PREVALENCE OF NOCTURNAL ENURESIS AND ASSOCIATED PSYCHOLOGICAL PROBLEMS AMONG CHILDREN WITH SICKLE CELL DISEASE AGED 6-14 YEARS ATTENDING HEALTHCARE SERVICES AT HOMABAY COUNTY TEACHING AND REFERRAL HOSPITAL

Principal Investigator:
Maria Ogaya Gerald
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Department of Paediatrics and Child Health

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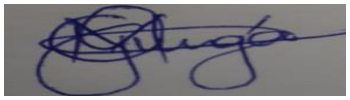
Declaration

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

Signature:  **Date:** 10/07/2023

Maria Ogaya Gerald

SUPERVISORS APPROVAL

This research dissertation has been submitted for external with approval as University supervisors:

Dr. Jacquie N Oliwa,

Signature:  **Date:** 27/07/2023

Lecturer and Consultant, Department of Paediatrics and Child Health, Faculty of Health Sciences, University of Nairobi.

Signature:  **Date:** 27th July, 2023

Dr. Beatrice Mutai,

Lecturer Department of Paediatrics, and Child Health, Faculty of Health Sciences, University of Nairobi.

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Endless gratitude to the participants in the research from Homabay County Teaching and Referral Hospital, your contribution made this work materialize in the hope of supporting children with SCD better.

DEDICATION

To the memory of grandma Atieno, you promised that this would be, but that you'll never see it.

It has come to pass Granma.

To Dad and Mum who believe in the versatility of the mind and in the ability to learn, that no one is born as anything, you learn to be something.

To my siblings, thank you for being my champions.

And to my husband, for making me want to be more.

COLLABORATING INSTITUTIONS

1. UNIVERSITY OF NAIROBI
2. KENYATTA NATIONAL HOSPITAL
3. HOMABAY COUNTY TEACHING AND REFERRAL HOSPITAL

LIST OF ABBREVIATIONS

ADHD - Attention-Deficit Hyperactivity Disorder

AOR - Adjusted odds ratio

BC - Bladder capacity

CKD - Chronic kidney disease

COR -Crudes odds ratio

DSM-V - Diagnostic and Statistical Manual of Mental Disorders, 5th Edition

Hb - Hemoglobin

HBCTRH - Homabay County Teaching Referral Hospital

HbE - Hemoglobin electrophoresis

HbS - Hemoglobin S

HRQOL - Health-related quality of life

KDIGO - Kidney Disease: Improving Global Outcomes

KNH -Kenyatta National Hospital

KMTC - Kenya Medical Training College

LUT - Lower Urinary Tract

NE - Nocturnal Enuresis

OR -Odds ratio

PedsQL - Pediatric Quality of Life)

PI - Primary investigator

PNE - Primary nocturnal enuresis

PSC	- Pediatric Symptom Checklist
SCA	- Sickle Cell Anemia
SCD	- Sickle Cell Disease
SCN	- Sickle Cell Nephropathy
SDQ	- Strength and Difficulties Questionnaire
SPSS	- Statistical Package for Social Science
TM	- Thalassemia major
UK	- United Kingdom
USA	- Unites States of America
UON	- University of Nairobi
VOC	- Vaso-occlusive crisis
Y- PSC	- Youth Self Report Pediatric Symptom Checklist

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DEFINITION OF TERMS

Factors associated with nocturnal enuresis among children: They include age, sex, parental history of enuresis, frequency of painful crises, siblings' history of enuresis, frequency of hospitalization, number of enuretic episodes, parental explanations for the child's enuretic episodes (deep sleeper, laziness)

Nocturnal enuresis as defined by Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-V): Repeated involuntary or purposeful voiding of urine into bed or clothes at least twice a week for at least 3 months consecutively.

Primary enuresis: Enuresis occurring in a child more than or equal to the age of five who has never achieved bladder control, which is defined as six months of regular nightly dryness or has at least 2 episodes of bedwetting a week

Psychological Health: Pediatric Symptom Checklist (PSC) tool consists of 35 things graded as 'Never', 'Sometimes' or 'Often' present scored as '0' '1' and '2' correspondingly in the evaluation of psychological and behavioral issues in children. Cut off score ≥28 indicate psychological impairment; Externalizing problems- disruptive behavior; Internalizing behavior problems- symptoms of depression or anxiety; School-related problems and inattention - absences and relationship with the teacher

Secondary enuresis: Resumption of incontinence in a child more than or equal to age of five years old following at least six months of nightly dryness

ABSTRACT

Background

Sickle cell disease (SCD) is a hereditary autosomal recessive hemoglobin disease condition characterized by sickling of red blood cells under conditions of stress and hypoxia. Studies have illustrated that children with sickle cell disease (SCD) present a higher likelihood for nocturnal enuresis (NE) compared to those children who have normal hemoglobin. Studies however report varying epidemiologic trends and prevalence rates of NE based on the diverse definition criteria and study methods. More poignantly, while NE prevalence is high in children with SCD, not much is known about the associated psychological problems in these children. Based on reports largely from Western studies, the stigma, ridicule and mental distress associated with NE among children are high. We set out to determine the prevalence of NE, as well as associated patient characteristics and psychological problems among children with SCD in our setting.

Methodology: A cross sectional study was conducted in Homabay County Teaching and Referral Hospital among 250 children aged 6-14 years with a positive preliminary or a confirmatory test for SCD. Children on medications that may induce NE, those with disease conditions like cerebral palsy, profound mental retardation, diabetes, and those aged older than 7 years and declined assent to participate or whose parents denied consent were excluded. Stratified weighted sampling by age category was done to achieve the desired sample size. Data was obtained on presence or absence of NE as well as on children's age, gender, sibling history of NE, school type and presence or absence of psychological disorders. The Pediatric Symptom Checklist (PSC) tool was used to evaluate psychological well-being of children. A cut off score of $\geq$ 28 defined presence of psychological impairment. Filled PSC questionnaires that had four or more blank items were considered incomplete and excluded from the analysis.

Results: Out of 250 participants there were 237 complete PSC forms. The prevalence of NE in the study population was 31.2% (95% CI 23.0-37.8). Only 1 participant had secondary NE giving a prevalence of 0.42%. Patient characteristics associated with NE were male gender, age less than 10 years and previous hospitalizations with an adjusted odds ratio (AOR) of 1.47(95% CI 1.14-1.89); 1.92(95% CI 1.45-2.53) and 2.13(95% CI 0-7.17) respectively. None of the children met the PSC threshold for psychological disorders as per the screening tool, however 6.7% presented with symptoms of attention problems, 9.7% with symptoms of internalizing problems, and 30% had symptoms of externalizing problems

Conclusion: The prevalence of NE among children with SCD in Homa Bay is high while prevalence of associated psychological problems is low. Male gender, age and previous hospitalizations were identified as predictors of NE in children with SCD.

Recommendations: Children with SCD should be routinely assessed for NE and appropriate treatment offered especially among boys, young children aged 6-9 years and children with increased frequency of hospitalization.

Key words: Nocturnal enuresis (NE); children and adolescents; Sickle Cell Disease (SCD); psychological health, mental health.

CHAPTER 1: INTRODUCTION

1.0 Background Information

Sickle cell disease (SCD) is a hereditary autosomal recessive hemoglobin disease which affects primarily people of Mediterranean, African, Indian, and Middle-Eastern origin (1). It affects a large group of people but is still poorly understood by the general public (1). Quantitatively, 20-25 million people have been affected globally, 12-15 million of whom live in Africa (2). The natural distribution covers a broad belt, including the Mediterranean, Western, Eastern and Central Africa, the Middle East, India, and Southeast Asia (2). Approximately 75-85% of affected children are of African origin, and 50-80% of the affected children die before reaching the age of 5 years (3, 4). Sub-Saharan Africa accounts for the highest prevalence of SCD worldwide, contributing to 75% of the global burden of SCD with approximately 240,000 children born with SCD in this region (5). There is a paucity of population-level data on SCD but , based on modelling projections it is estimated that almost 6,000 newborns (one in every 150 newborns) had sickle cell globally in 2010 and this number could rise to over 10,000 (one in every 100 newborns) per year by 2050 (2).

In SCD, there is replacement of the amino acid glutamate at the sixth position of the beta-globin chain with valine which leads to production of hemoglobin S (HbS) whose accumulation in oxidative stress settings, hypoxic tissue, or dehydrated status results in sickling and early destruction of red blood cells (RBC). Associated vaso-occlusive episodes (VOC), culminate in multi-organ damage. Kidney complications resulting from SCD, commonly termed as sickle cell nephropathy (SCN), include hyposthenuria, hematuria, necrosis of renal papilla, proteinuria, renal tubular disorders, acute and chronic renal damage among others. Hyposthenuria is presumed to cause NE in SCD, resulting in nocturnal polyuria, nocturnal bladder over-activity, a decrease in

bladder capacity (BC), increased arousal threshold, and disordered breathing during sleep (6). According to the American Society of Hematology, NE in SCD is a marker of renal impairment that often develops in early life and may advance to chronic kidney disease (CKD) in adulthood (7). Correspondingly, it is estimated that CKD is present in 16–27% of children who have SCD according to the Kidney Disease: Improving Global Outcomes (KDIGO) criteria (8).

NE colloquially known as "bedwetting refers to the involuntary passage of urine at night by a child who is reasonably expected to be dry, at a developmental age of five years, without underlying organic disease (9, 10). Bedwetting brings about emotional and social stigma, stress, and inconvenience to families and children struggling with enuresis despite it being pathologically benign with high chances of remitting spontaneously (9). The social, emotional and psychological costs of enuresis to the children can be dire (9). Enuretic children may face bullying and teasing by their siblings, parental criticism, and recurrent failure of treatment, all of which may affect their self-esteem (9). The risk of physical and emotional abuse is also high. As a result, adequate management of enuresis is required (11).

NE is not only socially stigmatizing but also stressful. Globally, 15% to 20% of five-year-old and up to 2% of young adults are affected (9). NE is often overly scrutinized and wrongfully criticized (12). However, in SCD presence of NE is often overlooked. NE is fairly common among young children and adolescents who have SCD with a prevalence of 20 to 58% (8). The bulk of the time, the rate is double that of the general population (8).

Studies done within the global context shows that NE prevalence among children with SCD is 29.1% in China between 25-29% in the UK and the USA and 47.1%, 31.4%, and 41.6% in the south-west, north-west, and south-east Africa (11, 13 and 14). Other studies report a prevalence rate of NE among SCD children of 32-45% in Africa (13). Nevertheless, the prevalence rates based

on these studies decrease with increasing age of respondents and NE appears to affect the males more than females (8-16).

Nonetheless, notwithstanding the high prevalence of NE amongst children who have SCD, little is known about the magnitude of the associated psychological problems. Consequently, this paper seeks to examine the prevalence of NE and the magnitude of associated psychological problems among children with SCD aged between 6-14 years in Homabay County, Kenya, which is an area with a high occurrence of SCD.

CHAPTER 2: REVIEW OF LITERATURE

2.0 Epidemiology of SCD and NE

SCD is the commonest hemoglobinopathy globally affecting 20-25 million people worldwide with 12-15million of the affected living in Africa (2, 15). Africa accounts for over 75 percent of the 300,000 SCD newborns worldwide each year, with significant childhood death rates ranging from 50 to 90 percent before the age of five (2, 15 - 17). However, the prevalence of NE varies depending on the diagnostic criteria or classifications employed.

