the table below.

Table 15. Parent's Perspective on Quality of Life with relation to their child's chronic cough

Theme (Domain)	**Subtheme**	**Quote**
Social/ financial	Loss of income/livelihood	"I *stopped working because our lives revolve around the hospital … When you are here (hospital), there is nothing else that you can think of, you can't think of what is happening out there because you can only leave the hospital for a very short period*." **Parent 4**
	Perceived as a burden	*"We have been hospitalized so many times since the child started coughing, in fact, I never tell anybody else except my husband … because even so, people no longer pick calls, I guess they assume you want to tell them about your sick baby and ask for financial help.*" **Parent 11**
Psychological	Stress/ frustration	"*It has affected me a lot to an extent we even parted ways with my husband because taking care of him was expensive. They (husband's family) discouraged me so much and my baby is very important to me, I saw no need to argue instead I decided to leave with the baby, to go try on my own … they stressed me a lot till I developed pressure"* **Parent 8**

	“If the child is not well, I am also not well”	*“My mind, my body, and my soul are focused on the baby and for as long as he is not doing well, am not well”* **Parent 11**
Physical	Poor growth and developmental delay	*“He can’t drink anything because every time he tries to drink, he coughs a lot and this makes me feel bad ... he is also not growing well”* **Parent 6** *“He has delayed milestones, even feeding is a problem”* **Parent 2**
Healthcare system factors	Reduce diagnosis to treatment time Need for improved quality of services	“*The services are also very slow; it takes time to get a procedure done. For example, my baby was diagnosed with GERD in July and the problem was addressed in December and that is why the child has been suffering because of the cough because of the slow services*.” **Parent 4** **“***We have been to so many doctors seeking a diagnosis why this cough doesn’t end....”* **Parent 3**
Coping strategies	Need for counselling Family and religious support	*“Counselling is good because someone has been tortured a lot, seeing how the child has been from day one up to now, if you don’t get someone to comfort you it gets to a place where you get discouraged, you start wishing you didn’t give birth to the child because of the torture you go through*.” **Parent 13** **“***Seeking divine intervention from the church, your friends and also the family can help you cope better”* **Parent 14**

A narrative of parent’s perspective on Quality of life cutting across all the domains (social, physical and psychological) have been summarized as subthemes and presented below:

i. ‘Our lives revolve around the hospital’

The majority of the caregivers we interviewed had spent a lot of time within the hospital due to their children’s chronic cough to the extent that they felt that their lives were tied around the hospital. The time spent in the hospital ranged from several weeks to months. As reflected by the caregivers, they felt their lives had moved to the hospital since that is where they were spending most of their time.

"I *stopped working because our lives revolve around the hospital ... When you are here (hospital), there is nothing else that you can think of. You can't think of what is happening out there because you can only leave the hospital for a very short period*." **Caregiver 4**

"I *have been taking him to the hospital at least 3 times a month*" **Caregiver 6**

"*Most of the time he gets sick after one week. It has never been two weeks of being well, if he tries it is one week. We are normally in the hospital every month*." **Caregiver 9**

Other caregivers felt that their lives had no relief since the child fell ill and this was causing them stress. They spent most of their time seeking treatment, yet the child's condition was not getting better.

"I get stressed wondering what is happening to the child. When I come to the hospital, I'm given drugs but it doesn't clear. Since I gave birth to this child I have never rested, he was born with issues," **Caregiver 10**

Others feel they are not able to perform activities that would otherwise be considered normal

"*You don't sleep, and you can't even do household chores because you just want to be with the baby."* **Caregiver 6**

ii. Loss of income/livelihoods

Caregivers reported that it was difficult to engage in work or income-generating activities as a result of the child's condition. This could further affect their ability to provide for their other children.

"You can't work, you are forced to stay at home and you can't depend on anyone. Like now I have other children, they haven't gone to school. They are just at home waiting for me" **Caregiver 2**

"I'm supposed to be at work but I had to stop so that I can take care of him. We depend on his father. Life changes since you can't go anywhere, you are just with him." **Caregiver 5**

iii. Caregivers feel they are viewed as a burden

Caregivers felt that the child's chronic cough had caused them to be viewed as a burden by their own families and friends. These children were frequently in hospital which meant they were required to often cater for hospital bills which was a strain on the family income. In some situations, the financial stress was extreme to the extent of causing family separation.

"*It has affected me a lot to an extent we even parted ways with my husband because taking care of him was expensive. They discouraged me so much and my baby is very important to me, I saw no need to argue instead I decided to leave with the baby, to go try on my own … they (husband's family) stressed me a lot till I developed pressure"* **Caregiver 8**

Some caregivers even reported that their close family and friends were no longer picking their phone calls as they may have been perceived to be always seeking financial support.

"We have been hospitalized so many times since the child started coughing. In fact, I never tell anybody else except my husband … because even so, people no longer pick calls, I guess they assume you want to tell them about your sick baby and ask for financial help." **Caregiver 11**

iv. 'If the child is not well, I am also not well'

Caregiving to children with chronic cough was stressful to the mothers we interviewed. They reported that their wellness was determined by the child's wellness, meaning that they were not at their optimal well-being during the prolonged periods of cough.

"If he gets well, I will at least feel comfortable. Now that he is ailing, I'm not comfortable. Even if I'm lacking (money) but he is fine I will be very comfortable." **Caregiver 12**
"My mind, my body, and my soul are focused on the baby and for as long as he is not doing well, I am not well" **Caregiver 11**

v. Children had low quality of life

Most of the mothers interviewed were concerned that the cough interfered with the child's feeding, growth, and development. The cough was often reported to precipitate vomiting, poor food intake, and subsequently poor weight gain. The children also did not achieve developmental milestones according to age.

"Currently, he is extremely underweight because whenever he is eating, he can't cough, and if he coughs, there is a risk of the food going to the lungs, so he eats but he is not growing because he cannot feed well' **Caregiver 7**

"He can't drink anything because every time he tries to drink, he coughs a lot and this makes me feel bad … he is also not growing well" **Caregiver 6**

"*The difficulties in breathing made it hard for him to walk, eat and he even lost a lot of weight"* **Caregiver 1**

Children were not able to engage in normal day-to-day activities because of the chronic cough they were experiencing.

"He can't be active at 2 years, because when he lacks oxygen (due to the cough), he develops a memory lapse and if at all he was sitting he maintains the same position" **Caregiver 8**

"*Before this condition, he used to play a lot, go to school but after this condition is when he started saying he is tired*" **Caregiver 12**

vi. Coping strategies and recommendations to improve caregiver quality of life

Those caregivers that had support from family, friends, and relatives felt that it helped improve their wellbeing. They also noted that they feel encouraged when they talk to other mothers whose children have a similar condition.

"*The support that I receive from the father makes me feel a little bit better, talking to friends too. I often look for mothers who have children who have the same condition and talk to them so that I don't start blaming myself and think I am the cause of my child's condition*" **Caregiver 9**

"*Seeking divine intervention from the church, your friends and also the family can help you cope better"* **Caregiver 14**

Others are encouraged by their religious faith

"Just praying … yes, sometimes you get to the end, you cry but God is the one that strengthens someone." **Caregiver 12**

Caregivers generally felt there is a need to improve the healthcare services they are currently receiving. They noted that sometimes the children were discharged from the hospital only to be admitted after a short while. They also felt that the services were rather slow and preferred if procedures were done within a reasonably short time.

