FREQUENCY AND FACTORS ASSOCIATED WITH HOSPITALISATION OF CHILDREN WITH SICKLE CELL ANAEMIA IN KENYATTA NATIONAL HOSPITAL AND GERTRUDE'S CHILDREN'S HOSPITAL

A CROSSECTIONAL STUDY

BY

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DECLARATION

I the undersigned, declare that this dissertation is my original work. It has not been presented to any other university, college or institution for the purpose of academic credit

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TABLE OF CONTENTS

DECLARATION i
ACKNOWLEDGMENTS ii
TABLE OF CONTENTS iii
LIST OF TABLES vi
LIST OF SYMBOLS, ABBREVIATIONS AND NOMENCLATURE vii
ABSTRACT viii
CHAPTER ONE 1
1.1 Introduction 1
CHAPTER TWO:LITERATURE REVIEW 4
2.1 Introduction 4
CHAPTER THREE:STUDY JUSTIFICATION, RESEARCH QUESTION AND OBJECTIVES. 8
3.1 Justification 8
3.2 Study Question 8
3.3 Objectives 8
3.3.1 Primary Objective 8
3.3.2 Secondary Objectives 9
CHAPTER FOUR: METHODOLOGY 10
4.1 Study Design 10
4.2 Study Area 10
4.3 Study Population 10
4.3.1 Inclusion criteria: 11
4.3.2 Exclusion criteria 11
4.4 Sample Size 11
4.5 Patient recruitment 12
4.6 Study Instruments 12
4.7 Ethical Considerations 12
4.8 Data Collection 13
4.9 Data Analysis 13

CHAPTER FIVE: RESULTS 16
5.1 Introduction 16
5.2 Child Demographic Characteristics 16
5.3 Frequency of hospitalization in the past one year 17
5.3.1 Nutritional status of children 19
CHAPTER SIX:DISCUSSION, CONCLUSION AND RECOMMENDATIONS 26
6.1 Discussion 26
6.2 Study limitations 28
6.3 Conclusion 29
6.4 Recommendations 29
REFERENCES 30
APPENDICES 34
Appendix I: Letter to Gertrude's hospital 34
Appendix II: Questionnaire 36
Appendix III: Consent form 44
Appendix IV: Assent form 51
Appendix V: Budget 62
Appendix VI: Work schedule 63

LIST OF FIGURES

Figure 4.1: Flow Chart depicting how the study will be conducted 15
Figure 5.1: Frequency of hospitalization in the last one year. 18
Figure 5.2: Frequency of admission categorized into two groups, ≤ 3 times and > 3 in one year. (Categorized into two groups based on disease severity) 19

LIST OF TABLES

Table5.1: Child demographics 17
Table5.2: Nutritional status of children. 20
Table 5.3 Care giver factor 21
Table 5.4: Family sickle cell characteristics 22
Table 5.5 Quality of care factors 23
Table 5.6: Factors associated with frequent hospitalization 24

LIST OF SYMBOLS, ABBREVIATIONS AND NOMENCLATURE

GGCH	Gertrude's Garden Children's Hospital
Hb	Hemoglobin oxygen carrying pigment contained in the red blood cells.
Hb F	Hemoglobin F
Hb S	Hemoglobin S
HU	Hydroxyurea also known as hydroxycarbamide.
KNH	Kenyatta National Hospital
Paed	Paediatrics
RCT	Randomized Controlled Trial
SCA	Sickle Cell Anaemia
SCD	Sickle Cell Disease
WHZ	Weight height Z score
WAZ	Weight age Z score
HAZ	Height age Z score
>	More than
<	Less than
Kshs	Kenya Shillings
ACS	Acute chest syndrome
CI	Confidence interval
Dept	Department
SD	Standard deviation
CVA	Cerebro vascular accident.
WHO	World Health Organization

DEFINITION OF TERMS

Severe Sickle Cell Anemia: having more than three episodes of hospitalization in one year (2)

ABSTRACT

Background: Sickle cell disease (SCD) is common in Sub-Saharan Africa in areas where plasmodium falciparum malaria is endemic and affects 3% of births. SCD is a disorders of red blood cells which sickle when deoxygenated. Majority of the patients with sickle cell anaemia are frequently admitted in a year, while some of the patients do stay a whole year without being admitted. A study to determine the frequency and the key factors associated with hospitalization of patients with sickle cell disease may inform strategies to improve care and therefore improve health outcome and quality of life.

Objective: The study's main objective was to determine the frequency of hospitalization among under 18-year-old children in one year with SCA at Kenyatta National Hospital and Gertrude's Children Hospital. The study also aimed to determine the factors associated with frequency of hospitalization of patients with SCA at KNH and GGCH.

Participants and Methods: A cross-sectional study design was employed to determine frequency of hospitalization in one year and factors associated with frequent hospitalization. The participants in the study were children less or equal to 18 years old with a diagnosis of sickle cell anemia confirmed by serum Hb electrophoresis and attending clinic and admitted in the wards at the Kenyatta National Hospital and Gertrude's Children Hospital. An interviewee administered questionnaire was used to collect data which was analyzed to find frequency of hospitalization and factors associated with frequent hospitalization. Descriptive analysis was done to explain summary values and characteristics of participants using means and medians for continuous variables and proportions for categorical data. Binary logistic regression analysis was done to determine caregiver quality of health factors and child factors associated with increased risk of hospitalization. All variables with an association with the outcome variable with p value ≤ 0.05 were included in multivariate analysis. Odds ratio with 95 % CI and p-values were used to decide whether the independent variables included in the multivariate analysis were statistically significant or not in relation with outcome variable (number of hospitalizations in the past 1 year).

Results: A total of 161 children participated in the study with a mean age of 7.7(SD 4.4) There was high rate of hospitalization with 76% of the children with SCA having at least an episode in the last one year. Risk factors that were statistically significant with frequent

hospitalization were age at hydroxyurea use, children in post primary level of education, being female and lack of follow up.

Conclusion: This study shows there is high frequency of hospitalization in children with sickle cell anemia between 0 years and 18 years. Follow up remains an important aspect in the care of children with SCA. Children in post primary level of education need more attention.