The natural distribution of SCD occurs along a broad belt, that includes the Mediterranean, Western, East, and Central Africa, the Middle East, India, and Southeast Asia. About 240,000 children in Sub-Saharan Africa are born with SCD, of whom an estimated 6,000 are in Kenya alone (2, 18). Despite a paucity of population-level data, it is estimated that almost 6,000 newborns (one in every 150 newborns) had sickle cell in 2010 and this number could rise to over 10,000 (one in every 100 newborns) per year by 2050 based on model projections (2). Nyanza, Western, and Coastal regions of Kenya have high burden of SCD (2).

2.1 Pathogenesis of NE in SCD

The various multifarious etiologies of NE which include psychological and physiological elements of the disorder, make it difficult to identify the pathogenesis of the disorder quickly (17). Reduced capacity of bladder, associated disturbances of sleep arousal, detrusor muscle over-activity, global maturation delay, and genetics form part of these multi-factorial etiologies for NE. In people with sickle cell anemia (SCA), there is “a tendency to fixation of specific gravity of the urine’’ as was first noted by Dr. Hugh Josephs in 1928 (18). Recurrent polymerization of HbS in the inner

medulla of the renal cortex result in hyposthenuria (diminished concentrating ability), hyperfiltration and, albuminuria which manifest as polyuria, nocturia, and NE (14, 19, 20). Transfusion of blood transiently reverses the lost concentrating capacity which occurs quite early in life (19, 21, 22).

Kidney involvement in SCD first manifests as an inability to maximally concentrate urine resulting in polyuria with an obligatory urine production of >2liters daily (23). This commonly leads to NE and makes the child susceptible to dehydration (23, 24). The concentrating defect results from the damage of vasa recta in renal medulla with a reduction of the former almost to zero in subjects with SCA (24). Hypoxic, acidic and, hyperosmolar states lead to reversible sickling of RBC resulting in blockage of vessels and washout of the gradient of the renal medulla (24).

There are two forms of NE; primary and secondary NE (25). Primary enuresis is defined as enuresis occurring in a child more than or equal to the age of five who has never achieved bladder control, which is defined as six months of regular nightly dryness or has at least 2 episodes of bedwetting a week (26, 27). Secondary enuresis on the other hand, is the resumption of incontinence in a child more than or equal to age of five years old following at least six months of nightly dryness (26). The latter is usually preceded by a particularly traumatic life event, substantial enough to elicit psychosocial regression, as the most prevalent trigger (28).

Additionally, NE can occur in the presence or absence of lower urinary tract (LUT) symptoms. Urgency, urinary hesitancy, bladder or urethral pain, decreased or increased voiding frequency ($\leq$3/ $\geq$8 times/day), daytime incontinence, straining, weak or intermittent stream, and spraying

urinary stream are all indications of LUT involvement (25). Monosymptomatic enuresis occurs when only NE is present. Non-monosymptomatic enuresis develops in the presence of additional symptoms that are indicative of LUT dysfunction.

NE is twice as frequent in boys as it is in girls with about 15% of children having it at age of 5 years, with primary enuresis accounting for the majority of the cases, about 80% (29). The condition is self-limiting and the percentage of affected patients decrease with age: about 15% at 5 years old, 13% at 6 years old, 10% at 7yrs old, 7% at 8yrs old, 5% at 10yrs old, 2-3% between 12 and 14years old and 1-2% incidence at ≥15 years old. Resolution is spontaneous at a rate of 15% annually, although presence at later years reduces the chances of spontaneous resolution. In the general population, daytime enuresis or LUT symptoms occurs in 20% of children who have NE, and about 15% of those with NE have encopresis, with a high male predominance (29).

Studies done within the global context show that the prevalence of NE among children who have SCD is 29.09% in China (17); between 25-29% in the UK and the USA (19) and 47.1%, 31.4%, and 41.6% in the south-west, north-west, and south-east Africa (11). Others show a prevalence rate of NE among SCD children to be between 32-45% in Africa (13). Nevertheless, the prevalence rates based on these studies slow down as the age of respondents increases and affects the male child more than the female (8 - 16). This aligns with studies done on NE in general that show that male children with SCD predominate the NE occurrence than their female counterparts.

2.2. Prevalence of Nocturnal Enuresis among Children with SCD

Barakat et al. (2001) performed structured telephone interviews in Philadelphia to investigate the prevalence, causes, therapies used, and emotional impact of NE among children and adolescents who have SCD. Primary caregivers to 217 children and adolescents who had SCD, aged 5 to 22,

were interviewed over the phone in a structured manner (30). NE was exhibited amongst 44 (20.3%) children with SCD and was significantly higher for males 33/117 (28.2%) compared to females 11/100 (11%). The commonest reason for enuresis was SCD. Caregivers used a variety of strategies to control NE, but few spoke to the health care provider concerning it. Based on this study's findings, a methodical assessment and intervention for NE should be performed regularly during follow-up and monitoring of children and adolescents suffering from SCD (30).

Ekinci et al. (2013) enrolled 106 patients aged 6 to 40 years old (55 (51.9%) with SCD and 51 (48.1%) with TM, as well as 80 age-matched healthy controls in Turkey to evaluate the prevalence and associated determinants of NE in SCD and thalassemia major (TM). Caregivers of children and adult patients were interviewed in semi-structured interviews about NE and psychosocial variables. Amongst these, twenty-eight (26.4 %) patients and three (3.7 %) controls had NE. Young ages, family problems, and familial history of NE were more common in patients with NE in TM diagnosis. Frequencies of painful crises and admissions were higher in those with enuresis and SCD (31).

Porter et al (2021) in the USA, purposed to estimate the prevalence of NE and establish associated socio-demographic, medical, and health-related quality of life (HRQOL) factors in 248 participants ages 6-18 years with SCD using semi-structured interviews and questionnaires. HRQOL was estimated using the Pediatric Quality of Life (PedsQL) inventory. It was established that 53 (21.4%) had current NE, 114 (46%) had lifetime NE and that NE was associated with HRQOL, reduced sleep, increased fatigue, and markers of disease severity. It is necessary to

routinely assess behaviors of sleep and fatigue while treating patients with SCD to understand the impact of NE on HRQOL (32).

In a Pediatric Hematology Clinic in a tertiary public hospital in Lagos, Esezobor et al (2018) interviewed primary caregivers for children who had SCA of ages between 5-17 years enrolling 243 children constituting both controls and children with SCA, and who were age and gender matched evenly. The cohort's mean age was 9.9 years (3.4 SD) and females constituted 111/243 (45.7%). Enuresis was found in 120/243 (49.4%) of children with SCA and 72/243 (29.6%) of children without. In addition, while there was a decline in prevalence in SCA with age, it remained 5 times more in children who had SCA aged 14–17 years old, at 25%, compared to controls. Enuretic children with SCA were discovered to be older, more likely to have the non-monosymptomatic form and to wet at night. As established by Ekinci et al (2013), familial history of enuresis and young ages were independent predictors of enuresis in children who had SCA (33).

From the aforementioned literature, it is evident that various studies sought to explore the prevalence of NE in SCD. The studies are similar as they all studied the same independent variable, prevalence of enuresis in the context of SCD but addressed different concepts of analysis. Whereas Barakat et al (2001) focused on perceived causes, interventions undertaken and emotional impact of NE, Ekinci et al (2013) on the other hand focused on psychosocial variables and Esezobor et al (2018) narrowed down to the classification of enuresis. These studies all differed on the age group of the cohort chosen ranging from ages 5 to 40 years. None of the studies however have been conducted in the context of Sub-Saharan Africa and in particular Kenya. On the other hand, the present study will look at the prevalence of NE among children 6 to 14 years with SCD receiving health care services in Homabay County Teaching and Referral Hospital.

2.3 Psychological Problems of Nocturnal Enuresis in SCD

Generally, NE is a frequent childhood disorder affecting children and families and that is usually associated with psychological problems such as internalizing, externalizing, and attention problems and impacts on the social, educational, and family life of the child (34). There is a need for the ability of all clinicians to identify and assess patients with NE due to its association with various conditions such as reduced self-esteem, attention deficit hyperactivity disorder, disturbance of sleep, and cognitive problems (29). It has been demonstrated that successful treatment helps affected children regain their self-esteem.

Jordan et al (2005) in Mississippi sought to establish the link between NE and psychosocial issues in childhood SCD and sibling controls. The Pediatric Symptom Checklist and structured interviews were given to primary caregivers of 126 children with SCD ranging in age from 5 to 17 years old, as well as 47 siblings. Lifetime rates of enuresis in children who had SCD was 50/126 (39.7%), exceeding population prevalence and sibling control rates of 10/47 (21.3%); a finding that was comparable to other similar studies. Further, overall psychosocial issues according to the checklist were greater in the enuretic children. As a result, the findings provided additional evidence to not only identify effective therapies for enuresis in children who had SCD, but also support the monitoring of hydration levels, screening for psychosocial issues in children who have SCD and enuresis, and psychometric assessment of psychosocial screening measures (35).

Owino et al in (2019) in Kenya conducted a phenomenological study in boarding secondary schools to investigate the psychological experiences of students with NE with their peers. Purposive sampling of 6 principals and 6 teachers was done. The outcomes of interest included

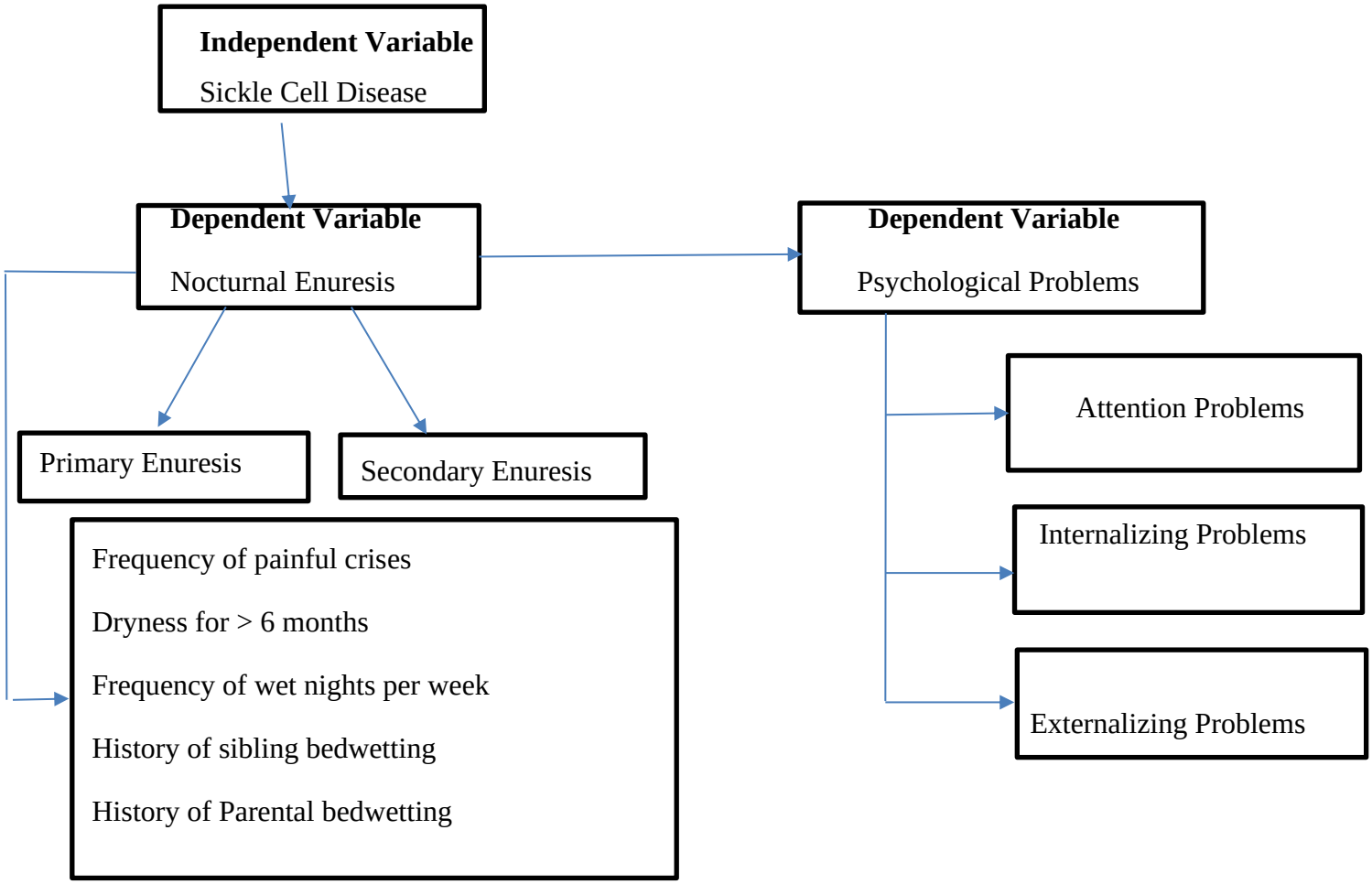
self-esteem, aggression, paranoia, stress, anxiety, and anger. Findings indicate that students with NE faced many psychological challenges with peers including increased levels; of stress, anxiety and anger, aggression, paranoia and low self-esteem. They also had a low capacity to surmount psychological encounters with peers necessitating the need for strong interventions including strengthening peer counseling in schools (36).