"*Some mothers also complain that you can be discharged even before the baby is completely well, so you just get readmitted after a short time*" **Caregiver 15**

"*The services are also very slow; it takes time to get a procedure done. For example, my baby was diagnosed with GERD in July and the problem was addressed in December and that is why the child has been suffering because of the cough because of the slow services*." **Caregiver 4**

Others further acknowledged the need for counselling.

"Counselling is good because someone has been tortured a lot, seeing how the child has been from day one up to now. If you don't get someone to comfort you it gets to a place where you get discouraged, you start wishing you didn't give birth to the child because of the torture you go through." **Caregiver 13**

CHAPTER 6. DISCUSSION

Cough is a major symptom in respiratory diseases and one of the most frequent reasons for which patients seek medical consult. Before receiving appropriate management, many children with chronic cough and their families continue to experience unnecessary or recurring medical consultations. Despite a high incidence of cough observed in clinical practice, there is little known about the impact of chronic cough from the patients' perspectives. To our knowledge, this is the first study to evaluate the burden of chronic cough in affected families in East Africa.

We used validated specific tools for quality-of-life assessment for chronic cough in children and their parents (PCQOL and CCQOL) in a peri-urban hospital in Kenya and also carried out in-depth interviews (IDIs) with parents to seek their perspective on QoL due to chronic cough. We also sought to evaluate sociodemographic and clinical factors associated with quality of life. Our results demonstrated that the burden of chronic cough on families was significant with both parents and older children reporting overall low quality of life. The presence of chronic cough was shown to cause a considerable impact on the physical, social and psychological functioning of those affected.

In our study, we found a wide spectrum of etiology of chronic cough, the top 5 diagnosis being recurrent infective pneumonia, GERD, cardiac disease, asthma and recurrent aspiration pneumonia. This finding mirrors those reported in other studies. A systematic review on existing literature on etiology of chronic cough in children by Bergamini et al (18) revealed that the commonest causes were asthma, GERD, upper airway disorders (post nasal drip) in the older population while the commonest etiology in the younger population was protracted bacterial bronchitis (a diagnosis which missed in our cohort).

Literature from adult cohorts has described that chronic cough is often trivialised by some health care providers(54). From our experience this is often similar for children. The finding in our study has shown that parents of children with chronic cough sought medical attention multiple times. Approximately 67% of parents had visited different health care workers ≥5 times in a year for their child's cough, perhaps suggesting that diagnosis and management could be greatly improved in the community. These findings are similar to those in a study done by Marchant et al in Australia(49) which showed that 80% of affected children had made ≥5 doctor visits for chronic cough. These sentiments were echoed by parents talked to during the in-depth interviews where one of the emerging themes was health care systems and the discussions surrounded a need for improved quality of services and need to reduce diagnosis to treatment time.

Our study reported an overall low quality of life of parents with children cough with a median score of 1. This finding is similar to an Australian study by Chang et al(54) that evaluated the burden of chronic cough on families although their overall median quality of life score was slightly higher at 3.5. The difference here could be due to a large disparity in health care services and socioeconomic status in the two countries. Another plausible explanation for our study reporting a significantly lower QoL score could be due to selection bias of potential study subjects. Majority (77%) of those we interviewed were found in the wards as outpatient services were limited due to Covid 19 pandemic at the time of the study. This could have greatly impacted on the responses given as majority of those interviewed had very sick children admitted compared to the Australian cohort who were majorly recruited from outpatient clinics.

Additionally, a number of items in our questionnaire depicting the highest burden on the impact of chronic cough from our study are also featured in two other studies (8) (29) . A qualitative study conducted on 30 British mothers by Conford et al sought to evaluate their beliefs and perceptions on their child’s illness as regards to chronic cough. It established that a major concern for the mothers was that their child was going to die (from cot death), choke or would develop long term chest damage. They thus expressed disturbed sleep because of worry (29). Another study by Fuller et al conducted on 96 children with chronic cough found that 50% of parents with children who had persistent nocturnal cough worried about their child’s loss of sleep. They also expressed concerns of whether the cough indicated a serious illness, choking, asthma and causing permanent chest damage(8). These findings were also expressed by parents we interviewed during the qualitative phase of our study.

Our study also sought to assess the quality of life of older children with chronic cough using the chronic cough specific QoL tool (CCQOL). The overall median score of all the 3 domains (physical, psychological and social) was less than 3.5 and the overall QoL score was 2 reflecting a poor QoL. The trend here was similar to those of Australian children in a study done by Newcombe et al (33)with feelings of anger, frustration, being bothered by physical pain and sleepless nights due to the cough emerging as dominant items that impacted their quality of life. It is however important to note that the overall QoL score was higher for the Australian children at 4.6. This difference again could be due to a difference in health care and socioeconomic status between the two countries. A small number of children(thirty-eight) who filled the CCQOL tool could also likely have biased our finding.

We sought to determine the clinical and sociodemographic factors associated with quality of life of children with chronic cough and their parents. Our results showed that young age of children, low education level of parents, environmental pollution, and low income were associated with a higher odds of having extremely poor quality of life. Having a young child (0-5 years), for instance, was associated with a 6-fold increase in the odds of reporting extremely low quality of life. Multiple studies (44) (55) (56)have revealed that parents of older children have better QoL than those caring for younger ones. This is similar to what was found in our study.

Income and parent’s level of education were other factors found to have an impact on the QoL of affected families in our study. Having a low level of education (primary or lower) was associated with an 8-fold increase in the odds of extremely poor quality of life scores, while earning less than KSh5,000 and 5000-10000 compared to >KSh 10,000 was associated with a 3-fold and 7-fold increase in the odds of reporting extremely poor quality of life scores respectively. During the IDIs, parents also expressed that they had to stop working to care for their chronically ill child and this took a toll on their finances compounded with the problem of having to seek medical attention from numerous health workers before a diagnosis was finally arrived at. This is consistent with findings in other studies (57)(58)(59). Mothers in less affluent socioeconomic groups were found to have worse QoL than those in higher status. Access to healthcare was found to be difficult in low-income families who were also less likely to receive a higher education and employment opportunities. Lastly, living next to a dusty road increased the odds for reporting extremely low quality of life three-fold. Studies have revealed that pollution has a significant causal link with chronic cough(60)(61), with resultant decrease in QoL of those affected.

Other sociodemographic factors such as age of caregiver, gender of caregiver and their marital status have been shown to influence their QoL in previous studies done. Older caregivers may suffer from poorer physical health and were shown to be more affected by depression while young caregivers usually keep a balance between their care responsibilities and work demand that affect their social and mental lives(62) (63) . Unmarried caregivers carry a burden of care of their affected children and often suffer from lack of support and difficulties in decision making regarding their sick children(62) (64). Lower QoL was found among female caregivers who were more likely to have stress and depression than men (65). Our study however showed no significant associations between these factors and QoL of those affected.