Key words: Sickle Cell Anaemia

CHAPTER ONE

1.1 Introduction

Sickle cell disease is an abnormality of red blood cell which sickle when deoxygenated. It was first reported in a black dental student in 1910 by Herrick (5). Sickle cell disease is a point mutation genetic defect which substitutes glutamic acid of the β-globin gene in codon 6 for valine that results in the formation of hemoglobin S (HbS). Patients who are homozygous (HbSS) have sickle cell anaemia. There are other several heterozygous form of haemoglobin mutations. Sickle cell anemia is the commonest form.

This abnormal haemoglobin polymerizes causing the red cell to become rigid fragile and sickle. The sickle cells clump together to obstruct blood vessels and destroy endothelial cell function. This results in tissue hypoxia and complications.

The highest frequency of sickle cell anemia (SCA) is found in tropical regions, particularly Sub-Saharan Africa, India and the Middle-East and is associated with very high child mortality. The World Health Organization has declared SCA a public health priority. Every year 300,000 children are born with sickle cell anemia, 75% of the births occur in Sub-Saharan Africa (6) and it is estimated that 50–80% of these patients will die before adulthood (7). In 2013 there were 176,000 deaths due to SCA up from 113,000 deaths in 1990.The use of hydroxyurea (HU) has reduced hospitalization by 44% (2).

Patients with SCA have increased hospital admission in a year with different complications. A study done in Britain showed that 63 of the 211 children who were followed up in the hematology clinic required 161 acute admissions in a year (21).

Frequent hospitalization has been associated with different risk factors. Children not on follow up in the outpatient clinic, those not on HU therapy, and those living in socio-economically deprived area are among the ones who are frequently admitted. (3)(2)(4). Individuals with SCA manifest with intermittent episodes called sickle cell crises which include acute vascular occlusion (painful crisis), acute chest syndrome (ACS), aplastic crises, haemolytic crises and splenic sequestration crisis. Painful crisis is responsible for the most common presentation in emergency departments. Patients with sickle cell anaemia

experience some chronic and intermittent pain daily and hence reduce quality of life of these patients (7).

The manifestations of SCA depend on patient's age [8]. The disease is asymptomatic in the first months of life. Dactylitis and splenic problems first develop in those aged 3 to 6 months. During the first year of life patients experience complications and the greatest mortality rate is from encapsulated bacteria causing septicemias, acute chest syndrome and splenic sequestrations. Among the 5-year old's, symptoms continue to be common and stroke develops. After the 5^{th} year of life the patient suffers numerous severe bone pain crisis.

In the adolescence period the patient experience bone pain crisis, leg ulcers, delayed sexual and growth development and priapism. In a Jamaican cohort enuresis > 2 times a week occurred in 8-year-old children (45% versus 19% among normal controls). (16)

By 25–30 years of age, bone pain crises become less frequent and most patients commonly default from clinic follow-up according to studies done in Jamaica and United States. In Sub-Saharan Africa no systemic data are available. Survival in Sub-Saharan Africa is as short as 5 years. Most treatment recommendation are extracted from studies conducted in resource-rich countries as description of clinical spectrum and natural history of SCA are scarce. A decrease in hemoglobin and renal impairment worsens with increase in age and results in cardiac and other problems. (17)

Despite sickle cell anemia having been discovered more than fifty years ago, progress towards definitive therapy for SCA has been considerably slow (9). Treatment consist of giving penicillin for preventing life-threatening pneumococcal infection because of asplenia or non-functional spleens and an impaired immune response (10). Vaccinations against encapsulated organisms are given as children with sickle cell disease have low immunity towards Streptococcus pneumoniae (11) with malarial chemoprophylaxis given in regions where malaria is endemic, such as most sub-Saharan African countries and Southeast Asia (12). Hydroxyurea is used to reduce the frequency of hospitalization and reduce the frequency of blood transfusion (13).

The mechanism of action of hydroxyurea is uncertain but the known pharmacologic effects of hydroxyurea that may contribute to its beneficial effects include: increasing hemoglobin F, increasing the water content of RBCs and altering the adhesion of RBCs to endothelium (17).

The current guideline is to offer hydroxyurea to all SCA patients from 9 months of age, regardless of clinical severity to reduce SCA-related complications (e.g., pain, dactylitis, ACS, anemia) (18). Despite the above treatment most children are very frequently admitted into hospitals. The frequent admissions greatly reduce the quality of life.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Sickle cell anemia presents a large burden of disease in Africa especially the Sub-Saharan region. A study done in Kilifi, Kenya to create awareness of the large burden of disease evaluated 124 children (median age 6.3 years) and identified that malaria and anemia greatly increased morbidity and mortality in children with sickle cell anemia with 6% of the children having malaria and a mean Hemoglobin (Hb) of 7.2g/dl compared to 10.7 in a controlled group. Splenomegaly and hepatomegaly were present in 41 subjects and 25 of subjects respectively. Liver function test were deranged. Children living in developed countries and those in Kilifi with SCA have similar degree of anaemia and liver function test derangement (14).

A retrospective cohort study by Melissa et al in 2009 reviewed 100 patients who were hospitalized in the last one year and were readmitted within 30 days after discharge. In this study, pain was found to be the commonest reason for admission and the greatest risk factor was no outpatient follow up (OR 7.7, 95% CI 2.4–24.4)(2). In an observational study, Ghida Aljuburi et al in 2013 in England, recruited 7679 patients with SCA who have been admitted in a one year period 2005/2006 and followed them up for five years. They found out that patients living in the most socio-economically deprived areas were at the highest risk of admission (HR 2.97, 95% CI 2.57-3.45). Mortality was also high in the socio-economically deprived patient with SCD (3).

In 2012 John Leschke et al did a retrospective cohort study N=408 in Wisconsin from 2003-2007 and reviewed patients with SCA readmitted at day 14 and 30 days after hospitalization. Of the 408 patients who were included in the study, 42(10.2%) were hospitalized within 14 days and 70(17.1%) were hospitalized after 30 days. Patients with outpatient follow up are associated with lower rates of both 30 day hospitalization (HR 0.442,95% CI 0.330-0.593) and 14- day rehospitalization (HR 0.226,95% CI 0.124-0.412) (2).