A cross-sectional descriptive-analytic study was implemented in Khorramabad, Iran by Mohsenzadeh et al (2017) and a census method used to investigate behavioral disorders in 100 children with primary enuresis ranging from age 5 to 14 years. Anxiety, academic failure, behavioral issues, sleep, and psychological disorders were evaluated using a questionnaire and the short screening instrument for psychological problems in enuresis (SSIPPE). The most common behavioral disorders were hyperactivity and restlessness, which were also significantly greater in 9 boys. Children above 10 years commonly had a headache, sleep, and obsessive disorders. In males, there was a strong link between headaches, eating problems, sleep difficulties, and unusual movements, whereas females frequently experienced sadness. Furthermore, teaching parents about enuresis might help children with enuresis develop their social personalities (37).

Children with enuresis have a 20-30% rate of behavioral and emotional disorders(38, 39). This is twice to thrice higher than in children without enuresis, with attention deficit hyperactivity disorder being the most strongly associated condition with enuresis (40). According to Baeyens et al comorbid ADHD and enuresis rates are at 28.3% compared to 10.3% in the general population (41).

According to Hamed et al, (2021) children with enuresis showed greater frequencies of emotional, conduct and hyperactivity- inattention symptoms and peer relationship and prosocial difficulties and higher overall and individual subscales' scores on the Strength and Difficulties Questionnaire (SDQ). Boys had more severe conduct symptoms and prosocial problems while girls showed more severe emotional symptoms (42).

2.4 Conceptual Framework



2.5 Justification of the study

SCD was classified by World Health Organization as a neglected chronic disease of public health importance in 2006 given its wide distribution, globally especially in malaria-endemic areas.

On July 30th, 2021, the Ministry of Health in Kenya released national guidelines for the management of SCD, with the goal of ensuring that people living with the condition receive quality and affordable care, that mainly focused on the management of acute complications. Studies in multiple settings outside of Kenya have reported early childhood enuresis as common chronic complication in SCD. According to these studies, children and adolescents who have SCD have a higher risk of NE compared to those with the normal hemoglobin.

NE is often humiliating for affected children and has been associated with long term consequences. Enuretic adolescents and adults may experience depression and low self-esteem, low academic achievement and work disruptions and poor social lives. Effective treatments for enuresis have been linked to not only cessation of bedwetting but also improvement of behavioral problems and quality of life. Several simple behavioral treatments have been demonstrated to be effective. Successful treatment among affected children has been demonstrated to restore self-esteem. The burden of disease among children with SCD in our setting is unknown. This study seeks to raise awareness on enuresis among parents, affected children and healthcare workers as well as to sensitize them on the need for early recognition and treatment.

2.6 Research Questions

What is the prevalence of NE and what is the magnitude of associated psychological problems among children aged 6-14 years with SCD attending healthcare services at Homabay County Teaching and Referral Hospital?

2.7 Objectives:

2.7.1 Primary Objective

To determine the prevalence of NE among children with SCD aged 6-14 years attending healthcare services at Homabay County Teaching and Referral Hospital

2.7.2 Secondary objectives

1. To describe patient characteristics associated with NE among children with SCD at Homabay County Teaching and Referral Hospital
2. To determine the magnitude of associated psychological problems among children with SCD at Homabay County Teaching and Referral Hospital.

CHAPTER 3: METHODOLOGY

3.1 Study Design

A cross-sectional study design was adopted to investigate the prevalence of NE among children with SCD. This design was appropriate to determine both the prevalence of NE and the factors associated with it amongst study participants (43).

3.2 Study Site

The research was done at Homabay County Teaching and Referral Hospital (HBCTRH), a Level IV hospital in Homabay County serving a catchment population of 1,131,950 people according to the 2019 census. It has a bed capacity of 300 beds and provides various services including inpatient and outpatient services in, pediatrics, internal medicine, surgery, obstetrics, and gynecology. The hospital has diverse cadres of healthcare workers including specialist consultants, medical officers, pharmacists, clinical officers, nurses, pharmaceutical technologists, and interns. It also serves as a teaching facility for students enrolled at Kenya Medical Training College (KMTC) in Homabay and its environs. The hospital attends to approximately 75,000 inpatients, and 600,000 outpatients each year. All children and adolescents diagnosed with SCD are followed up and monitored closely at the pediatric hematology clinic conducted every Friday. Cumulatively, the clinic has enrolled between 700-900 children and adolescents who have SCD. Each month, the hematology clinic provides services to about 60-80 children and adolescents.

3.3 Study population

The study population comprised children aged 6-14 years with SCD on follow-up in the hematology clinic at the HBCTRH**.**

Inclusion Criteria

Children who met the following criteria were considered for enrolment:

- Aged 6-14 years.
- Diagnosis of SCD based on preliminary tests (sickle cells on peripheral blood film, sickling test, or hemoglobin solubility test) or by confirmatory test (Hb electrophoresis, high-performance liquid chromatography, or isoelectric focusing).
- Assent to participate by children aged > 7 years and consent by parents or guardians for children to participate

Exclusion criteria

Children were excluded if they:

- Did not have parental consent to participate/ or if older children (7 years) did not assent to participate
- Suspected to have SCD but not confirmed

Case definitions

Independent study variables included the following;

- Patients' characteristics associated with NE in children with SCD (frequency of painful crises, history of sibling bedwetting, type of school, gender and history of parental bedwetting).

The dependent variable was:

- Proportion of children with SCD who had NE.

- Proportion of children with NE reporting psychological problems (attention problems, internalizing problems and externalizing problems)

3.4 Sample size and sampling technique

Fischer formula was used to determine the number of children to include in the study Fisher's et al, 1998 formula;

$$N = \frac{Z^2 p(1-p)}{d^2}$$

Where:

N = estimated study population

Z = the normal standard deviation at 95% confidence level (1.96)

d = desired error margin at 0.05

p = the proportion of children with SCD estimated will have NE (20.3%) based on the study by Barakat et al (2001)(30)

so, N= the desired sample size = **250**

Thus, the required sample size was 250 participants.

3.5 Sampling Method

Stratified proportionate sampling was done by age and sex based on the clinic case load to determine the number of children to be enrolled from each age strata. Consecutive sampling was then done within each of the age categories until the desired sample size was reached. The actual numbers sampled per strata, ultimately depended on the number of children within that age group attending care at the start of the data collection as well as their sex distribution. The proportion of children in the two age categories seen at the SCD clinic in Homabay was determined at the beginning of the study period based on the previous month's clinic attendance records.

Table 1: **Sampling**

Age Category	Numbers Sampled
6-10 years	109 children
11-14 years	141 children
Total	250

3.6 Recruitment Strategy, Consenting Process, and Data Collection

The principal investigator (PI) identified children aged 6-14 years as they arrived for the Friday clinic with their caregivers to determine if they were eligible for inclusion. Details of the study were explained to the caregivers of potential participants after which parents/guardians who consented to have their children enrolled in the study gave their written approval. Participants were requested to remain behind for a few minutes after engaging with the health practitioner for data collection to be done. Participants waiting in line to be seen by clinicians were issued with a questionnaire prior to being seen by the health practitioner. One of the rooms in the outpatient department was used for the data collection procedure with each participant filling in the questionnaires within a duration of between 15-30 minutes. Where a parent declined to consent for the child to participate in their absence, the child was interviewed in the presence of the parent/s. If the child refused to participate in the presence of the parent, then the child was excluded from the study not issued with a questionnaire. The questionnaire was divided into 3 sections, A, B, and C. Section A contained sociodemographic data, section B contained medical data and section C was the PSC form. Parents' assistance in filling sections A and B of the questionnaire was sought as the child participant filled section C for children aged 11 years and above. Parents of younger children (6 – 10 years old), were asked to provide responses to section C.

3.7 Data Collection Tool

3.7.1 Socio-demographic Factors

A standard questionnaire developed by the PI was used to collect socio-demographic data from participants on factors like child's sex, age, family structure, and type of school. Section A of the questionnaire primarily constituted this information (See appendix 1: Section A)

3.7.2 Medical Data

Data on frequency of painful crisis and hospitalization in the child, number of enuretic episodes, parental history of enuresis, siblings' history of enuresis, and parental explanations for the child's enuretic episodes (deep sleeper, laziness) was also obtained in section B of the study questionnaire (see appendix 1: section B). This section was filled by either the parent or the adolescent with the help of the parent.

3.7.3 Psychological Health of children

A standard guideline, PSC, was used to evaluate the psychological well-being of SCD children in section C of the study questionnaire (see appendix 1 section C). There were two versions of the PSC that were used depending on the child's age. The parent- version of the PSC that was filled by the parents for children aged 6-10 years, and the youth self-report (Y-PSC) version was administered to adolescents aged 11 and above.

The PSC tool was used because it is suitable for comprehensive assessment of emotional and behavioral aspects in children aged 6-16 years. So far, the PSC tool has been used to assess psychological health among children in various settings and has been reported to have a test-retest reliability and internal consistency (40, 41). Using the Cronbach's Coefficient alpha test, this tool

was found to have high-reliability, with one study showing reliability index results for the PSC at 0.89 and 0.86 (40, 41).

Using the PSC tool we assessed for presence of the following psychological problems: Externalizing problems, Internalizing behavior problems, poor attention and school-related problems among children. The PSC tool is a 35-item scale with scores of never (0), sometimes (1), or often present (2) for each of the items. The total score was then used to determine if a child had a psychological health problem or not. On this tool ≥ 28 is the cutoff score that determines presence psychological impairment for a child aged 6-16 years while for 4-5-year-olds, the cutoff score is 24 or more.

3.8 Data Management

The PI checked completed questionnaires for completeness and ensured that all information captured was accurate. The filled questionnaires were locked in a safe cupboard with access only to the PI. Data was entered onto Epi data version 3.1. Following data entry, the coded data was exported into Statistical Package for Social Science (SPSS) version 25 for analysis. The PI and the research statistician saved data on a password-protected computer that could only be viewed in soft copy form. The informed consent forms and completed questionnaires will be kept in a secure location for five years before being destroyed. Information on participants' contacts was obtained to enable follow up in the event of identification of psychological impairment so as to facilitate communication to parents and referral to a child psychiatrist.