Among the clinical factors assessed, attending five or more consultations per year increased odds for having extremely poor quality of life 5.32-fold. This finding is consistent with the Australian studies(30) (32)that showed parents who sought medical help for their children's cough more times had worse quality of life. Other studies (32) (35) (30)have shown a negative correlation between severity of cough and quality of life such that the worse the cough (intensity, frequency and duration) the worse the quality of life. Our study however did not establish this relationship.
Lastly from the IDIs conducted, we sought to establish some coping strategies the parents employed to help improve their QoL. The emerging strategies were family and religious support, and need for psychological counselling.

6.1 Study Strengths and Limitations

6.1.1 Strength

To our knowledge, this was a pioneer study in East Africa that sought to evaluate the burden of chronic cough on affected families.

6.1.2 Limitations

We may not be able to generalize our results to other parent-child cohorts. Although KNH is the largest referral hospital in Kenya, enrolment of study subjects from one hospital may limit generalization. Secondly, we were not able to have a representation of the full spectrum of children with chronic cough due to the Covid 19 pandemic that limited outpatient services. Majority of those we recruited were found in the wards and this could have greatly impacted the responses as they had very sick children. Thirdly, our small sample size is likely to bias our findings. It is also worth mentioning that confounders such as life stressors may influence QoL.

CHAPTER 7. CONCLUSIONS AND RECOMMENDATIONS

7.1 Conclusions

We conclude the following from this research:

1. Parents of children with chronic cough have overall poor quality of life across all domains.
2. Older children/teenagers with chronic cough have overall poor quality of life.
3. Quality of life was worse among parents of younger sicker children, and who were of lower education, and those living close to high polluting roads.

In-depth interviews revealed high level of psychosocial and financial distress, fear about child's current and future well-being, and health system deficiencies negatively impacting timely treatment; parents perceived that all these factors negatively impact parent and child QoL.

7.2 Recommendation

Our study has shown that the burden of chronic cough in children is significant to the affected families. We therefore recommend designing interventions that provide psychosocial support, and optimised structured health care to improve health related QoL for these children and their parents.

CHAPTER 8. REFERENCES

1. Marchant JM, Newcombe PA, Juniper EF, Sheffield JK, Stathis SL, Chang AB. What Is the Burden of Chronic Cough for Families? Chest. 2008 Aug;134(2):303–9.

2. Ioan I, Poussel M, Coutier L, Plevkova J, Poliacek I, Bolser DC, et al. What is chronic cough in children? Frontiers in Physiology. 2014 Aug 28;5.

3. Chang AB, Oppenheimer JJ, Weinberger MM, Rubin BK, Weir K, Grant CC, et al. Use of Management Pathways or Algorithms in Children With Chronic Cough: CHEST Guideline and Expert Panel Report. Chest. 2017 Apr;151(4):875–83.

4. Craven V, Everard ML. Protracted bacterial bronchitis: reinventing an old disease. Archives of Disease in Childhood. 2013 Jan 1;98(1):72–6.

5. Birring SS. Development of a symptom specific health status measure for patients with chronic cough: Leicester Cough Questionnaire (LCQ). Thorax. 2003 Apr 1;58(4):339–43.

6. Irimu G, Nduati RW, Wafula E, Lenja J. Community understanding of pneumonia in Kenya. African health sciences. 2008 Jun;8(2):103–7.

7. Waring G, Kirk S, Fallon D. The impact of chronic non-specific cough on children and their families: A narrative literature review. J Child Health Care. 2019 Jan 3;136749351881492.

8. Fuller P, Picciotto A, Davies M, McKenzie SA. Cough and sleep in inner-city children. European Respiratory Journal. 1998 Aug 1;12(2):426–31.

9. Nriagu J, Robins L, Gary G, Liggans R, Davila K, Supuwood C, et al. Prevalence of asthma and respiratory symptoms in south-central Durban, South Africa. European Journal of Epidemiology. 1999;15(8):747–55.

10. Kiboneka A, Levin M, Mosalakatane T, Makone I, Wobudeya E, Makubate B, et al. Prevalence of asthma among school children in Gaborone, Botswana. African Health Sciences. 2016 Oct 17;16(3):809.

11. Faniran AO, Peat JK, Woolcock AJ. Prevalence of atopy, asthma symptoms and diagnosis, and the management of asthma: comparison of an affluent and a non-affluent country. Thorax. 1999 Jul 1;54(7):606–10.

12. Irwin RS. Introduction to the Diagnosis and Management of Cough. Chest. 2006 Jan;129(1):25S-27S.

13. Jurca M, Ramette A, Dogaru CM, Goutaki M, Spycher BD, Latzin P, et al. Prevalence of cough throughout childhood: A cohort study. Singer F, editor. PLOS ONE. 2017 May 24;12(5):e0177485.

14. Carter ER, Debley JS, Redding GR. Chronic productive cough in school children: prevalence and associations with asthma and environmental tobacco smoke exposure. BMC. 2006;2(11).

15. Galassi C, Forastiere F, Biggeri A, Gabellini C, De Sario M, Ciccone G, et al. [SIDRIA second phase: objectives, study design and methods]. Epidemiologia e prevenzione. 2005;29(2 Suppl):9–13.

16. Pan G, Zhang S, Feng Y, Takahashi K, Kagawa J, Yu L, et al. Air pollution and children's respiratory symptoms in six cities of Northern China. Respiratory Medicine. 2010 Dec;104(12):1903–11.

17. Di Filippo P, Scaparrotta A, Petrosino M, Attanasi M, Di Pillo S, Chiarelli F, et al. An underestimated cause of chronic cough: The protracted bacterial bronchitis. Annals of Thoracic Medicine. 2018;13(1):7.

18. Bergamini M, Kantar A, Cutrera R, Interest Group IPC. Analysis of the Literature on Chronic Cough in Children. The Open Respiratory Medicine Journal. 2017 Apr 27;11(1):1–9.

19. Chang AB, Peake J, McElrea MS. Anti-histamines for prolonged non-specific cough in children. In: Chang AB, editor. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2008.

20. Marchant JM, Masters IB, Taylor SM, Cox NC, Seymour GJ, Chang AB. Evaluation and outcome of young children with chronic cough. Chest. 2006 May;129(5):1132–41.

21. Asilsoy S, Bayram E, Agin H, Apa H, Can D, Gulle S, et al. Evaluation of chronic cough in children. Chest. 2008 Dec;134(6):1122–8.

22. Khoshoo V, Edell D, Mohnot S, Haydel R, Saturno E, Kobernick A. Associated factors in children with chronic cough. Chest. 2009 Sep;136(3):811–5.

23. Chang AB, Robertson CF, Van Asperen PP, Glasgow NJ, Mellis CM, Masters IB, et al. A multicenter study on chronic cough in children : burden and etiologies based on a standardized management pathway. Chest. 2012 Oct;142(4):943–50.

24. French C. Examining Change in Symptoms of Depression, Anxiety, and Stress in Adults After Treatment of Chronic Cough. 2014.

25. Vertigan AE, Theodoros DG, Gibson PG, Winkworth AL. Voice and Upper Airway Symptoms in People With Chronic Cough and Paradoxical Vocal Fold Movement. Journal of Voice. 2007 May;21(3):361–83.