A retrospective study done in 2012 by Amy Sobota et al had 12104 patients from 33 free standing hospitals in the pediatric Health information system database. 2074(17%) of those patients were readmission within 30 days and the commonest risk factor was age. The cause for admission was pain(OR 1.06/ year) and for transfusion(OR 0.58) (2).

In a double-blind RCT conducted among 299 patients with SCD, use of HU at a dose of 15mg/kg/day reduced the rate of painful crisis compared to placebo (2.5 crisis/year verses 4.5 cases per year), reduced the annual rate of admission to 1 hospitalization per annum compared to 2.4), ACS reduced (25 events in those on HU verses 51 on placebo) and the number of transfusion was also reduced (48 verses 73 on placebo). Hydroxyurea was approved by the FDA to be used in patients with sickle cell disease in 1998 (4).

In another randomized multicenter study on the use of hydroxyurea in SCD showed that patients on HU get fewer complications than those on placebo. HU decreased the number of crisis by 44%, decreased the number of patients with acute chest syndrome and number of transfusion (4) (14).

A descriptive study by Zeina et al in children with SCD at Basra Maternity and Children hospital identified 160 patients admitted between January 2012 and July 2012 ages 9-14 years. The 160 patients had 237 hospitalization events and the mean of hospital stay was 4.34. The length of stay of patients on HU was shorter than that for patients who are not ($P<0.05$). The readmission rates were significantly higher among patients with frequent hospitalization in the previous year. Patients on HU were less likely to be readmitted (OR 0.082) (19).

In a prospective cohort study by Ballas et al followed up 182 patients with SCA over a period of five years.136 of the patients were admitted to hospital 1540 times with an average stay in hospital of 7.6 days. Males were admitted more frequently than females (56.5% vs 38.1 %) and there was no difference in the ages of admitted patients. Several patients were not admitted at all during the period of the study (21).

In a case control study by Fuggle et al in London in children 6-16 years of age with SCD,25 children were recruited in both arms of the study. One arm had children with sickle cell anaemia and the other arm had randomly selected children without sickle cell anameia but matched for age sex and ethnicity and were to complete a hospital children health diary each day for a period of four weeks. The diary recorded a 5point rating scale of 24 common childhood symptoms e.g. cough, pain, tiredness, and daily events like going to school, doing school work, daily sport and sleeping. The study did not indicate a significant difference in the quality of life but 4% rated their health as poor compared to the control (2%). the control had positive rating (very good days) compared to SCD patients (46% versus 25%).SCD patients had frequent waking up at night than controls. (19.6% verses 4%) (22).

A study done in Kilifi District Hospital, Kenya by Amendah et al estimated the average per patient cost to routine outpatient care was at USD 138 in 2010 with a range of USD 94 to USD 219 (23).

In an observational study done by Brozovic et al in Britain they had 211 children being followed in the hematology clinic.63 of the 211 children required 161 acute admissions in a year. The children spent 1572 days in hospital, 9.7 days per admission, 24.9 days for each patient admitted (20).

Woods et al in 1997 found that 85.7% of 7202 hospital admissions in Illinois were for patients with SCD that came through emergency departments and the total charges for admission in Illinois were found to be USD 30M a year. (26)

Sophie Lanzkrons et al had a total of 50418 emergency visits for patients with SCA sampled in the nationwide emergency department samples (NEDS) in 2006.44188 were paediatric visits. More female than male and painful crisis was the main cause. (13)

In a retrospective study by Mcmillan et al in single center looked for clinical and geographical characterization of 30day readmission in paediatric patients with SCA. They identified 373 patients, 125 of the them had at least one 30day readmission. Characteristics

identified were age (2.2 years P <0.001), length of hospital stay (mean 1 day P< 0.001), admission pain score >7 out of 10 (OR 2.21), living within 5 miles of hospital center main hospital (OR 0.573) and >3 hospital utilization in the previous 12 months OR 5.103).Therefore the main characteristics identified were increase in age, high admission pain score, decreased length of hospital stay and increased hospital utilization were found to be associated with an increased risk of readmission. (25)

CHAPTER THREE

STUDY JUSTIFICATION, RESEARCH QUESTION AND OBJECTIVES.

3.1 Justification

Sickle cell disease poses a burden especially in Sub-Saharan Africa. Kenya being one of the countries affected. There is increased hospitalization of patients with SCA in the country, making it expensive for the patients and reduces the quality of life of children. The study aimed in identifying modifiable factors that predict risk of hospitalization in SCA that could help in targeting groups particularly at risk and possibly reduce the frequency of hospitalization and reduce complications associated with the disease.

Interventions may be designed to improve their health outcomes and quality of life. Increasing the quality of life in the patients will minimize their hospital stay enabling them to participate as active members of the community. Locally there is no data available to predict risk and improve the quality of life of children.

3.2 Study Question

What is the frequency and factors that are associated with hospitalization of children with sickle cell anaemia ages 0-18 years on follow up in KNH and Gertrude's Garden Children Hospital?

3.3 Objectives

3.3.1 Primary Objective

To determine the frequency of hospitalization within one year among under 18-year-old children with SCA followed up at KNH and GCCH.

3.3.2 Secondary Objectives

To determine factors associated with frequency of hospitalization of children with SCA at KNH and GGCH

Potential factors include child factors, care givers factor, quality of health factors.

i.) Age at diagnosis, age at hydroxyurea, level of education

ii.) Sex, employment

iii.) Adherence to clinic follow up, follow up times

iv.) Medication use

CHAPTER FOUR: METHODOLOGY

4.1 Study Design

In this study a cross-sectional design was employed to examine the frequency of hospitalization in one year and factors associated with frequent hospitalization in children less than 18 years. Participants are asked to recall how many times they were admitted in the last one year and with the aid of medical records the investigator corroborates information provided.

4.2 Study Area

The study took place in two hospitals in Nairobi which provide care to a large number of patients with SCA: Kenyatta National Hospital and Gertrude's children hospital. KNH is located in Upper hill Nairobi, is currently the largest public referral and teaching hospital in Kenya. It has a capacity of 2000 beds and has over 6,000 staff members that include nurses, medical officers, residents and consultants who provide basic and highly specialized healthcare services, which include hematology clinics overseen by certified hematologists. On average, 15 patients with SCA are seen every Monday and an average of 5 patients is admitted weekly. Some of the patients are admitted directly from the paediatrics emergency unit.