3.9 Data Analysis

The SPSS version 25 was used to do data analysis. Categorical data (gender, parental history of enuresis, siblings' history of enuresis, family type, school type and parent's explanations about the

child's enuretic episodes (deep sleeper, laziness)) was analyzed and presented using frequencies and percentages, while means and medians were used to describe continuous variables. The Shapiro-Wilk test was used to test for the normality of continuous data (age, family type and school type, frequency of painful crises). The Pearson's Chi-Square test was used to determine the significance of statistical association between categorical variables like gender, parental history of enuresis, siblings' history of NE with the dependent variable NE. Further, an independent samples t-test was used to ascertain the significance of statistical association between continuous variables like age, frequency of painful crises, frequency of hospitalization, number of enuretic episodes, and the dependent variable NE.

Logistic regression analysis was conducted to identify the factors that were independently associated with the presence of NE and psychological problems among children with SCD. From the inferential statistics, the desired error margin was 5% at 95% CI. Odds ratios were calculated to determine the strength of association between exposure and outcome variables. Associations were determined as significant if the 95% CI of calculated odds ratios did not cross the null value of 1 and the associated p value was <0.05. The regression model controlled for continuous variables like age, family type and school type, frequency of painful crises, frequency of hospitalization, frequency of nocturnal enuresis, parental explanations for the child's enuretic episodes (laziness, deep sleeper) and the dependent variable NE.

The following formula was used to determine the prevalence of NE among children with SCD:

$$\text{prevalence} = \frac{\text{Number of children with SCD with NE}}{\text{The total number of SCD children included in the study}} * 100$$

Prevalence was presented as a percentage with a 95% confidence interval.

Adjusted odds ratio was calculated to adjust for potential confounders (recurrent pain crisis and hospitalisation) for psychological problems.

3.10 Results Presentation and Dissemination

The results from the findings were presented to the University of Nairobi, Department of Pediatrics and Child Health to meet the requirements of qualifying for degree in Master of Medicine Pediatrics and Child Health. Further, the findings will be submitted for publication in a peer-reviewed journal, to allow for access to global readership. The study findings were also shared with the hospital management team at HBCTRH and the caregivers for informational purposes.

3.11 Ethical Considerations

The PI sought ethical approval from the University of Nairobi (KNH/UoN) Ethics and Research Committee as well as permission from the HBCTRH administration to conduct the study within the facility. Caregivers were requested to sign a written informed consent form and assent was also sought from the children before enrolling them in the study. Participants' identities were delinked from study data prior to analysis to guarantee confidentiality. Participants with psychological problems were referred to a child psychiatrist for further evaluation and management. To ensure confidentiality, the respondents were assured that this endeavor was for academic purposes only. To assure them of integrity and security, data obtained was stored in a password-protected computer with access only to the research team. Further, all COVID-19 protocols were adhered to strictly.

The informed consent form was translated to Kiswahili to ensure that parents and some children with problems understanding English fully understood what the study was about as well as study procedures. Whenever there were parents and children who were unable to communicate in both English and Kiswahili, a translator was used to make the consent clear in the local vernacular language which is Dholuo. In addition, a research assistant who is a qualified clinical officer was

employed to assist in data collection and was trained on research ethics as well as on study procedures.

CHAPTER 4: STUDY RESULTS

A total of 237 participants comprising 94.8% of the desired sample size were recruited to the study. Males constituted 48.5% (115) of the study population and females 51.5% (122). Majority of the participants (57.4%) were in the age group 10-14 years and 69 (29.1%) of the participants were firstborns. The mean age of children was 10.2 (SD 2.76) years. Mean age of males was lower than that of females at 9.9 (SD 2.75) years and that of females was 10.4 (SD 2.75) years. Most children, 35.0%, had parents with primary level of education while 12.7% and 3.0% of the children had parents with college and university level education respectively. Among the parents, 22.4% had no formal education. The sociodemographic characteristics of the study population are presented in table 2.

Table 2: **Sociodemographic Characteristics of Study Participants (n=237)**

Variable	Category	Frequency/ Mean	Percent/ SD
Gender	Females	122	51.5
	Males	115	48.5
Age (years)	6-9yrs	101	42.6
	10-14yrs	136	57.4
Mean Age (years)	Females	10.46	2.75
	Males	9.97	2.75
Parental level of education	College/certificate/Diploma	30	12.7
	None	53	22.4
	Primary	83	35.0
	Secondary	64	27.0
	University/Degree/Masters	7	3.0
Family type	Single parenthood	44	18.6
	Both parents	184	77.6
	Other	9	3.8
School type	Day	224	94.5
	Boarding	13	5.5
Children's birth order	First born	69	29.1
	Second born	68	28.7
	Third born	47	19.8
	Fourth born and above	23	9.7

Clinical Characteristics of study participants:

Forty-nine-point four percent of the children reported having painful crisis at least once a year Sixty-seven-point five percent (67.5%) of children had history of previous transfusion whereas 40.5% had previously been hospitalized at least once. Ninety-eight-point seven percent (98.7%) had no underlying comorbidities. Family history of bedwetting was reported among siblings for 19% of the children and among parents for 0.4% of the children. (see Table 3)

Table 3: Clinical Characteristics of Study Participants (n=237)

Variable	**Category**	**Frequency N = 237**	**Percent**
Frequency of pain crisis	None	1	0.4
	Weekly	3	1.3
	Monthly	104	43.9
	Yearly	117	49.4
	Twice yearly	8	3.4
	Thrice yearly	2	0.8
	>Year	2	0.8
Previous blood transfusion	No	77	32.5
	Yes	160	67.5
Previous hospitalizations	None	87	36.7
	Once	96	40.5
	Twice	36	15.2
	Thrice or more	18	7.6
Comorbidities	None	234	98.7
	Yes	3	1.3
Siblings bedwetting	None	192	81.0
	Yes	45	19.0
Parents bedwetting	None	236	99.6
	Yes	1	0.4

Study objective 1: Prevalence of NE among children with SCD:

The prevalence of NE in the study population was 31.2% (95% CI 23.0-37.8). Secondary NE was reported in only 1 child who was initially dry for at least six months at the age of 8 years and had later resumed bedwetting giving a percentage of 0.42% (95% CI 0.23- 0.57) for secondary NE. (see Figure 1)

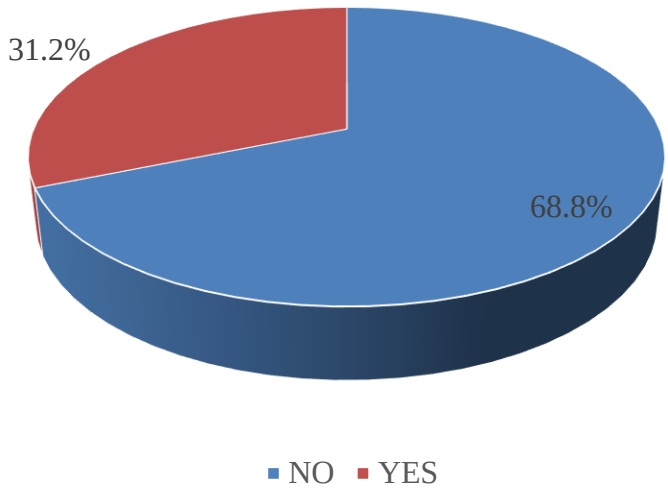


Figure 1: **Prevalence of NE**

Frequency of NE among children

Majority of the children in our study reported no NE. Among the children with NE, 12.7% reported frequent NE at 3-4 wets per week and 10.5% more frequent episodes at more than 5 wet nights a week. (see Figure 2)

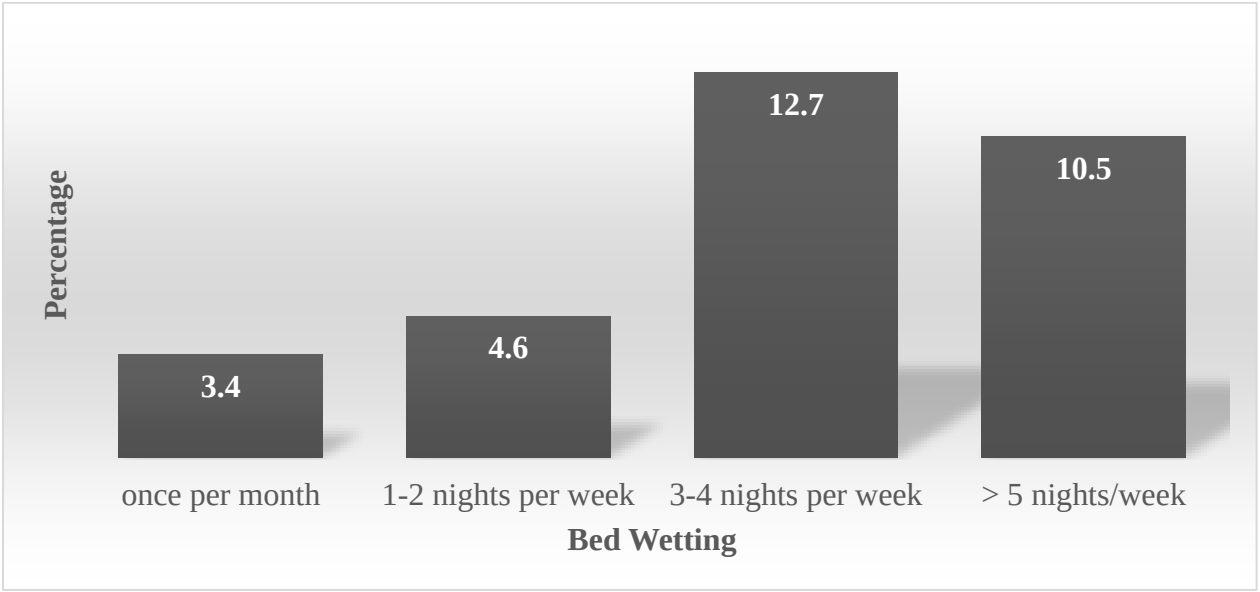


Figure 2: **Frequency of NE**

Study objective 2: Patient sociodemographic characteristics associated with NE among children with SCD:

On multivariable analysis, males were more likely to be enuretic compared to females with an AOR of 1.47, 95% CI 1.14-1.89 (p value 0.005). Younger children aged 6-9 years had 1.92 higher odds for NE compared to older children aged 10-14years 95% CI 1.45-2.53(p value <0.001). Compared to children whose parents had university education, children whose parents had no formal education had 1.41 higher odds for NE, 95% CI 0.15-6.51 (p value 0.31). This association was however not statistically significant. Children raised in a single family had lower odds for NE compared to those raised in a nuclear, AOR 0.82, 95% CI 0.31-2.79, p value 0.6. This association was again not statistically significant. Children in boarding school had lower odds for NE compared to children in day school with AOR of 0.33, 95% CI 0.06-1.13, and p value 0.27. This association was not statistically significant. Second born children were 5.72 times likely to be enuretic compared to children who were firstborns, 95 % CI 4.58-6.86, p value 0.12, but this association was not statistically significant. This is illustrated on table 4.