26. McGarvey LPA, Carton C, Gamble LA, Heaney LG, Shepherd R, Ennis M, et al. Prevalence of psychomorbidity among patients with chronic cough. Cough (London, England). 2006 Jun 16;2:4.

27. Irwin RS. Introduction to the Diagnosis and Management of Cough: ACCP Evidence-Based Clinical Practice Guidelines. CHEST. 2006 Jan 1;129(1):25S-27S.

28. Guo M, Gao G, Guo J, Wen L, Zeng L. Burden among caregivers for children with asthma: A mixed-method study in Guangzhou, China. International Journal of Nursing Sciences. 2015 Dec 1;2(4):394–401.

29. Cornford C, Morgan M, Ridsdale L. Why do Mothers Consult when their Children Cough? Fam Pract. 1993;10(2):193–6.

30. Marchant JM, Newcombe PA, Juniper EF, Sheffield JK, Stathis SL, Chang AB. What Is the Burden of Chronic Cough for Families? CHEST. 2008 Aug 1;134(2):303–9.

31. Solans M, Pane S, Estrada M-D, Serra-Sutton V, Berra S, Herdman M, et al. Health-Related Quality of Life Measurement in Children and Adolescents: A Systematic Review of Generic and Disease-Specific Instruments. Value in Health. 2008 Jul;11(4):742–64.

32. Newcombe PA, Sheffield JK, Juniper EF, Marchant JM, Halsted RA, Masters IB, et al. Development of a parent-proxy quality-of-life chronic cough-specific questionnaire: clinical impact vs psychometric evaluations. Chest. 2008 Feb;133(2):386–95.

33. Newcombe PA, Sheffield JK, Chang AB. Parent cough-specific quality of life: Development and validation of a short form. Journal of Allergy and Clinical Immunology. 2013 Apr;131(4):1069–74.

34. Hartnick CJ, Zurakowski D, Haver K. Validation of a pediatric cough questionnaire. Ear, nose, & throat journal. 2009 Nov;88(11):1213–7.

35. Newcombe PA, Sheffield JK, Petsky HL, Marchant JM, Willis C, Chang AB. A child chronic cough-specific quality of life measure: development and validation. Thorax. 2016 Aug;71(8):695–700.

36. Baiardini I, Braido F, Fassio O, Tarantini F, Pasquali M, Tarchino F, et al. A new tool to assess and monitor the burden of chronic cough on quality of life: Chronic Cough Impact Questionnaire. Allergy. 2005 Apr;60(4):482–8.

37. Chang AB. [No title found]. Cough. 2005;1(1):7.

38. Jones KDJ, Berkley JA. Severe acute malnutrition and infection. Paediatrics and International Child Health. 2014 Dec 5;34(sup1):S1–29.

39. Guilleminault L. Chronic cough and obesity. Pulmonary Pharmacology & Therapeutics. 2019 Apr;55:84–8.

40. Couriel J. Assessment of the child with recurrent chest infections. British Medical Bulletin. 2002 Mar 1;61(1):115–32.

41. Kelsall A, Decalmer S, McGuinness K, Woodcock A, Smith JA. Sex differences and predictors of objective cough frequency in chronic cough. Thorax. 2009 May 1;64(5):393–8.

42. Gui P, Ebihara T, Sato R, Ito K, Kohzuki M, Ebihara S. Gender differences in the effect of urge-to-cough and dyspnea on perception of pain in healthy adults. Physiological Reports. 2014 Aug;2(8):e12126.

43. Chamberlain SAF, Garrod R, Douiri A, Masefield S, Powell P, Bücher C, et al. The Impact of Chronic Cough: A Cross-Sectional European Survey. Lung. 2015 Jun;193(3):401–8.

44. Pan G, Zhang S, Feng Y, Takahashi K, Kagawa J, Yu L, et al. Air pollution and children's respiratory symptoms in six cities of Northern China. Respiratory Medicine. 2010 Dec;104(12):1903–11.

45. Pattenden S. Parental smoking and children's respiratory health: independent effects of prenatal and postnatal exposure. Tobacco Control. 2006 Aug 1;15(4):294–301.

46. Charlton A. Children's coughs related to parental smoking. BMJ. 1984 Jun 2;288(6431):1647–9.

47. Ellison-Loschmann L, Sunyer J, Plana E, Pearce N, Zock J-P, Jarvis D, et al. Socioeconomic status, asthma and chronic bronchitis in a large community-based study. European Respiratory Journal. 2007 May 1;29(5):897–905.

48. General practice activity in Australia 2008-09, Summary [Internet]. Australian Institute of Health and Welfare. [cited 2020 Feb 23]. Available from: https://www.aihw.gov.au/reports/primary-health-care/general-practice-activity-australia-2008-09/contents/summary

49. Marchant JM, Newcombe PA, Juniper EF, Sheffield JK, Stathis SL, Chang AB. What is the burden of chronic cough for families? Chest. 2008 Aug;134(2):303–9.

50. Lovie-Toon YG, Grimwood K, Byrnes CA, Goyal V, Busch G, Masters IB, et al. Health-resource use and quality of life in children with bronchiectasis: a multi-center pilot cohort study. BMC Health Services Research. 2019 Aug 13;19(1):561.

51. Van den Broeck J, Argeseanu Cunningham S, Eeckels R, Herbst K. Data Cleaning: Detecting, Diagnosing, and Editing Data Abnormalities. PLoS Medicine. 2005 Sep 6;2(10):e267.

52. Albers MJ. Quantitative Data Analysis—In the Graduate Curriculum. Journal of Technical Writing and Communication. 2017 Apr 26;47(2):215–33.

53. Sims JM. A Brief Review of the Belmont Report. Dimensions of Critical Care Nursing. 2010 Jul;29(4):173–4.

54. Irwin RS, French CT, Fletcher KE. Quality of Life in Coughers. Pulmonary Pharmacology & Therapeutics. 2002 May;15(3):283–6.

55. Moonie S, Huang X, Sterling DA. Quality of Life Estimation with Structural Equation Modeling in School Aged Children with Asthma. :17.

56. Duncan CL, Hogan MB, Tien KJ, Graves MM, Chorney JM, Zettler MD, et al. Efficacy of a Parent-Youth Teamwork Intervention to Promote Adherence in Pediatric Asthma. Journal of Pediatric Psychology. 2013 Jul 1;38(6):617–28.

57. Uchmanowicz I, Uchmanowicz B, Panaszek B, Rosińczuk J. Sociodemographic factors affecting the quality of life of patients with asthma. PPA. 2016 Mar;345.

58. Victorino CC, Gauthier AH. The social determinants of child health: variations across health outcomes – a population-based cross-sectional analysis. BMC Pediatr. 2009 Dec;9(1):53.

59. Ellison-Loschmann L, Sunyer J, Plana E, Pearce N, Zock J-P, Jarvis D, et al. Socioeconomic status, asthma and chronic bronchitis in a large community-based study. Eur Respir J. 2007 May;29(5):897–905.

60. Bergamini M, Kantar A, Cutrera R, Interest Group IPC. Analysis of the Literature on Chronic Cough in Children. TORMJ. 2017 Apr 27;11(1):1–9.