Gertrude's Children's Hospital is the largest Pediatric Hospital in East and Central Africa. Located in Muthaiga in Nairobi it offers a wide range of services, among these services is the care of children with hematological conditions by a qualified hematologist. In GGCH an average of 20 patients are seen in the clinic every Friday.

4.3 Study Population

These study participants were selected from paediatric SCA patients who received care from the aforementioned paediatric hematology clinics. The study population consists of female and male patients who were evaluated in any of the stated clinics to ascertain the eligibility as compared to the exclusion/ inclusion criteria listed below.

4.3.1Inclusion criteria:

i.) Children aged < 18 years with a diagnosis of sickle cell anaemia (typically HbSS confirmed by Serum electrophoresis)

ii.) Children with sickle cell anaemia on follow up in the haematology clinic and wards in KNH and Gertrude's hospital,

iii.) Consent from the caregiver or both consent and assent from a child aged 7 years and above where applicable

4.3.2 Exclusion criteria

i.) Children with sickle cell trait, B thalassemia and alpha thalassemia.

4.4 Sample Size

The sample size required was calculated using fischer's formula.

$$n = \frac{Z_{\alpha}^{2}\, p\,(1-p)}{d^{2}}$$

$Z_{\alpha} = 1.96$

$$n = \frac{(1.96)^{2}\ 0.3\ (1-0.3)}{(0.075)^{2}}$$

n = 161

n = estimated sample size

Z_{α} = standard normal deviate for 95% CI (1.96)

p = estimated proportion of children admitted with sickle anemia to be 30% (a study done by Kushner at el (2)

d = level of precision (set at 7.5%)

The sample size =161

Consecutive sampling was done in the two institution until sample size was attained.

KNH=141 GGCH=20

4.5 Patient recruitment

Consecutive sampling was employed whereby participants were recruited at the respective hematology clinics and wards with the help of the multidisplinary health care team at the clinics and wards consisting of consultants, registrars and nurses. The legal guardian/parent of the paediatric participants were then approached directly during the clinical appointment by the principal investigator and briefed about the study. Participants and the parents/legal guardian were offered the opportunity to enroll in the study upon satisfying the inclusion/exclusion criteria. The principal investigator provided review of the research study, research team expectations and protocol procedures. The participating children and parent/legal guardian were required to ask questions at any time during the session. Consent was obtained from a parent/legal guardian for all participants with an assent being obtained from those participants over 7 years of age whenever possible

4.6 Study Instruments

Questionnaires were piloted and then used to capture relevant data from the enrolled patients. Demographic as well as medical information specifically associated with their history and management of SCA was collected from the study participants. The questionnaires were devised and handed out directly to the participants/respondents during the regular clinic visit to achieve a higher response rate. The questionnaire was designed for self-completion but an option of being administered by the investigator was also provided. The questionnaire was available in both Kiswahili and English language for easy understanding to the responders and it contained a general information section as well as a medical information section.

4.7 Ethical Considerations

Authority to conduct the study was pursued from the Ethics and Research Committee in University of Nairobi/Kenyatta National Hospital. After which approval was obtained from Gertrude's Garden Children's Hospital to enable collection of data in their institution.

All respondents were given information on the purpose and procedure of the study before the study was carried out.

A consent and an assent form for children more than 7 years old were issued to study participants who met the inclusion criteria prior to enrolment. The respondents were informed that there will be no victimization or any consequences for not participating or for withdrawing from the study. Questions and clarifications were welcomed before and during the study.

All respondents were assured of confidentiality. The questionnaires were coded and did not include the respondents' names. The questionnaires were placed in envelopes that were sealed and the information was only accessible to the researcher.

4.8 Data Collection

Data were collected in forms of:

1. **Categorical variables:** age, gender, weight, height.
2. **Independent variables:** number of admissions.
3. **Dependent variables: divided into three broad categories**
    i.) Child factors: current age, age at diagnosis, sex, level of education, nutritional status
    ii.) Care giver factors: who is the care giver, level of education, residence, knowledge of sickle cell
    iii.) Quality of health factor: follow up, follow up times, hydroxyurea use, age at hydroxyurea use, medications, vaccination

The data were the entered in a Microsoft Excel spreadsheet.

4.9 Data Analysis

Double entry was done for all questionnaires in Microsoft excel; then data was cross-checked for entry errors, cleaned and validated before analysis. Data was then transferred to SPSS version 25.0 for analysis.

Descriptive analysis was done to explain summary values and characteristics of participants using means and medians for continuous variables and proportions for categorical data. Results are presented in the form of frequency tables, charts and graphs.

The children were categorized into two groups, more than three episodes of hospitalization and less than three in a year as severe disease is defined as three or more episode of hospitalization in a year.

The socio-demographic and individual characteristics of children and caregivers associated with hospitalization in children with sickle cell anemia were assessed. Binary logistic regression analysis was done to determine caregiver and child factors associated with increased risk of hospitalization. All variables with an association with the outcome variable with p value less than 0.05 were included in multivariate analysis. Odds ratio with 95 % CI and p-values were used to decide whether the independent variables included in the multivariate analysis were statistically significant or not in relation with outcome variable (number of hospitalizations in the past 1 year).