Table 4: **Univariate and Multivariable Analysis of Sociodemographic Characteristics Associated with NE**

Variable		NE		Crude OR (95% CI)	p value	Adjusted OR (95% CI)	p value
		Yes	No				
Gender	Female	28(23.0%)	94(77.0%)	Ref group		Ref group	
	Male	46(40.3%)	69(60%)	2.24(1.27-3.93)	0.0051	1.47(1.14-1.89)	0.005
Age	10-14yrs	27(19.9%)	109(80.1%)	Ref group		Ref group	
	6-9yrs	47(46.5%)	54(53.5%)	3.51 (1.98-6.24)	< 0.001	1.92 (1.45-2.53)	< 0.001
Parental education	University	2(28.6%)	5(71.4%)	Ref group		Ref group	
	None	20(37.7%)	33(62.3%)	1.60 (0.21-12.07)	0.65	1.41(0.15-6.51)	0.312
	Primary	23(27.7%)	60(72.3%)	3.5936E-09	1	0	0.23
	Secondary	18(28.1%)	46(71.9%)	1.98 (1.6-2.36)	0.09	0.57 (0.24-0.81)	0.99
	College	11(36.7%)	19(63.3%)	2.4166E-09	1	1.9885E-09	0.99
Family Type	Nuclear	54(29.3%)	130(70.7%)	Ref group		Ref group	
	Single parenthood	16(36.4%)	28(63.6%)	0.69 (0.48- 1.82)	0.46	0.82 (0.31-2.79)	0.6
	Other	3(37.5)	5(62.5%)	0.12(0.06-1.43)	0.768	0.04 (0.001-1.13)	0.65
School type	Day	72(31.2%)	152(67.9%)	Ref group		Ref group	
	Boarding	2(15.4%)	11(84.6%)	0.38(0.08-1.78)	0.22	0.33(0.06-1.13)	0.27
Birth order	First born	22(31.9%)	47(68.1%)	Ref group		Ref group	
	Second born	17(25.0%)	51(75.0%)	2.39(1.49-3.29)	0.27	5.72 (4.58-6.86)	0.12
	Third born	18(38.8%)	29(61.7%)	0.96 (0.59-1.33)	0.16	0.55 (0.13-1.27)	0.53
	Fourth born and above	17(65.5%)	36(34.5%)	1.11(0.13-1.52)	0.45	0.98(0.11-1.42)	0.46

Patient clinical characteristics associated with NE among children

On multivariable analysis 3 or more previous hospitalizations was significantly associated with 2.13 higher odds for nocturnal enuresis among children compared to no previous hospitalization with a 95% CI of 0-7.13 (p value < 0.001). Previous history of blood transfusion was associated with 1.21 times higher likelihood of NE compared to children who had no transfusion, 95% CI 0.79-1.86, p value 0.37. This association was not statistically significant. Children whose siblings had history of bed-wetting had 1.61 times higher likelihood for NE compared to children whose siblings did not have similar history with a, 95% CI 0.95-2.71, p value 0.07 however this association was not statistically significant. There was again no significant relationship between NE and parental history of bedwetting although children whose parents had positive history of bedwetting were 6.56 times more likely to have NE compared to their peers. Presence of underlying comorbidities was also not significantly associated with NE among children, with an AOR of 1.10, 95% CI 0.10-11.96, p value 0.9. This is illustrated in table 5.

Table 5: Multivariable Analysis of Clinical Characteristics Associated with NE (n =237)

Variable	Category	Enuresis		COR (95% CI)		AOR (95% CI)	
		Yes	No	Value	p-value	value	P value
Previous blood transfusion	None	107(66.9%)	56(72.7%)	Ref group		Ref group	
	Yes	53(33.1%)	21(27.3%)	1.32(0.73-2.41)	0.36	1.21 (0.79-1.86)	0.37
Previous hospitalizations	None	23(9.7%)	64(27%)	Ref group		Ref group	
	Once	29(12.2%)	67(28.3%)	0.68 (0.24-1.68)	0.65	0.63 (0.19-1.56)	0.35
	Twice	12(5.1%)	24(10.1%)	0.43 (0.17-1.69)	0.65	0.52 (0.13-1.43)	0.19
	Thrice or more	10(4.2%)	08(3.4%)	6.26(1.23,31.88)	<.001	2.13(2.01-7.16)	<.001.
Comorbidities	None	73(31.2%)	161(68.8%)	Ref group		Ref Group	
	Yes	1(33.3%)	2(66.7%)	1.10 (0.99-12.37)	0.9	1.10 (0.10-11.96)	0.9
Siblings' history of bedwetting	None	55(66.3%)	137(33.7%)	Ref group		Ref group	
	Yes	19(85.7%)	26(14.3%)	1.82 (0.93- 3.55)	0.07	1.61(0.95-2.71)	0.075
Parental history of bedwetting	None	73(66.3%)	163(33.7%)	Ref group		Ref group	
	Yes	1(85.7%)	0(14.3%)	6.67 (0.2687-165.77)	0.24	6.56(0.27 - 159.17)	0.23

Study objective 3: Magnitude of psychological problems among children with NE

The cut off score used by the primary investigator (PI) for attention impairment on the PSC tool was ≥ 7 out of 10, for internalizing impairment, ≥ 5 out of 10 and for externalizing impairment was ≥ 7 out 14. The maximum scores attained for attention and internalizing problems was 2 while maximum score attained for externalizing problems was 4. None of the participants attained the minimum score required to define psychological impairment of clinical concern in any of the domains based on the PSC. However, 6.75% of children were identified to have some of the symptoms of attention problems, 9.7% had some symptoms of internalizing problems and 29.96% had some symptoms of externalizing problems. (see Figure 3).

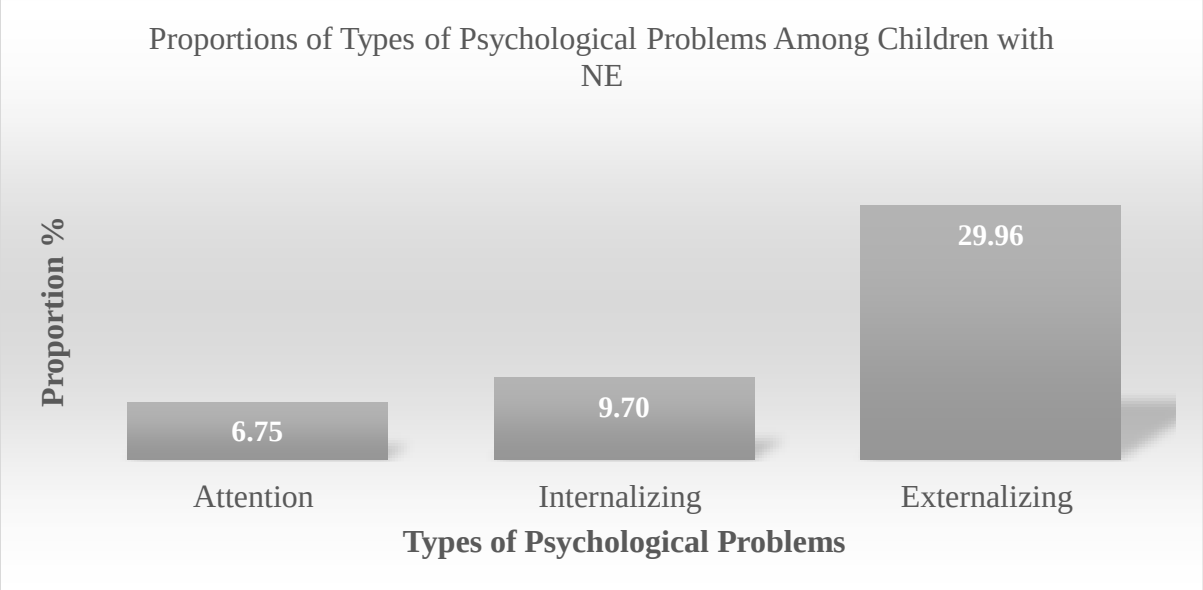


Figure 3: Types of Psychological Problems Among Children with NE

CHAPTER 5: DISCUSSION

This study was the first of its kind in Western Kenya to examine the prevalence of NE and associated psychological problems among children with SCD. NE is the commonest chronic complication in SCD and its presence is associated with psychological problems and impacts the social, academic and family life of affected individuals.

In this study, the mean age of children was 10.23 (SD 2.76) years, which is higher than that reported in the study by Esezobor et al in Nigeria where the mean age of children was 9.9 (SD 3.4) years (46). The prevalence of NE in our study was high at 31.2% similar to that reported in the study by Alhifthy et al in Saudi, who also found a prevalence of 31.2% (47). Prevalence in our study was lower than that reported in the study by Akinyaju et al of 36.8% among children with SCD aged 4 years and above in Nigeria (48). Esezobor et al however demonstrated a higher prevalence of NE in Nigeria of 49.4% in children with SCD aged 5-17 years (46). These differences in prevalence of NE in the current study compared to that reported by Akinyanju and Esezobor could have resulted from differences in age of study participants. The studies by Akinyanju and Esezebor had a wider age range of participants, of 2-20 years and 5-17 years respectively.

In our study males were 1.47 times more likely to be enuretic compared to females. Barakat et al in a study conducted in Philadelphia also found that NE was significantly higher in males (28.2%) compared to females (11%) with SCD (49). Similarly, Bakhtiar et al. reported higher prevalence of NE in boys (10.7%) compared to girls (5.4%) among primary school and preschool children of Khorramabad in 2013 (50). In Iran, the prevalence of enuresis was found to be 1.65-fold greater in boys by Makrani et al (51). However, our findings differed from findings in a study conducted by Gunes et al in Turkey that showed no significant difference in prevalence of NE between boys

and girls (14.3% versus 16. 8%)(52). Similar to Gunes, Alhifthy in Saudi Arabia found no significant relation between NE and gender, and the same finding was also reported in a study done in Taif that showed a prevalence of 7.33% and 8.42% in boys and girls, respectively (47)(53). These last two studies were however conducted among children who did not have SCD.

In comparison to children aged 10–14 years, younger children aged 6–9 years were 1.92 times more likely to be more enuretic. This finding is similar to that by Barakat et al in Philadelphia and Ekinci et al in Turkey, who found that NE was more prevalent in SCD patients who were younger in age (49)(54). In Nigeria, Esezobor et al demonstrated that prevalence of NE declined with increasing age (46).

According to Gumus et al in Turkey, the prevalence of NE was higher among children whose mothers had lower level of education (55). Similarly, Mbinya et al in Kenya demonstrated a significant association of maternal level of education with enuresis whereby lower level of maternal education was associated with higher prevalence of NE among children (56). In Iran, Bahktiar demonstrated significant relationship between maternal education and NE but not paternal education (52). Our study however showed that parental education was not a significant predictor of NE in SCD. Similar to Mbinya et al, children of parents without formal education in our study had the highest risk of NE, AOR of 1.41 (56). Failure to demonstrate a significant association between parental level of education and NE among children in our study could be based on the fact that this was a secondary study objective and we may not have had adequate sample size to assess for associations.

In our study children going to boarding school had lower odds for NE with an AOR of 0.33. Similarly, Gunes et al in Turkey, showed that enuresis was more frequent among children

attending the day-time school compared to boarding school (52). One explanation could be that enuretic children might not want to go to boarding school for fear of shaming and ridicule if NE occurred.

The frequency of hospitalization in the previous year was highest in patients with NE when compared with those without, reaching statistical significance. Likewise, Ekinci et al found that the frequency of previous hospitalization was higher in patients with NE, although the finding was not statistically significant (54). A previous study on SCD in African American children by Gold et al linked frequent hospitalizations with psychiatric and psychosocial problems (57).