61. Pan G. Air pollution and children's respiratory symptoms in six cities of Northern China. :9.

62. Shaikhan FM, Makhlouf MM. Quality of life among caregivers of asthmatic children attending pulmonology clinics at Hamad General Hospital, Qatar. SAGE Open Medicine. 2020 Jan;8:205031212097350.

63. Given B, Sherwood PR. Family Care for the Older Person With Cancer. Seminars in Oncology Nursing. 2006 Feb;22(1):43–50.

64. Cerdan NS. Asthma severity in school-children and the quality of life of their parents. 2009 [cited 2021 May 4]; Available from: https://digitalscholarship.unlv.edu/thesesdissertations/1186

65. The Foundations of Lifelong Health Are Built in Early Childhood. :32.

CHAPTER 9. APPENDICES

9.1 Study Questionnaire

Quality of Life of Children with Chronic Cough and their Parents at KNH

Fill all sections

Study number: __ __ __ Date: __________________

Site of interview: Clinic (specify) ______________ Ward (specify) _______________

Who is filling this questionnaire (circle) ☐Mother ☐Father ☐Other caregiver ☐Teenager?

If other caregiver, specify the relationship to child or teenager (circle):

Aunt Uncle Grandmother Grandfather Elder sibling female Elder sibling male

Cousin female Cousin male Stepfather Stepmother

Personal Information of child/teenager

Date of birth: ___ ___/___ ___/___ ___ ___ ___

1. Child’s age in years and months: years____________ (months__________

2. Gender of child: ☐Male ☐Female

3. Child education – current class__________________

Personal Information of parent/caregiver

4. Caregiver age (years) __ __ __

5. Parent/caregiver gender: ☐Male ☐Female

6. Caregiver's marital status: ☐Married ☐Single ☐Divorced/separated ☐Widowed

7. Caregiver's education level: ☐Non-formal ☐Primary ☐Secondary ☐Tertiary

8. Caregiver’s relationship with child: ☐Father ☐Mother ☐Uncle ☐Aunt ☐Grandmother

☐Other (specify)……………………………………………..

7. Household monthly income (Kshs) : ☐ <5000 ☐5001-10,000 ☐> 10,000 ☐I do not know

☐I am not comfortable disclosing this information

Medical Information of child

8. Duration of cough in weeks……………………………….

9. How often do you/your child cough? ☐Throughout the day ☐Mainly morning ☐Mainly night ☐At night and early morning ☐When eating or after food ☐Other (specify)

10. In the past one hour, how many times have you/your child coughed? __________

11. Cause of cough (if more than one disease present, tick all that apply) ☐Asthma

☐Tuberculosis
☐GERD
☐Non-asthmatic bronchitis
☐Bronchiectasis
☐Cardiac disease (specify)……………………………………..
☐Bronchiolitis
☐Rickets
☐Other (Specify……………………………………………)

13. Does your child have any of these problems? (Tick if yes)

☐Nose allergy, ☐Skin allergy, ☐HIV, ☐Kidney disease, ☐Liver disease

14. Nutritional status

Weight (kg) ______
Height (cm) _______
BMI (percentile) ________
MUAC ________
WHZ score________

15. Number of consultations (in the past 1 year)……………………………………..

16. History of parental/caregiver smoking:

☐Yes
☐No

17. Main fuel used for cooking

☐Electricity
☐Gas
☐Slow burning charcoal
☐Kerosene
☐Firewood
☐Other (specify)………………………..

18. How often do you do the cooking (older child): ___ days of the week

☐Every day ☐Most days ☐Rarely ☐Never

19. Younger child – a) How often are you close to cooker when food is being cooked? ____ days of the week

b) For how many hours of the day? ______________

20. Home ventilation: ___ number of rooms in house _____number of windows

21. Do you live near a busy main road where many cars pass (within 100 m)? ☐Yes ☐No

22. Number of persons living in house_____________________

9.2 Parent Cough-Specific Quality Of Life Questionnaire (PC-QOL)

Name of Parent/Caregiver: ______________________

Child's Name: __________________________ **DOB:** __ __/__ __/__ __ __ __

Date: _________________ **Cough** (Please circle)**:** Wet / Dry /Variable

Below is a list of items that describe how people might feel about their child's cough. For each item please mark the box that best corresponds to how you have felt over the last week. Please respond to all the items as well as you can, even if some do not seem to apply to your child.

During the past week, <u>how often</u>:

		All the time	Most of the time	Quite often	Some of the time	Once in a while	Hardly any of the time	None of the time
1.	Did you feel frightened when your child experienced cough?	☐	☐	☐	☐	☐	☐	☐
2.	Did you feel frustrated because of your child's cough?	☐	☐	☐	☐	☐	☐	☐
3.	Did your child's cough interfere with your job or work around house?	☐	☐	☐	☐	☐	☐	☐
4.	Did you feel upset because of your child's cough?	☐	☐	☐	☐	☐	☐	☐
5.	Did you have sleepless nights because of your child's cough?	☐	☐	☐	☐	☐	☐	☐
6.	Were you awakened during the night because of your child's cough?	☐	☐	☐	☐	☐	☐	☐
7.	Did you feel anxious about your child's cough?	☐	☐	☐	☐	☐	☐	☐
8.	Did you feel <u>helpless</u> because of your child's cough?	☐	☐	☐	☐	☐	☐	☐
9.	Did you feel <u>stressed</u> because of your child's cough?	☐	☐	☐	☐	☐	☐	☐
10.	Did you feel <u>sad</u> about your child's cough?	☐	☐	☐	☐	☐	☐	☐
11.	Did you feel <u>scared</u> because of your child's cough?	☐	☐	☐	☐	☐	☐	☐

12. Did you feel <u>tired or exhausted</u> because of your child’s cough?	☐	☐	☐	☐	☐	☐	☐
13. Did you feel being <u>over protective</u> because of your child’s cough?	☐	☐	☐	☐	☐	☐	☐
14. Did you feel <u>powerless</u> because of your child’s cough?	☐	☐	☐	☐	☐	☐	☐

During the past week, how <u>worried or concerned</u> were you?

	Very, very worried/ concerned	Very, worried/ concerned	Fairly, worried/ concerned	Some what worried/ concerned	A little worried/ concerned	Hardly worried/ concerned	Not worried/ concerned
16. About your child’s performance of <u>normal activities</u> including feeding and schooling?	☐	☐	☐	☐	☐	☐	☐
17. Over the <u>medications</u> your child takes and the side effects of them?	☐	☐	☐	☐	☐	☐	☐
18. About your child being able to lead a <u>normal life</u>?	☐	☐	☐	☐	☐	☐	☐
19 About the <u>cause</u> of your child’s cough?	☐	☐	☐	☐	☐	☐	☐
20. About your child’s cough indicating a <u>serious illness</u>?	☐	☐	☐	☐	☐	☐	☐

21.	About your child choking when coughing?	☐	☐	☐	☐	☐	☐	☐
22	About leaving your child with others because of his/her cough?	☐	☐	☐	☐	☐	☐	☐
23	About your child not being able to breathe again after coughing?	☐	☐	☐	☐	☐	☐	☐
24.	About the effects of your child’s cough on him/her?	☐	☐	☐	☐	☐	☐	☐
25.	About your child feeling tired because of the cough?	☐	☐	☐	☐	☐	☐	☐
26.	About your child not sleeping well because of the cough?	☐	☐	☐	☐	☐	☐	☐
27.	About the cough causing damage to your child’s chest or lungs?	☐	☐	☐	☐	☐	☐	☐

Anything else that we have not discussed that impacts on you and your family’s lives as a result of cough?