Flowchart

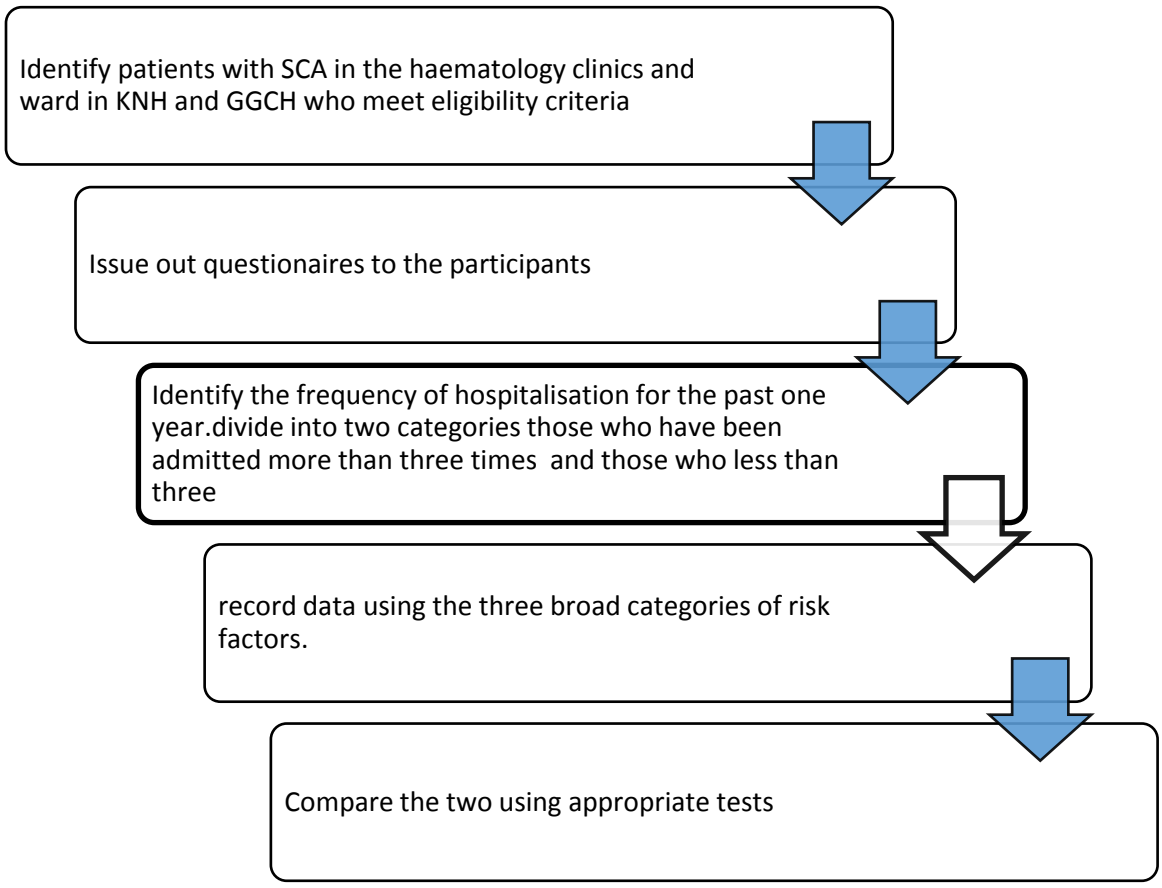


Figure4.1: Flow Chart depicting how the study will be conducted

CHAPTER FIVE: RESULTS

5.1 Introduction

This section describes the characteristics of children who were on follow up care for sickle cell anemia at Kenyatta National Hospital and Gertrude's children Hospital.

Caregiver characteristics and quality of care factors have been explained in the second and third section respectively.

In addition, logistic regression was performed to determine risk factors associated with hospitalization.

5.2 Child Demographic Characteristics

We enrolled 161 children from November 2017 to February 2018.Most of the children, 70.2% were aged 0-9 years and 29.8% of the children were 10-18 years mean age 7.74(SD 4.44).

The number of male and female were almost equal at, 81 (50.3%) and 80 (49.7%) respectively.

Most of the children were in primary school which was about 54.6% with 9.9% post primary

Majority of the children live in permanent houses 132 (82%) while 29 (18%) live in semi-permanent houses.

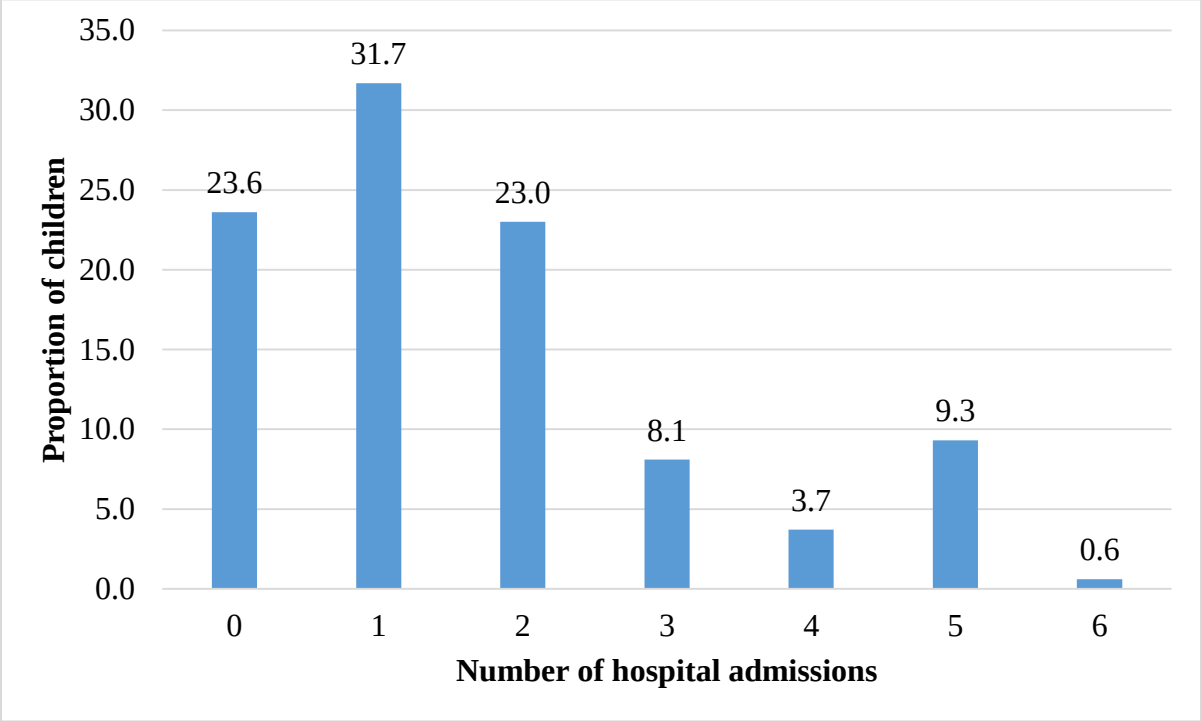
Table5.1: Child demographics

Characteristics	Frequency (N)=161	Percent (%)
Current Age (Years)		
0-9	113	70.2
10-18	48	29.8
Gender		
Female	81	50.3
Male	80	49.7
Level of education(child)		
Primary School	88	54.6
Post primary School	16	9.9
Not in school	57	35.4
Housing		
Permanent (brick)	132	82.0
Semi-permanent (mud, carton, mabati)	29	18.0