There was a higher likelihood of NE among children whose siblings and parents had history of bedwetting compared to their peers at AOR of 1.61 and 6.56 respectively. These associations were however not significant. A possible explanation is that parents might not have been totally honest about previous history of enuresis because of the shame associated with NE, especially in the context of rural African culture. In a study by Ekinci et al, family history of NE was found to be higher at 65.2% in patients with NE when compared to those without NE ($p = 0.030$) (54).

Children with NE in our study reported a wide range of psychological symptoms such as attention deficit, and internalizing and externalizing problems among others, however none of the children attained the psychological impairment threshold as per the screening tool. Similarly, Gunes et al found that the spectrum of psychological impairment disorders in enuretic children ranged from no impairment to 4.3 times higher likelihood for psychological difficulties compared to non-enuretic peers (52). On the contrary, using the Child Behavior Checklist (CBCL) in a study entitled 'Psychosocial And Behavioral Outcomes In Children with SCD And their Healthy Siblings', Gold et al established that both groups did not have clinically significant behavioral problems (57). The

vast difference in prevalence of psychological disorders may be explained by the fact that mental health is not clearly understood particularly in the rural areas where poor mental health is colloquially known as bad brain, ‘wich marach’. As a result, people would tend to not give an accurate answer concerning the state of psychological wellness. Furthermore, cultural biases about psychological wellbeing and people equating it to madness may make people deny it or unable to recognize it. As long as a person is not acting irrationally or running around naked in the village then there is no psychological problem. In addition, respondents are stigmatized against the topic by the framing as a psychological "problem," which causes them to deny it.

Dissemination of Results

The results of this study were initially presented to the UON department of Pediatric Child Health and then the KNH/UON ERC. Following completion of the manuscript, it will then be sent to a scholarly journal for review and approval of publication before being disseminated further for discussion, policy interventions, and advocacy on behalf of kids with SCD.

5.1 Study Strengths and Limitations

Strength

This is the initial study of its kind among SCD patients in Kenya therefore forms a baseline for further research. The study describes the prevalence of NE as well as associated factors in SCD.

Study Limitations

This study was conducted in a hospital setting thus was prone to selection bias. Children who would have been potential participants were excluded by their inability to attend services at the clinic or because they missed over the period of data collection for not having any scheduled clinic

visits. However, this was mitigated by taking sibling history of enuresis as a proxy for the population unable to go to the hospital. Secondly, the design was open to responder bias and recall bias. However, the study addressed recall and responder bias by choosing measurable research questions and selected validated research instruments which this study had done by using the PSC tool. Also, the study was limited by self-reporting.

CHAPTER 6: CONCLUSION AND RECOMMENDATION

6.1 CONCLUSION

1. The prevalence of NE among children with SCD in Homa Bay County Teaching and Referral Hospital is high.

2. Male gender, age and previous history of hospitalization were identified as predictors of NE in children with SCD.

3. Prevalence of associated psychological problems in children SCD in Homa Bay is low.

6.2 RECOMMENDATIONS

Children with SCD should be routinely assessed for NE and appropriate treatment offered specially among boys, young age and children with increased frequency of hospitalization.

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APPENDICES

Appendix 1: Data Collection Instruments

Instruction: Please answer all the questions

Section A: Socio-Demographic Factors

To be filled by parent/guardian

1. Gender
   Male ( ) Female ( )
2. Age ( ) years
3. Number of children in the family ( )
4. Birth order in the family
   1st ( ), 2nd ( ), 3rd ( ), 4th ( ), ≥4th ( )
5. Family Type
   Single Parenthood ( ) Both parents ( ) Other……
6. School Type
   Day school ( ) Boarding ( ) other……
7. Parental Education (Tick appropriate answer)
   Mother Primary ( ) Secondary ( ) College( ) University ( )
   Father Primary ( ) Secondary ( ) College( ) University ( )
   Guardian Primary ( ) Secondary ( ) College( ) University ( )

Section B: Medical Data

To be filled by parent/guardian or adolescent (11-14 years) with the help of the parent/guardian.

<table>
<tr><td>1. Age at diagnosis of SCD</td><td colspan="2"></td><td>5. Do you currently urinate in bed at night</td><td>YES</td><td>NO</td></tr>
<tr><td>2. Frequency of painful crises</td><td colspan="2">Tick the correct one
a) Daily----
b) Weekly----
c) Monthly------</td><td>6. If, NO to #5 above, at what age did you stop wetting the bed</td><td colspan="2"></td></tr>
<tr><td rowspan="2">3. History of previous transfusions</td><td colspan="2" rowspan="2"></td><td rowspan="2">7. If, YES to #5 above, have you ever had ≥ 6 months of nighttime dryness</td><td>YES</td><td>NO</td></tr>
<tr><td></td><td></td></tr>
<tr><td>4. Frequency of hospitalization in last 12 months</td><td colspan="2"></td><td>8. If, YES to #7, at what age did bedwetting recur?</td><td colspan="2">Enter age at recurrence
a) Age----</td></tr>
<tr><td colspan="6">9. Frequency of wet nights per week (Tick the correct one)
No wet night --- 1-2 nights/week --- 3-4 nights/week--- > 5 nights/week----
Once per month----</td></tr>
<tr><td colspan="6">10. Parental attributions for the child’s enuretic episodes (laziness, deep sleeper, SCD)</td></tr>
<tr><td colspan="4" rowspan="2">11. Are you on any medications inducing bedwetting such as (antipsychotics- clozapine; antidepressants- fluoxetine)</td><td>YES</td><td>NO</td></tr>
<tr><td></td><td></td></tr>
<tr><td rowspan="2">12. Do you have any other medical conditions other than SCD</td><td>YES</td><td>NO</td><td rowspan="2">13. Sibling’s history of bed wetting</td><td>YES</td><td>NO</td></tr>
<tr><td></td><td></td><td></td><td>YES</td><td>NO</td></tr>
</table>

			14. Parental history of bedwetting		

Section C: Psychological Health of children

I. Pediatric Symptom Checklist (PSC) (To be filled by Parent/ Guardian)

Please mark under the heading that best describes your child:

		Never	Sometimes	Often
1.Complains of aches and pains	1	_____	_____	_____
2.Spends more time alone	2	_____	_____	_____
3.Tires easily, has little energy	3	_____	_____	_____
4.Fidgety, unable to sit still	4	_____	_____	_____
5.Has trouble with teacher	5	_____	_____	_____
6.Less interested in school	6	_____	_____	_____
7.Acts as if driven by a motor	7	_____	_____	_____
8.Daydreams too much	8	_____	_____	_____
9.Distracted easily	9	_____	_____	_____
10.Is afraid of new situations	10	_____	_____	_____
11.Feels sad, unhappy	11	_____	_____	_____
12.Is irritable, angry	12	_____	_____	_____
13.Feels hopeless	13	_____	_____	_____
14.Has trouble concentrating	14	_____	_____	_____
15.Less interested in friends	15	_____	_____	_____
16.Fights with other children	16	_____	_____	_____
17.Absent from school	17	_____	_____	_____
18.School grades dropping	18	_____	_____	_____
19.Is down on him or herself	19	_____	_____	_____
20.Visits the doctor with doctor finding nothing wrong	20	_____	_____	_____
21.Has trouble sleeping	21	_____	_____	_____
22.Worries a lot	22	_____	_____	_____
23.Wants to be with you more than before	23	_____	_____	_____
24.Feels he or she is bad	24	_____	_____	_____
25.Takes unnecessary risks	25	_____	_____	_____

26.Gets hurt frequently	26	_____	_____	_____
27.Seems to be having less fun	27	_____	_____	_____
28.Acts younger than children his or her age	28	_____	_____	_____
29.Does not listen to rules	29	_____	_____	_____
30.Does not show feelings	30	_____	_____	_____
31.Does not understand other people's feelings	31	_____	_____	_____
32.Teases others	32	_____	_____	_____
33.Blames others for his or her troubles	33	_____	_____	_____
34.Takes things that do not belong to him or her	34	_____	_____	_____
35.Refuses to share	35	_____	_____	_____

Total score_____

II. Pediatric Symptom Checklist—Youth Report (Y-PSC)
To be filled by adolescents 11 years and above.

Please mark under the heading that best fits you:

		Never	Sometimes	Often
1.Complain of aches and pains	1	_____	_____	_____
2.Spend more time alone	2	_____	_____	_____
3.Tire easily, little energy	3	_____	_____	_____
4.Fidgety, unable to sit still	4	_____	_____	_____
5.Have trouble with teacher	5	_____	_____	_____
6.Less interested in school	6	_____	_____	_____
7.Act as if driven by a motor	7	_____	_____	_____
8.Daydream too much	8	_____	_____	_____
9.Distract easily	9	_____	_____	_____
10.Are afraid of new situations	10	_____	_____	_____
11.Feel sad, unhappy	11	_____	_____	_____
12.Are irritable, angry	12	_____	_____	_____
13.Feel hopeless	13	_____	_____	_____
14.Have trouble concentrating	14	_____	_____	_____
15.Less interested in friends	15	_____	_____	_____
16.Fight with other children	16	_____	_____	_____
17.Absent from school	17	_____	_____	_____
18.School grades dropping	18	_____	_____	_____
19. Down on yourself	19	_____	_____	_____
20.Visit doctor with doctor finding nothing wrong	20	_____	_____	_____
21.Have trouble sleeping	21	_____	_____	_____
22.Worry a lot	22	_____	_____	_____
23.Want to be with parent more than before	23	_____	_____	_____
24.Feel that you are bad	24	_____	_____	_____
25.Take unnecessary risks	25	_____	_____	_____
26.Get hurt frequently	26	_____	_____	_____
27.Seem to be having less fun	27	_____	_____	_____
28.Act younger than children your age	28	_____	_____	_____
29.Do not listen to rules	29	_____	_____	_____

30.Do not show feelings	30	_____	_____	_____
31.Do not understand other people's feelings	31	_____	_____	_____
32.Tease others	32	_____	_____	_____
33.Blame others for your troubles	33	_____	_____	_____
34.Take things that do not belong to you	34	_____	_____	_____
35.Refuse to share	35	_____	_____	_____

Total score_____

Appendix 2: Consent Forms

CONSENTING PROCEDURE

Participants shall be taken through the purpose of the study, procedures employed, voluntary study participation, potential benefits and risks, and participants' choice to withdraw at any time from the study without any consequences. The participants would seek clarifications on whatever aspects of the study shall be unclear to them. Both verbal and written approval will be sought from the appropriate participants before the issuing the questionnaires.

Appendix 2a: Parental Consent (English Version)

Title of Study: Prevalence and Effect of Nocturnal Enuresis on Childhood Psychological Health among Children with SCD aged 6-14yrs Attending Healthcare Services at Homabay County Teaching and Referral Hospital

Principal Investigator \ and institutional affiliation: Dr. Maria Ogaya Gerald**,** Department of Pediatrics and Child Health, University of Nairobi

Co-Investigators and institutional affiliation: Dr. Jacquie Narotso Oliwa, Dr. Beatrice Mutai, Department of Pediatrics and Child Health, University of Nairobi

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not your child should participate in the study. Feel free to ask any questions about the purpose of the research, what happens if your child participates in the study, the possible risks and benefits, the rights of your child as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide if you want your child to be in the study or not. This process is called 'informed consent'. Once you understand and agree for your child to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in medical research: i) Your child decision to participate is entirely voluntary ii) You child may withdraw from the study at any time without necessarily giving a reason for his/her withdrawal iii) Refusal to participate in the research will not affect the services your child is entitled to in this health facility or other facilities.