9.3 Approval to use PCQOL tool

Greetings Prof Chang,

My name is Dr Joy Odhiambo. I am a Paediatrics resident at the University of Nairobi. I am carrying out a research on the Quality of Life of children with chronic cough at our National Teaching Hospital here in Kenya, and Prof Obimbo is my supervisor. I am grateful for the approval granted to me to use the CC QOL tool.
Following the COVID-19 pandemic, I have had to modify my study and will thus be using the Parent- Proxy Quality of Life Chronic Cough-Specific Questionnaire (PC-QOL 27). I am requesting for your approval to use this tool for my study. I am also unable to access the PC QOL 27 tool online, as what is available is the original 50 item questionnaire and the short version of 8 items. I will appreciate it if you can facilitate me to access this questionnaire.

Kind regards,
Joy.

Anne Chang <Anne.Chang@menzies.edu.au>

Aug 20, 2020,
2:46 PM

to me, Lisa, steve.graham@rch.org.au

Hi Joy,
Here it is.
All the best for your project.
anne

9.4 Child Chronic Cough Specific Quality Of Life Questionnaire (CC-QoL)

This questionnaire is designed to assess the impact of cough on various aspects of your life. Read each question carefully and answer by CIRCLING the response that best applies to you. Please answer ALL questions, as honestly as you can.

#	QUESTION: In the past one week how often did/were:	1-All the time 2-Most of the time 3-A good bit of the time 4-Some of the time 5-A little of the time 6-Hardly any of the time 7-None of the time							
1	You hate your cough		1	2	3	4	5	6	7
2	Coughing annoy you in the past week		1	2	3	4	5	6	7
3	Your cough make you feel frustrated		1	2	3	4	5	6	7
4	Your cough disturb others		1	2	3	4	5	6	7
5	You annoyed by your cough doing activities		1	2	3	4	5	6	7
6	Your chest or stomach pains other you		1	2	3	4	5	6	7
7	Your cough make you feel tired		1	2	3	4	5	6	7
8	You troubled sleeping at night because of cough		1	2	3	4	5	6	7
9	Your cough wake you during night		1	2	3	4	5	6	7
10	You have trouble getting to sleep because of cough		1	2	3	4	5	6	7
11	Coughing up phlegm annoy you		1	2	3	4	5	6	7
12	You find it difficult to do things because of cough		1	2	3	4	5	6	7
13	You feel uncomfortable because of cough		1	2	3	4	5	6	7
14	Your chest feel bad		1	2	3	4	5	6	7
15	Your cough annoy others		1	2	3	4	5	6	7
16	You feel frustrated because you couldn’t keep up with other		1	2	3	4	5	6	7

9.5 Approval to use CCQOL tool

Dear Anne,

I am happy to say that we are planning to use the QOL among children with chronic cough tool to evaluate the same among children at our National Teaching Hospital. One of my postgraduate mentees is interested in pursuing this as part of her MMed research, her name is Joy Adhiambo (cc'd).

We wish to seek your permission to use the tool.

Yours sincerely

Lisa Obimbo
Paediatric Pulmonologist
University of Nairobi

Anne Chang Sat, Feb 29, 2020, 1:48 PM

Hi Lisa, Please go ahead. All the best for your research. Kind regards,

Lisa Obimbo <lisaobimbo@gmail.com> Sat, Feb 29, 2020, 3:38 PM

to Anne, steve.graham@rch.org.au, me

Thank you very much.
Thank you for your prompt response!

Regards

Lisa

9.6 In depth Interview Guide for Parents of Children with Chronic Cough

Quality of Life of Children with Chronic Cough and their Parents at KNH

Study Number: ________
Study Site: (Clinic)___________ ________ Ward________________
Tick: Male_____ Female_____
Moderator: __________ Notes taker: __________________
Date___________ Start time: __________ End time: ______________

***Instructions to the facilitators**:* Begin by introducing yourselves. Ensure the participants are feeling comfortable. Ask the participants to introduce themselves using their initials and age. Thank them for accepting to take part in the discussion, reconfirm their consent for participation and reassure them of confidentiality. Request them for permission to tape record the session and take notes.

***Standard procedure for discussion**.*

- You will do the talking during the discussion. I will guide you using some questions
- We will not call you by name, but by pre-allocated numbers so as to keep your identity confidential.
- There are no wrong answers.
- Everyone's views are important and will be respected.
- Whatever is said here will remain here.
- In the course of this discussion, we will be using a recording device and taking notes.

IDI Guide (Parents):

1.Please describe your child’s cough *Probes: Duration of cough, nature of cough, other associated conditions, causes of the cough and treatment, coughing at night vs during the day*
2.How does his/her cough affect his or her daily activities and/or physical functioning?
3.How does his/her cough affect your daily activities and life in general?
Probes: time spent in hospital, affects ability to work to provide for family
4.How has your child’s cough affected his or her relationship with others? Siblings, friends, relatives? Has this changed with COVID-19?
5.What are some of the strategies you use to cope with the challenges you and your child experience as a result of chronic cough?
6.Do you have any suggestions of what you think can be done to improve the overall wellbeing of your child as pertains his or her cough?

***Closing session**:* The moderator of the session will ask if there are any pending additions to the discussion. If none, the session will be closed by thanking everyone for their time and participation. Refreshments will then be served afterwards

9.7 Consent Form for Parents of Children with Chronic Cough

Title of study: Quality of life of children with chronic cough and their Parents at KNH

Institution: Department of Paediatrics and Child Health, UON

Principal Investigator: Dr Joy Rose Odhiambo

Supervisors: 1. Prof Elizabeth Obimbo Maleche 2. Dr Paul Laigong
Department of Paediatrics and Child Health
University of Nairobi

Ethical Approval: This study has the approval of Kenyatta National Hospital/University of Nairobi Ethical and Research Committee (KNH-UON ERC)

Introduction:

I wish to inform you about a medical research conducted by the above researchers. The purpose of having this discussion with you is to inform you on the aim of this study so that you can make an informed choice on whether to participate. Please feel free to ask any questions regarding any risks or benefits accorded to you for agreeing to participate in this research. We will clarify anything you have not understood. I will ask you to sign the consent form below once you are satisfied. Kindly read through the rest of this form to understand the general principles that apply to all medical researches.

What is this research about?

The purpose of this study is to find out how the wellbeing of patients who have a cough for a prolonged period is affected. The findings of this research will enable the clinicians taking care of your child manage them more holistically. This research also aims to look for factors that may contribute to the overall wellbeing of your child as pertains the cough.

Procedure

With your permission, I will ask you questions on personal information on your view of your wellbeing regarding the chronic cough. All information obtained will be handled in secrecy. This process will take about 20 minutes.

Are there any risks involved?

There will be no dangers to your health since we will not give you any medicine or perform any procedures on you, only questions will be asked. None of your rights will be infringed during this research**.**

Benefits

There will be no direct benefits to you, however, the findings of this research will be shared with your child's doctor so that his/her illness can be better understood and managed better.