5.3 Frequency of hospitalization in the past one year

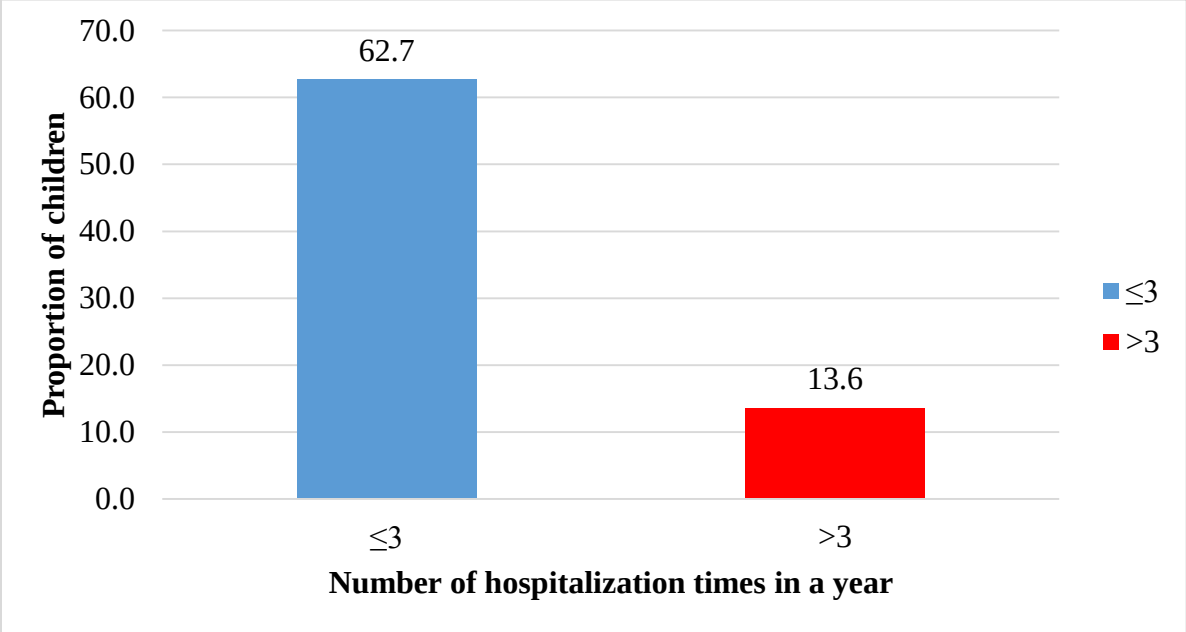
Of the 161 children in the study 38 (23.6%) were not hospitalized in the past one year. Majority 51 (31.7%) were hospitalized once and 37 (23%) were hospitalized twice in the last year. Thirteen (8.1%) were hospitalized 3 times in the last year and 13.6% were hospitalized more than 3 times. One hundred and one children (62.7%) had less than or 3 hospitalization episodes while 22 (13.6%) of the children had been hospitalized more than 3 times.

Figure 5.1: Frequency of hospitalization in the last one year.



The mean frequency of admission was1.67 (SD 1.528) and median was 1(IQR 0-1)

Figure 5.2: Frequency of admission categorized into two groups, ≤ 3 times and > 3 in one year. (Categorized into two groups based on disease severity)



5.3.1 Nutritional status of children

We defined BMI for children above 5 years old using international standards (18-25 defined as normal range) Majority of the children, 92 (82.9%) were underweight while the mean BMI for the group was 15.46.

Of the 50 children below the age of 5 years, we calculated the Weight for Height, Weight for Age and Height for Age Z-scores. A relatively high number of children 16 (32%) had wasting (WHZ <-2) while 13(26%) were underweight (WAZ <-2) and 9(18%) were stunted (HAZ <-2).

Table5.2: Nutritional status of children.

Development/ Nutritional status	Frequency (N)	Percent (%)	Mean (SD)	Median (IQR)
BMI (Kg/m²) >5years n=111				
Underweight	92	82.9	15.46 (±4.34)	15.08
Normal Range	16	14.4		
Overweight	3	2.7		
Z scores < 5 years n=50				
WHZ				
<-2	16	32.0	-1.52 (±2.64)	-1.07 (3.36)
≥-2	34	68.0		
WAZ				
<-2	13	26.0	-0.81 (±1.75)	-1.14 (2.40)
≥-2	37	74.0		
HAZ				
<-2	9	18.0	0.66 (±3.09)	0.45 (3.12)
≥-2	41	82.0		

N - Number; **(%)** - Percentage; **SD** - Standard deviation; **IQR** - Interquartile range

Table 5.3 Care giver factor

Characteristics	Frequency (N=161)	Percent (%)
Level of education		
primary	115	71.4
Post primary	43	26.7
None	3	1.8
Monthly Income (Kshs)		
<20,000	51	31.7
⩾20,000	30	18.6
None	80	49.6
Employment		
Employed	74	46.0
Not Employed	87	54.0
Knowledge on SCD		
Yes	125	78.0
No	36	22.0
Facts known on SCD (N=125)		
Blood abnormality	35	21.7
Hereditary disease	90	55.8

Only 43 (27.2%) of caregivers had post primary education and 30 (37.0%) had a monthly income above 20,000.

Of the caregivers in this study, 125 (78.0%) had some knowledge on sickle cell anemia and of those with knowledge 90 (55.8%) knew that it was a hereditary disease.