May I continue? YES / NO

For children below 18 years of age we give information about the study to parents or guardians. We will go over this information with you and you need to give permission in order for your child to participate in this study. We will give you a copy of this form for your records.

If the child is at an age (7 years and above) that he/she can appreciate what is being done then he/she will also be required to agree to participate in the study after being fully informed).

WHAT IS THE PURPOSE OF THE STUDY?

The researchers listed above are interviewing individuals with Sickle Cell Disease (SCD) attending health care services at the Homabay County Teaching and Referral Hospital (HBCTRH) SCD clinic. The purpose of the study is to obtain information on prevalence and effect of nocturnal enuresis on childhood psychological health among children with SCD aged 6-14 years receiving

healthcare services at Homabay County Teaching and Referral Hospital. Participants in this research study will be asked questions about bedwetting and their mental health status. There will be approximately 250 participants in this study randomly chosen. This study is being conducted in this facility with permission from the management of the hospital. We are asking for your consent to consider your child to participate in this study.

WHAT WILL HAPPEN IF YOU DECIDE YOU WANT YOUR CHILD TO BE IN THIS RESEARCH STUDY?

If you agree for your child to participate in this study, the following things will happen:

You will be given a questionnaire to fill by a trained research assistant in a private area where you feel comfortable answering questions before or after you are attended to as you wait in line. This will last approximately 10 minutes. The questionnaire will cover topics such as history of SCD illness, history of bedwetting, and mental health issues _.

You will be informed about the results.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include negative score on the Pediatric symptom checklist warranting referral to a mental health specialist.

ARE THERE ANY RISKS, HARMS, DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify your child in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting confidentiality can be absolutely secure so it is still possible that someone could find out your child was in this study and could find out information about your child.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse to answer to questions in the questionnaire.

It may be embarrassing for you to have history of bedwetting. We will do everything we can to ensure that responses are done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

There is no physical harm that will be inflicted on you during this process since it does not involve an invasive procedure, but there are minimal risks to you for participating in this study. There is a possibility that some of the questions you will be asked may make you uncomfortable. Should this happen, feel free to inform the researcher.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

We will refer your child to a hospital for care and support if necessary. Also, the information you provide will help us better understand the prevalence of nocturnal enuresis in SCD and the magnitude of psychological problems among children with SCD with enuresis thus improve care for such children. This information is a major contribution to science and academia.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Being in this study will not cost you anything.

IS THERE REIMBURSEMENT FOR PARTICIPATING IN THIS STUDY?

There is no reimbursement for participating in this study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about your child participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your child's rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

If you have further questions or concerns about your child participating in this study, please call or send a text message to the researcher, Dr Maria Ogaya Gerald, University of Nairobi, College of Health Sciences Department of Paediatrics and Child Health. Mobile number 0727361366; email – ogayag11@gmail.com or the lead supervisor Dr. Jacquie Narotso Oliwa, University of Nairobi, College of Health Sciences Department of Paediatrics and Child Health, mobile number 0722854812 email joliwa@uonbi.ac.ke. You may also contact the Chairperson of Ethics and Research Committee, KNH/UON through the following address: University of Nairobi, College of Health Sciences, P. O. Box 19676-00202 Nairobi or Tel no. +2542726300 Ext 44102.

WHAT ARE YOUR OTHER CHOICES?

Your decision to have your child participate in this research is voluntary. You are free to decline or withdraw participation of your child in the study at any time without injustice or loss of benefits. Just inform the study staff and the participation of your child in the study will be stopped. You do not have to give reasons for withdrawing your child if you do not wish to do so. Withdrawal of your child from the study will not affect the services your child is otherwise entitled to in this health facility or other health facilities.

CONSENT FORM (STATEMENT OF CONSENT)

The person being considered for this study is unable to consent for him/herself because he or she is a minor (a person less than 18 years of age). You are being asked to give your permission to include your child in this study.

Parent/guardian statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered by him or her in a language that I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation and that of my child in this study is voluntary and that I may choose to withdraw it any time.

I understand that all efforts will be made to keep information regarding me and my child's personal identity confidential.

By signing this consent form, I have not given up my child's legal rights as a participant in this research study.

I voluntarily agree to my child's participation in this research study:
Yes **No**

I agree to provide contact information for follow-up: Yes No

Parent/Guardian signature /Thumb stamp: _____ Date _____

Parent/Guardian printed name: _____Contact_____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his/her consent.

Printed Name: _____ **Date**: _____

Signature: _____

Role in the study: _____ *[i.e., study staff who explained informed consent form.]*

Appendix 2b: Child Assent Form (English Version)

Project Title: **Prevalence and Effect of Nocturnal Enuresis on Childhood Psychological Health among Children with SCD aged 6-14yrs Attending Healthcare Services at Homabay County Teaching and Referral Hospital**

Investigator(s): Dr. Maria Ogaya Gerald, Department of Pediatrics and Child Health, University of Nairobi

Co-Investigators and institutional affiliation: Dr. Jacquie Narotso Oliwa, Dr. Beatrice Mutai, Department of Pediatrics and Child Health, University of Nairobi

We are doing a research study about bedwetting and the effect on psychological health in children 6-14 years with SCD.

Permission has been granted to undertake this study by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN ERC Protocol No. _____)

This research study is a way to learn more about people. At least 250 children will be participating in this research study with you.

If you decide that you want to be part of this study, you will be asked to fill in a list of questions about your mental health that will take about 10 minutes.

There are some things about this study you should know. These include being uncomfortable to disclose whether you wet your bed at night out of fear and shame but you should know we are not out to embarrass you.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be money or medicines or sweets.

When we are finished with this study, we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

_____(Signature/Thumb stamp) _____ (Date)

Appendix 3a: Parental Consent (Swahili Version)

RIDHAA YA MZAZI

Kichwa cha Utafiti: Kuenea na Madhara ya Enuresis ya Usiku juu ya Afya ya Kisaikolojia ya Utoto miongoni mwa Watoto wenye SCD wenye umri wa miaka 6-14 Wanaohudhuria Huduma za Afya katika Hospitali ya Kufundisha na Rufaa ya Kaunti ya Homabay.

Mpelelezi Mkuu \ na uhusiano wa kitaasisi: Dk. Maria Ogaya Gerald, Idara ya Madaktari wa Watoto na Afya ya Mtoto, Chuo Kikuu cha Nairobi

Wachunguzi-wenza na uhusiano wa kitaasisi: Dkt. Jacquie Narotso Oliwa, Dkt. Beatrice Mutai, Idara ya Madaktari wa Watoto na Afya ya Mtoto, Chuo Kikuu cha Nairobi.

Utangulizi:

Ningependa kukuambia kuhusu utafiti unaofanywa na watafiti walioorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa utakayohitaji ili kukusaidia kuamua kama mtoto wako atashiriki au la. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, nini kitatokea ikiwa mtoto wako atashiriki katika utafiti, hatari na manufaa yanayoweza kutokea, haki za mtoto wako kama mtu wa kujitolea, na jambo lingine lolote kuhusu utafiti au fomu hii ambayo sivyo. wazi. Wakati tumejibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kama ungependa mtoto wako awe kwenye utafiti au la. Utaratibu huu unaitwa 'ridhaa iliyoarifiwa'. Ukishaelewa na kukubali mtoto wako awe kwenye utafiti, nitakuomba utie sahihi jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wa mtoto wako kushiriki ni wa hiari kabisa ii) Mtoto wako anaweza kujiondoa kwenye utafiti wakati wowote bila ya kueleza sababu ya kujiondoa iii) Kukataa. kushiriki katika utafiti hakutaathiri huduma ambazo mtoto wako anastahili kupata katika kituo hiki cha afya au vituo vingine.

Naweza kuendelea? NDIO LA

Kwa watoto walio chini ya umri wa miaka 18 tunatoa taarifa kuhusu utafiti kwa wazazi au walezi. Tutapitia maelezo haya nawe na unahitaji kutoa ruhusa ili mtoto wako ashiriki katika utafiti huu. Tutakupa nakala ya fomu hii kwa rekodi zako.

Ikiwa mtoto yuko katika umri (miaka 7 na zaidi) kwamba anaweza kufahamu kinachofanyika basi atahitajika pia kukubali kushiriki katika utafiti baada ya kufahamishwa kikamilifu).

NINI KUSUDI LA MASOMO HAYO?

Watafiti walioorodheshwa hapo juu wanawahoji watu ambao_wana SCD na wanahudhuria huduma za afya katika kliniki ya HBCTRH SCD. Madhumuni ya utafiti huu ni kupata taarifa kuhusu kuenea na athari za enuresis ya usiku kwa afya ya kisaikolojia ya watoto miongoni mwa watoto wenye SCD wenye umri wa miaka 6-14 wanaopokea huduma za afya katika Hospitali ya Kufundisha na Rufaa ya Kaunti ya Homabay. Washiriki katika utafiti huu wataulizwa maswali kuhusu kukojoa kitandani na hali yao ya afya ya akili. Kutakuwa na takriban washiriki 250 katika utafiti huu waliochaguliwa bila mpangilio. Utafiti huu unafanywa katika kituo hiki kwa idhini kutoka kwa usimamizi wa hospitali. Tunaomba idhini yako ya kuzingatia mtoto wako kushiriki katika utafiti huu.

JE, NINI KITAENDELEA UKIAMUA KUTAKA MTOTO WAKO AWE KATIKA UTAFITI HUU?

Ukikubali mtoto wako kushiriki katika utafiti huu, mambo yafuatayo yatafanyika:

Utapewa dodoso la kujaza na mtafiti msaidizi aliyefunzwa katika eneo la faragha ambapo unahisi vizuri kujibu maswali kabla au baada ya kuhudumiwa unaposubiri kwenye foleni. Hii itachukua takriban dakika 10. Hojaji itashughulikia mada kama vile historia ya ugonjwa wa SCD, historia ya kukojoa kitandani, na masuala ya afya ya akili.

Utajulishwa kuhusu matokeo.

Tutaomba nambari ya simu ambapo tunaweza kuwasiliana nawe ikibidi. Ukikubali kutoa maelezo yako ya mawasiliano, yatatumiwa na watu wanaofanya kazi katika utafiti huu pekee na kamwe hayatashirikiwa na wengine. Sababu kwa nini tunaweza kuhitaji kuwasiliana nawe ni pamoja na alama hasi kwenye orodha ya dalili za watoto inayothibitisha rufaa kwa mtaalamu wa afya ya akili.

JE, KUNA HATARI, MADHARA, FURAHA ZINAZOHUSIANA NA UTAFITI HUU?

Utafiti wa kimatibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili. Jitihada zinapaswa kuwekwa kila wakati ili kupunguza hatari. Hatari moja inayoweza kutokea ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unachotuambia kama siri iwezekanavyo. Tutatumia nambari ya msimbo kumtambua mtoto wako katika hifadhidata ya kompyuta iliyolindwa na nenosiri na tutaweka rekodi zetu zote za karatasi kwenye kabati ya faili iliyofungwa. Hata hivyo, hakuna mfumo wa kulinda usiri unaoweza kuwa salama kabisa kwa hivyo bado kuna uwezekano kwamba mtu anaweza kujua mtoto wako alikuwa katika utafiti huu na kupata taarifa kuhusu mtoto wako.

Pia, kujibu maswali katika mahojiano kunaweza kuwa na wasiwasi kwako. Ikiwa kuna maswali yoyote ambayo hutaki kujibu, unaweza kuyaruka. Una haki ya kukataa kujibu maswali katika dodoso.