Assurance of confidentiality

All the information obtained from you will be kept in utmost confidence. Your name will not be used or mentioned during handling of the data or in any resulting publication. Serial numbers will be used instead.

What are your rights as a participant?

1. You agree to participate in this research voluntarily.
2. You are free to withdraw from this research at any point without having to explain your reasons.
3. Your refusal to participate in this research will not be held against you and it will not influence the services you are entitled to in this hospital.
4. You can ask a questions that will enable you to clearly comprehend the nature of this research.
5. A copy of this form will be given to you for your records.

Contacts

Should you have any questions about your rights as a research participant, feel free to get in touch with any of the following:

1. Principal investigator : Dr Joy R. Odhiambo
   Tel 0727513746
   Email joy.adhyambo@gmail.com
2. Supervisors:
   - Prof E. Obimbo Maleche
     Tel 0722720402
     eombimbo@yahoo.com
   - Dr Paul Laigong
     Tel 0720386861
     drlaigongp@gmail.com
3. The Chairperson, KNH-UON ERC Committe
   Tel 2726300/2716450 Ext 44102
   Email uonknh-erc@uonbi.ac.ke

I now request you to sign the attached consent form below:

CONSENT TO PATICIPATE IN THE STUDY

I have read and have also been clarified to the content on this consent form and I have fully understood. The risks and benefits have been explained to me. I understand that my participation is voluntary and that I am free to withdraw from the study at any point without any loss of benefit or injustice to me. I have also understood that all efforts will be made to keep my personal identification confidential.

Name of participant………………………………… Date……………………
Signature of participant…………………………….

Researcher's statement

I confirm that I have explained the details of the research to the participant and that he/she has understood.

Name of researcher…………………………………… Date…………………….
Signature of researcher……………………………….

9.8 Kiswahili consent form/ Fomu ya Idhini kwa wazazi/ walezi wa washiriki

Kichwa cha masomo: Ubora wa maisha ya watoto walio na kikohozi sugu na ya walezi wao katika Hospitali ya Taifa ya Kenyatta.

Taasisi: Idara ya watoto, Chuo Kikuu cha Nairobi

Mtafiti mkuu: Daktari Joy Rose Odhiambo

Wasimamizi: 1. Prof Elizabeth Obimbo Maleche 2. Dkt Paul Laigong

Idara ya watoto, Chuo Kikuu cha Nairobi

Idhini ya maadili: Utafiti huu umeruhusiwa na Kamati ya Maadili na Utafiti katika Hospitali ya Taifa ya Kenyatta na Chuo Kikuu cha Nairobi (KNH-UON ERC)

Utangulizi:

Ningependa kuwajulisha kuhusu utafiti utakaofanywa na watafiti waliotajwa hapo awali. Kusudi la majadiliano haya nanyi ni kuwajulisha nia ya utafiti huu ili muweze kufanya uamuzi bora kushiriki katika utafiti huu. Tafadhali jisikie huru kuuliza maswali yoyote kuhusu hatari au faida utakayopewa utakapo kubali kushiriki katika utafiti huu. Tutafafanua jambo lolote ambalo hamtaelewa. Nitawaomba muweke sahihi kwenye idhini mtakapoelewa kila kitu. Kwa fadhili someni ukurasa uliobakia ili muelewe kanuni za jumla zinazo hitajika katika utafiti huu.

Utafiti huu unahusu nini?

Umuhimu wa utafiti huu ni kugundua jinsi ustawi wa wagonjwa wa kikohozi cha muda mrefu unavyoathirika. Matokeo ya utafiti huu yatawawezesha wauguzi wanaowatunza watoto wenu kuwatunza bora zaidi. Utafiti huu pia unaazimia kutafuta sababu zinazoweza kuchangia katika ustawi wa jumla wenu kulingana na kikohozi kinachowaathiri watoto wenu.

Utaratibu:

Kwa ruhusa yenu, tutawauliza maswali kuhusu maelezo yenu ya kibinafsi kuhusu maoni yenu katika ustawi wenu kulingana na kikohozi kinachowaathiri. Maoni yote yatakayotolewa yatabebwa kwa usiri. Mchakato huu utachukua kama dakika 20.

Je, kuna hatari zinazohusika?

Ni maswali tu yatakayo ulizwa kwa hivyo hatari yoyote kwa afya yako haitakuwemo kwa kuwa hakuna dawa zitakazopeanwa wala utaratibu utakaofanywa. Utafiti huu utahakikisha kuwa haki zote zimedumishwa.

Faida

Hakutakuwa na faida za moja kwa moja lakini daktari wa mtoto wako atajulishwa kuhusu matokeo ya utafiti huu ili ugonjwa huu ueleweke na utibiwe vyema zaidi.

Uhakikisho wa Usiri

Habari yote itakayo patikana kwako itahifadhiwa kwenye usiri mkubwa kabisa. Jina lako halitatajwa katika utunzaji wa habari wala katika chapisho lolote. Nambari za kodi zitatumiwa badala yake.

Haki zako kama mshiriki ni zipi?

1. Umekubali kushiriki kwa hiari yako kwenye utafiti huu
2. Unaweza jiondoa kutoka kwenye utafiti huu wakati wowote bila kueleza sasabu za kujiondoa.
3. Kukataa kushiriki kwenye utafiti huu hautatumiwa dhidi yako na hautashawishi huduma unazostahili kupokea hospitalini.
4. Unaweza uliza maswali zitakazokuwezesha kuelewa kwa upana muundo wa utafiti huu.
5. Utapewe nakala ya hati hii ujiwekee.

Mawasiliano

Ukiwa na maswali kuhusu haki zako kama mshiriki wasiliana nasi kupitia njia hizi:

1. Mchunguzi Mkuu: Dkt Joy Rose Odhiambo
   Tel 0727513746
   Email joy.adhyambo@gmail.com

2. Wasimamizi :
   - Prof E. Obimbo Maleche
     Tel 0722720402
     Email eobimbo@yahoo.com
   - Dr Paul Laigong
     Tel 0720386861
     Email
     drlaigongp@gmail.com

3. Mwenyekiti wa kamati KNH-UON ERC Tel 2726300/2716450 Ext 44102
   Email: uonknh-erc@uonbi.ac.ke

Nakuomba sasa uweke sahihi kwenye idhini hapo chini

IDHINI YA KUSHIRIKI KWENYE UTAFITI

Nimesoma na nikaelezewa yaliyomo kwenye idhini hii na nimeelewa kabisa. Hatari na manufaa yote yameelezewa. Naelewa kuwa kushiriki kwangu ni kwa hiari yangu na nikona uhuru wa kujiondoa kutoka kwenye utafiti huu wakati wowote bila kupoteza manufaa wala haki zozote zangu. Pia nimeelewa kuwa juhudi zote zitachukuliwa kuhakikisha kuwa jambo lolote linaloweza kunitambuluisha litatunzwa kisiri kabisa.

Jina la mshiriki………………………………… Tarehe……………………

Sahihi ya mshiriki…………………………….

Taarifa ya mtafiti

Ninathibitisha kuwa nimefafanua maelezo yote ya utafiti kwa mshiriki na kuwa ameelewa.