Table 5.4: Family sickle cell characteristics

Characteristics	**Frequency n=161**	**Percentage**
Siblings		
Yes	113	70%
No	48	30%
Siblings known to have sickle cell disease	n=113	
Yes	29	26%
No	68	60%
Not known	16	14%
Mother ever done Hb electrophoresis		
Yes	26	16
No	116	72
Not known	19	12
Father ever done Hb electrophoresis		
Yes	23	14
No	111	70
Not known	27	16

Table 5.5 Quality of care factors

Characteristics	Frequency n=161	Percentage (%)
Hydroxyurea use		
Yes	105	65
No	56	35
Age at starting hydroxyurea n=105		
≤3	43	41
>3	62	59
Follow-up (Last one yr)		
Yes	135	83.9
No	26	16.1
Follow-up times last 1yr n=135		
12	71	52.5
<12	64	47.4
Other medications		
Folic and Penicillin V	144	92.9
Folic acid	11	7.1

Majority, 65% of the children were on hydroxyurea as part of the management of sickle cell anemia with 62 (59.0%) having started the treatment when they were older than 3 years.

Nearly 84% of the children were on follow up in the past one year with about half 71 (52.5%) of them on monthly follow up.

Table 5.6: Factors associated with frequent hospitalization

Characteristics	N(%)	Hospitalization		Univariate analysis		Multivariate analysis	
		< 3 times	≥ 3times	P	OR (95%CI)	P	OR (95%CI)
Gender (child)							
Male	81(50.3)	68 (84.0)	13 (16.0)				
Female	80(49.7)	58 (72.5)	22 (27.5)	0.08	1.98(0.92-4.28)	0.03	2.4(1.10-5.26)
Current Age (yrs)							
0-9	113(70.2)	83(73.5)	30(26.5)	0.03	3.11(1.13-8.58)	0.06	2.71(0.97-7.59)
10-8	48(29.8)	43(89.6)	5 (10.4)				
Age at diagnosis (Years)							
≤5	139 (88.0)	108 (77.7)	31 (22.3)	0.27	3.20(0.41-25.3)	0.12	1.98(0.84-4.66)
>5	19 (12.0)	15 (78.9)	4 (21.1)				
Hydroxyurea n=139							
Yes	105 (75.5)	86 (81.9)	19 (18.1)				
No	34 (24.5)	30 (88.2)	4 (11.8)	0.39	0.60(0.19-1.92)	0.26	0.51(0.16-1.65)
Age at hydroxyurea (Years)							
≤3	43 (41.0)	29 (67.4)	14 (32.6)	<0.001	5.50(1.81-16.7)	<0.001	5.54(1.79-17.1)
>3	62 (59.0)	57 (91.9)	5 (8.1)				
level of education(child)n= 104							
Primary School	88 (84.6)	79 (89.9)	9 (10.2)				
Post primary School	16 (15.4)	5 (31.3)	11 (68.8)	<0.001	19.3(5.47-68.2)	<0.001	15.4(4.27-55.6)
level of education (care giver) n=158							
Secondary school	115 (72.8)	86 (74.8)	29 (25.2)				
Postsecondary School	43 (27.2)	37 (86.0)	6 (14.0)	0.13	0.48(0.18-1.26)	0.39	0.06(0.15-1.02)
Follow-up (last one year)							
Yes	135 (83.9)	112 (83.0)	23 (17.0)				
No	26(16.1)	14(53.8)	12(46.2)	<0.001	4.17(1.71-10.1)	<0.001	4.26(1.70-10.66)
Follow up times (last one year) n=131							
<12	67(51.1)	53(79.1)	14(20.9)				
>12	64(48.9)	55(85.9)	9(14.1)	0.31	0.62(0.25-1.55)	0.34	0.63(0.25-1.61)
Employment							
Yes	74(46.0)	60(81.1)	21(18.9)	0.42	0.73(0.34-1.57)	0.31	0.67(0.31-1.45)
No	87(54.0)	66(75.9)	21(24.1)				
Income n=81							
≤ 20000	51(63.0)	40(78.4)	11(21.6)				
>20000	30(37.0)	29(96.7)	1(3.3)	0.05	0.13(0.14-0.54)	0.02	0.09(0.01-0.71)
Knowledge SCA							
Yes	125(77.6)	97(77.6)	28(22.4)				
No	36(22.4)	29(80.6)	7(19.4)	0.71	0.84(0.33-2.11)	0.62	0.79(0.31-2.03)
WHZ							
<-2	16 (32.0)	10 (62.5)	6 (37.5)	0.31	1.95 (0.54 - 7.05)	0.34	1.90 (0.51 - 7.11)
≥-2	34 (68.0)	26 (76.5)	8 (23.5)				
WAZ							
<-2	13 (26.0)	11 (84.6)	2 (15.4)	0.25	0.38 (0.07 - 1.99)	0.29	0.40 (0.07 - 2.18)
≥-2	37 (74.0)	25 (67.6)	12 (32.4)				
HAZ							
<-2	9 (18.0)	7 (77.8)	2 (22.2)	0.67	0.69 (0.12 - 3.82)	0.57	0.60 (0.11 - 3.45)
≥-2	41 (82.0)	29 (70.7)	12 (29.3)				

N - Number; **(%)** - Percentage; **P** - P value (level of significance <0.05); **OR** - Odds Ratio; **CI** - Confidence interval

Risk factors associated with hospitalization in children with sickle cell anemia

We performed a binary logistic regression to determine the risk factors for hospitalization in children with sickle cell anemia, children who started hydroxyurea at the age of 3 years and below had about 5 times higher odds of hospitalization. (p=<0.001)

Children in post primary were more likely to be hospitalized compared to those that were in primary school. (p=<0.001)

Children not on follow up in the last year had 4 times higher odds of hospitalization.

Being male was associated with decreased frequency of hospitalization. (p=0.03)

Patients whose caregivers had a lower income < Ksh 20000 had less frequent hospitalization. (p=0.02)

Age at diagnosis and number of times on follow up in the last year were not associated with increased hospitalization.

CHAPTER SIX

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

6.1 Discussion

Sickle cell anemia (SCA) remains an important health problem in Kenya and the frequency of hospital admission remains unacceptably high. Several approaches in management of SCA exist but the frequency of hospitalization remains high. The present study was undertaken to explore the frequency and risk factors associated with frequent hospitalization. It also looked at the common causes of hospitalization and duration of stay in the hospital.