Inaweza kuwa aibu kwako kuwa na historia ya kukojoa kitandani. Tutafanya kila tuwezalo kuhakikisha kuwa majibu yanafanywa kwa faragha. Zaidi ya hayo, wafanyakazi wote wa utafiti na wahojaji ni wataalamu walio na mafunzo maalum katika mitihani/mahojiano haya.

Hakuna madhara ya kimwili ambayo yataletwa kwako wakati wa mchakato huu kwa kuwa hauhusishi utaratibu wa vamizi, lakini kuna hatari ndogo kwako kwa kushiriki katika utafiti huu. Kuna uwezekano kwamba baadhi ya maswali utakayoulizwa yanaweza kukukosesha raha. Hili likitokea, jisikie huru kumfahamisha mtafiti.

JE, KUNA FAIDA YOYOTE KUWA KATIKA UTAFITI HUU?

Tutampeleka mtoto wako hospitali kwa matunzo na usaidizi ikibidi. Pia, taarifa utakazotoa zitatusaidia kuelewa zaidi kuenea kwa enuresis usiku katika SCD na ukubwa wa matatizo ya kisaikolojia miongoni mwa watoto wenye SCD wenye enuresis hivyo kuboresha huduma kwa watoto hao. Habari hii ni mchango mkubwa kwa sayansi na taaluma.

JE, KUWA KWENYE SOMO HILI LITAKUGHARIMU LOLOTE?

Kuwa katika utafiti huu hakutakugharimu chochote.

JE, KUNA MALIPO YA KUSHIRIKI KATIKA SOMO HILI?

Hakuna fidia kwa kushiriki katika utafiti huu.

VIPI IKIWA UNA MASWALI BAADAYE?

Ikiwa una maswali zaidi au wasiwasi kuhusu mtoto wako kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi wa maandishi kwa wafanyikazi wa utafiti kupitia nambari iliyotolewa chini ya ukurasa huu.

Kwa maelezo zaidi kuhusu haki za mtoto wako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu/Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi Nambari 2726300 Ext. 44102 barua pepe uonknh_erc@uonbi.ac.ke.

Wafanyikazi wa utafiti watakurudishia malipo yako kwa nambari hizi ikiwa simu ni ya mawasiliano yanayohusiana na masomo.

Ikiwa una maswali zaidi au wasiwasi kuhusu mtoto wako kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi kwa mtafiti, Dkt Maria Ogaya Gerald, Chuo Kikuu cha Nairobi, Chuo cha Sayansi ya Afya Idara ya Magonjwa ya Watoto na Afya ya Mtoto. Namba ya simu 0727361366; barua pepe - ogayag11@gmail.com au msimamizi mkuu Dkt. Jacquie Narotso Oliwa, Chuo Kikuu cha Nairobi, Chuo cha Sayansi ya Afya Idara ya Madaktari wa Watoto na Afya ya Mtoto, nambari ya simu 0722854812 barua pepe joliwa@uonbi.ac.ke. Unaweza pia kuwasiliana na Mwenyekiti wa Kamati ya Maadili na Utafiti, KNH/UON kupitia anwani ifuatayo: Chuo Kikuu cha Nairobi, Chuo cha Sayansi ya Afya, P. O. Box 19676-00202 Nairobi au Nambari ya Simu. +2542726300 Ext 44102.

UCHAGUZI WAKO MENGINE NI GANI?

Uamuzi wako wa kumfanya mtoto wako ashiriki katika utafiti huu ni wa hiari. Uko huru kukataa au kuondoa ushiriki wa mtoto wako katika utafiti wakati wowote bila dhuluma au hasara ya faida.

Wajulishe tu wafanyakazi wa utafiti na ushiriki wa mtoto wako katika utafiti utasitishwa. Sio lazima utoe sababu za kumwondoa mtoto wako ikiwa hutaki kufanya hivyo. Kuondolewa kwa mtoto wako kutoka kwa utafiti hakutaathiri huduma ambazo mtoto wako anastahili kupata katika kituo hiki cha afya au vituo vingine vya afya.

FOMU YA RIDHAA (TAARIFA YA RIDHAA)

Mtu anayezingatiwa kwa ajili ya utafiti huu hawezi kujikubali kwa sababu yeye ni mtoto mdogo (mtu chini ya miaka 18). Unaombwa kutoa idhini yako ya kujumuisha mtoto wako katika utafiti huu.

Taarifa ya mzazi/mlezi

Nimesoma fomu hii ya idhini au nimesomewa maelezo. Nimepata nafasi ya kujadili utafiti huu na mshauri wa utafiti. Nimejibu maswali yangu kwa lugha ninayoielewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa nitapewa nakala ya fomu hii ya idhini baada ya kuitia saini. Ninaelewa kuwa ushiriki wangu na wa mtoto wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kuuondoa wakati wowote.

Ninaelewa kuwa juhudi zote zitafanywa ili kuweka maelezo kunihusu na ya mtoto wangu kuwa siri.

Kwa kutia saini fomu hii ya idhini, sijaacha haki za kisheria za mtoto wangu kama mshiriki katika utafiti huu.

Ninakubali kwa hiari ushiriki wa mtoto wangu katika utafiti huu:

Ndio la

Ninakubali kutoa maelezo ya mawasiliano kwa ufuatiliaji: Ndiyo Hapana

Sahihi ya Mzazi/Mlezi /Muhuri wa kidole gumba: _____ Tarehe _____

Jina lililochapishwa la Mzazi/Mlezi: _____

Kauli ya mtafiti

Mimi, aliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki ameelewa na ametoa ridhaa yake akijua.

Jina Lililochapishwa: _____ Tarehe: _____

Sahihi: _____

Jukumu katika utafiti: _____ [i.e. wafanyikazi wa utafiti ambao walielezea fomu ya idhini iliyo na taarifa.]

Appendix 3b: Child Assent Form (Swahili Version)

Fomu ya Kuridhwa kwa Mtoto

Kichwa cha Mradi: Kuenea na Madhara ya Enuresis ya Usiku kwa Afya ya Kisaikolojia ya Utoto miongoni mwa Watoto Wenye SCD wenye umri wa miaka 6-14 Wanaohudhuria Huduma za Afya katika Hospitali ya Kufundisha na Rufaa ya Kaunti ya Homabay.

Wachunguzi: Dkt. Maria Ogaya Gerald, Idara ya Madaktari wa Watoto na Afya ya Mtoto, Chuo Kikuu cha Nairobi
Wachunguzi-wenza na uhusiano wa kitaasisi: Dkt. Jacquie Narotso Oliwa, Dkt. Beatrice Mutai, Idara ya Madaktari wa Watoto na Afya ya Mtoto, Chuo Kikuu cha Nairobi

Tunafanya utafiti kuhusu kukojoa kitandani na athari kwa afya ya kisaikolojia kwa watoto wa miaka 6-14 walio na SCD.

Ruhusa imetolewa kufanya utafiti huu na Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi (KNH-UoN Itifaki ya ERC Na. _____)

Utafiti huu ni njia ya kujifunza zaidi kuhusu watu. Angalau watoto 250 watashiriki nawe katika utafiti huu.

Ukiamua kuwa ungependa kuwa sehemu ya utafiti huu, utaombwa kujaza orodha ya maswali kuhusu afya yako ya akili ambayo itachukua kama dakika 10.

Kuna baadhi ya mambo kuhusu utafiti huu unapaswa kujua. Hizi ni pamoja na kukosa raha kufichua ikiwa unalowesha kitanda chako usiku kwa woga na aibu lakini unapaswa kujua hatuko tayari kukuaibisha.

Sio kila mtu atakayeshiriki katika utafiti huu atafaidika. Faida inamaanisha kuwa kitu kizuri kinatokea kwako. Tunafikiri manufaa haya yanaweza kuwa pesa au dawa au peremende.

Tukimaliza na somo hili, tutaandika ripoti kuhusu kile tulichojifunza. Ripoti hii haitajumuisha jina lako au kwamba ulikuwa kwenye utafiti.

Si lazima uwe katika utafiti huu ikiwa hutaki kuwa. Ukiamua kuacha baada ya sisi kuanza, hiyo ni sawa pia. Wazazi wako wanajua kuhusu utafiti pia.

Ukiamua ungependa kuwa katika utafiti huu, tafadhali saini jina lako.

Mimi, _____, nataka kuwa katika utafiti huu.

_____(Sahihi/Muhuri wa kidole gumba)
_____ (Tarehe)

Appendix 4: Work Plan

Table 9 below shows the study timelines.

No	Activity	2021		2022												2023			
		N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M-J	
1	Concept and proposal development and presentation																		
2	Proposal submission for ethical review and approval																		
3	Data Collection																		
4	Data analysis and reporting																		
5	Thesis writing and defense																		
7	Final submission of thesis and examination																		

Appendix 5: Budget

Table 2 below shows the study budget

No	Category	Description	Qty	Unit cost	Total (KSh)
1	Proposal development	Printing and copies	4	500	2,000.00
		Internet and airtime costs	4	2,000.00	8,000.00
2	Transport and Accommodation	To and from site	6	15,000.00	90,000.00
3	Data collection	Stationery	5	3,000.00	15,000.00
		Training Research assistants	1	32,000.00	32,000.00
		Allowance for RA for 4 months	4	5,000.00	20,000.00
4	Data entry	Data entry clerk	1	10,000.00	10,000.00
5	Data analysis	Statistician	1	30,000.00	30,000.00
6	Thesis write up	Printing drafts	5	1,000.00	5,000.00
		Printing thesis	5	1,000.00	5,000.00
7	Contingency	10% Contingency			9800.00
Total					226,800.00

Appendix 6: Turnitin Report

PREVALENCE OF NOCTURNAL ENURESIS AND ASSOCIATED PSYCHOLOGICAL PROBLEMS AMONG CHILDREN WITH SICKLE CELL DISEASE AGED 6-14 YEARS ATTENDING HEALTHCARE SERVICES AT HOMABAY COUNTY TEACHING AND REFERRAL HOS

ORIGINALITY REPORT

14%	11%	8%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.ncbi.nlm.nih.gov Internet Source	2%
2	ncdak.org Internet Source	2%
3	erepository.uonbi.ac.ke Internet Source	2%
4	SARA SYTSMA JORDAN. "Nocturnal Enuresis and Psychosocial Problems in Pediatric Sickle Cell Disease and Sibling Controls", Journal of Developmental & Behavioral Pediatrics, 12/2005 Publication	1%
5	www.science.gov Internet Source	1%
6	Jerlym S Porter, Andrew J Paladino, Kathryn Russell, Rebecca Rupff et al. "Nocturnal	<1%

Appendix 7: KNH-UON ERC Approval

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/391

3rd October, 2022

Dr. Maria Ogaya Gerald
Reg.No. H58/37408/2020
Dept. of Paediatrics & Child Health
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL P.O. Box 20723 - 00202 NAIROBI KNH/UoN-ERC 03 OCT 2022

Dear Dr. Gerald,

RESEARCH PROPOSAL: PREVALENCE OF NOCTURNAL ENURESIS AND MAGNITUDE OF ASSOCIATED PSYCHOLOGICAL PROBLEMS AMONG CHILDREN WITH SICKLE CELL DISEASE AGED 6-14 YEARS ATTENDING HEALTHCARE SERVICES AT HOMABAY COUNTY TEACHING AND REFERRAL HOSPITAL (P225/03/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P225/03/2022.** The approval period is 3rd October 2022 – 2nd October 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept of Paediatrics & Child Health, UoN
Supervisors: Dr. Jacqueline N Oliwa, Dept of Paediatrics & Child Health, UoN
Dr. Beatrice Mutai, Dept of Paediatrics & Child Health, UoN