Jina la mtafiti.. Tarehe……………………

Sahihi ya mtafiti……………………………..

9.9 Assent Form for Children aged 7-17 years

Study title: Quality of life of Children with Chronic Cough and their Parents at Kenyatta National Hospital.

Institution: Department of Paediatrics and Child Health. University of Nairobi.

Principle Investigator: Dr Joy Rose Odhiambo (MBChB)

Supervisors:

1. Prof Elizabeth Maleche Obimbo (MBChB,MMed,MPH,FPulm)
2. Dr Paul Laigong (MBChB, MMed, FEndoc)

Ethics Approval: This study has the approval of Kenyatta National Hospital/University of Nairobi Ethical and Research Committee (KNH-UON ERC)

Introduction: We want to give you some information on something called a research study**.** A research study helps us learn new things and test new ideas. We will provide you with sufficient information regarding our study, then we will ask you if you want to take part in it or not.

Why are we doing this study?

We are doing this study to see if your daily life is affected by your cough. This will help doctors know how to take better care of you and those with similar problems like you.

The researcher in charge is Dr Joy Rose Odhiambo.

What will happen if I am part of the study?

If you decide to be in this study, we will do the following in about 30 minutes.

We will ask you questions about your personal information like your age and how your daily life is affected by your cough.

We will also measure your weight and height.

Will this study be of help to me?

There will be no direct benefit to you. However the findings of this study will be shared with your doctor so that they can take better care of you and those with similar conditions like you.

Could bad things happen to me if I join this study?

There will be no dangers to your health, as we will not give you any medicine or take your through any procedure. You will only be required to answer a few questions.

Are there any costs to me?

You will not be required to pay for participating in this study, as it will occur during your routine visit to the clinic/hospital.

You will also not be paid for being in the study.

There are some important things you need to know:

1. You are allowed to decide if you want to take part in this study.
2. You can say "NO" OR "YES".
3. If you say NO, you will not be punished or denied any services in the hospital.
4. It is okay to say YES then change your mind later.
5. We will keep all your information private and your name will be labelled as a coded number.
6. You are allowed to ask any questions about this study at any time.
7. Your parent/guardian will also be asked if it is okay for you to take part in the study.

Do you want to participate in this study?

Should you want to be part of this study, please write your name below. I will also write my name under yours. This will show that we explained to you about this research and you are willing to be part of it.

Name or thumb print of participant ………………………… Date………………

(To be written by child)

Name of Researcher... Signature ……………
Date…………………………………

9.10Kiswahili Assent Form / Fomu ya Idhini kwa watoto wa miaka 7 hadi 17

Kichwa cha masomo: Ubora wa maisha ya watoto walio na kikohozi sugu kwenye hospitali kuu ya Kenyatta.

Taasisi : Idara ya afya ya watoto katika Chuo Kikuu cha Nairobi.

Mtafiti mkuu: Dr Joy Rose Odhiambo

Wasimamizi:

1. Prof Elizabeth Maleche Obimbo
2. Dr Paul Laigong

Idhini ya maadili: Utafiti huu umeruhusiwa na Kamati ya Maadili na Utafiti katika Hospitali ya Taifa ya Kenyatta na Chuo Kikuu cha Nairobi (KNH-UON ERC)

Kifunguo: Tungependa kukupa habari kuhusu utafiti huu na kukukaribisha kuwa mshiriki. Baada ya kukueleza kuhusu utafiti huu, tutakuuliza ukiwa una nia ya kuwa mshiriki.

Ni kwanini tunafanya utafiti huu?

Tunafanya utafiti huu kuona kama maisha yako yanaadhirika na kikohozi chako. Utafiti huu utawawezesha madaktari kujua jinsi ya kukusaidia wewe na wengine walio na matatizo sawa na yako.

Mtafiti mkuu atakuwa Dr Joy Rose Odhiambo.

Je, ni nini kitakachofanyika nikiwa mshiriki wa utafiti huu?

Ukiamua kuwa mshiriki wa utafiti huu tutafanya yafuatayo ndani ya dakika kama 30 hivi.

Tutakuuliza habari ya kibinafsi kwako kama umri waki na pia maswali kuhusu jinsi maisha yako ya kila siku yanavyoadhirika na kikohozi chako.

Pia tutapima uzito na urefu wako.

Je, utafiti huu utakuwa na manufaa gani kwangu?

Hakuna manufaa ya moja kwa moja kwenye utafiti huu kwako lakini daktari wako ataweza kujulishwa kuhusu matokeo yako ili aweze kukutibu wewe pamoja na wengine walio na ugonjwa sawa nawe vyema zaidi.

Je, kuna chanzo cha mambo mabaya kunitendekea katika utafiti huu?

Afya yako haimo hatarini kwani hatutakupa dawa zozote wala kukupitisha kwenye utaratibu wowote. Utahitajika kujibu maswali kidogo tu.

Je, kuna gharama yoyote nitakayo tozwa?

Hutatakikana kulipa chochote ili ushiriki kwenye utafiti huu kwani itafanyika wakati unapotembelea kliniki/hospitali kama ilivyo kawaida.

Ni vyema pia kujua kuwa hutalipwa kushiriki kwenye utafiti huu.

Mambo ya muhimu unayostahili kujua:

1. Umeruhusiwa kuamua iwapo unataka kushiriki kwenye utafiti huu.
2. Unaweza kusema “NDIO” au “LA”
3. Ukisema LA hutaadhibiwa wala kunyimwa huduma zozote hospitalini.
4. Umeruhusiwa kubadili uamuzi wako baada ya kukubali.
5. Tutahakikisha kuwa maelezo yako yote ya kibinafsi yamefichwa na jina lako litaandikwa tu kama nambari iliyokadiriwa.
6. Umeruhusiwa kuuliza maswali wakati wowote wa utafiti huu.
7. Mzazi/mlinzi wako pia ataulizwa iwapo ni sawa kwako kushiriki kwenye utafiti huu.

Je, unataka kushiriki kwenye utafiti huu?

Iwapo unataka kushiriki kwenye utafiti huu, tafadhali, andika jina lako hapo chini. Nami pia nitaandika jina langu chini ya lako.

Hii itaonyesha kuwa tumekueleza kuhusu utafiti huu na ukona nia ya kushiriki.

Jina au kuchapa kwa kidole cha mshiriki ________________________________

(Iandikwe na mtoto yaani mshiriki)

Tarehe_____________________

Jina la mtafiti ___________________ Sahihi ya mtafiti_______________

Tarehe______________________

9.11 Study Timelines

	2020				2021				
	Mar-April	May-June	July-Sept	Sept-Dec	Jan-Mar	Mar-April	May-Aug		
Proposal development	■								
ERC approval		■							
Initial data collection			■						
Study modification				■					
Data collection					■				
Data analysis						■			
Results presentation							■		
Final report								■	
Internal marking									■

9.12 Study Budget

Item	Cost (Kshs)
Printing and photocopy	15,000
Tape recorder and batteries	5,000
PPEs/Sanitizers	5,000
Principal Investigator	60,000
Research assistant 1000/day for 60 days	60,000
Statistician	40,000
Contingency fund (10% of budget)	18,000
Total	**203,000**