The study found high frequency of hospitalization with 123(76%) of children having atleast an episode in the past 12 months (higher than the rate in Kilifi[14] (0.45 per patient year) Nigeria (Akinyanjua 2005 -1.21 per patient per year).

Majority of them 51 (31%) had one episode of hospitalization in the past one year, 22 (14%) had more than 3 episodes and almost 38(24%) had no episode of hospitalization. These results concur with a study done by Ballas et al[21].The study showed that 68% of the children had more than a week of hospital stay in their last admission. This finding concurs with studies done by Ballas et al[21] and Amendah et al [20.]

Majority of the children 105 (65%) were on hydroxyurea and 41% started at the age 3 years and below. In this study children who started hydroxyurea at the age 3 years or less had about 5 times higher odds of being hospitalized (p=**<0.001)** .Hydroxyurea has been approved by FDA since 1998.In this study Hydroxyurea use at an early age was associated with an increased risk of frequency of hospitalization, most studies have shown that hydroxyurea reduces the frequency of admission[4], number of transfusion[4], patients get fewer complication[12], decreases number of crisis[4] reduces the length of stay of patients in hospital[19] but none has shown at what age is to be started. The recommended age to start is 9 months.

In the current study it showed that children in post primary level of education had high frequency of admission a p value of **<0.001.** This indicates that older children need more attention and follow up. This finding can also be explained by age of the child, the older you

are the more attention needed. In this study age was not statistically significant but rather showed a trend and maybe with a larger sample size the association would be evident. P value 0.06 OR 95%CI 2.71(0.97-7.59). In sickle cell anemia the older you are the more complications you get and therefore more hospitalization (16) (17). This finding agrees with a study done by Ballas et al [21] although it differs with other studies that found age to be a contributing factor[2, 25]

In the current study 84% of children were on follow up in the hematology clinic and 51% were on monthly follow up. There was statistically significant association in those patients who were not on follow up with the frequency of hospitalization p value of <0.001**.** Children not on follow up were 4 times more likely to hospitalized as compared to those that were on follow up in the past year. Our study agrees with John Leschke et al[2]. This shows that follow up is key in management of patients with sickle cell anaemia.

The study population included children between the ages of 0-18 years, with a mean age of 7.74(SD 4.441) and median of 7. The overall rate of consent 98% was of all children approached; this good response may have been due to absence of blood sampling requirement. 88% of children were diagnosed before 5 years of age. The study revealed there was almost equal number of males and females with Sickle cell anemia 81 (50.3%) and 80 (49.7%) respectively. Male were less frequently admitted than female. (p value of 0.03). This finding differs with a study done by Ballas et al[21] but concurs with Lanzkros et al[13].

In this study majority of children above 5 years were found to be underweight with a mean BMI of 15. Children below 5years had a relatively high number of children 16 (32%) who had wasting (WHZ <-2) while 13(26%) were underweight (WAZ <-2) and 9(18%) were stunted (HAZ <-2). This finding concurs with a study done by Nelson[27],that showed 11% of the participants were underweight. This could be explained by the comorbidities and frequency of hospitalization.

The study found that pain was the main reason for frequent admission 52% and transfusion 41%. This finding concurs with studies done by Melissa et al[2], Amy Sobota et al[2] and Sophie Lanzkrons[13]

The primary care givers in the study were found mostly to be the mothers 60% and fathers 4%. Only 27.2% had post primary level of education and 46% were employed. Care givers level of education had no significance with the frequency of hospitalization (p value 0.39) 63% had monthly income of less than Ksh.20000.In this study care givers who had an income of less than Ksh.20000 had reduced frequency of admission with a p value of <0.001, this finding differs with a study done by Ghida et al [3].This may be because parents with lower income are not able to access care and afford admission. 78% of the care givers had knowledge on SCA and 55.8% knew it was a hereditary disease.

The study showed that 70% of the children had siblings and 26% of them were known to have sickle cell anaemia.16% of the mothers and 4% of the fathers had done Hb electrophoresis. These finding agrees with a study done by Nelson[27]This low number of parents having done the Hb electrophoresis could be explained by the fear of knowing there status and also the cost of testing as 63% are earning less than ksh 20000.

In this study 93% of children were on both pen v and folic acid and 7% were on folic acid only. This finding is in agreement with a study done by Nelson[27]**.**

6.2 Study limitations

i.) The study was carried out in Kenyatta national Hospital and Gertrude's Children Hospital and only included children with SCA that visit these two institutions. As such it is possible that generalizability of the study may be limited by the fact the children studied are not a random sample of all children with SCA in Kenya and this may result in some level of selection bias.

ii.) The very setting may have provided selection bias as one of the objectives of the study is to seek to understand the frequency of hospitalization from a catchment area of children already visiting the hospital.

6.3 Conclusion

The current study concludes that:

i.) The frequency of hospitalization of children with sickle cell anemia 76% is still very high with at least an episode in every year.

ii.) Hydroxyurea started at an early age increases frequency of hospitalization.

iii.) Children in post primary level of schooling were more likely to be hospitalized.

iv.) Follow up is an important aspect in care of children with sickle cell anemia.

v.) Monthly income plays a role is seeking health services.

6.4 Recommendations

The study recommends that

i. Children with Sickle cell anemia and in post primary school may need more attention.

ii. Regular follow up of children with sickle cell anemia is an important aspect of their care.

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APPENDICES

Appendix I: Letter to Gertrude's hospital

Mahaa Salim Swaleh
Reg No. H58/80670/15
University of Nairobi
College of Health Sciences
P. O. Box 19676-00202
Kenyatta National Hospital
Nairobi Kenya
Date:

Gertrude's Garden Children Hospital
The ERC/ Director of Clinical services
P. O. Box 42325
Muthaiga Rd,
Nairobi, Kenya

Dear Ms/Mr

RE: REQUEST FOR PERMISSION TO CONDUCT RESEARCH IN YOUR FACILITY

I am Dr. Mahaa Salim (student number H31/80670/15), a registered master's student in the Department of Paediatrics and Child Health at the University of Nairobi.

I am hereby seeking your consent to conduct a study at your facility's Haematology Clinic in November and December. The proposed topic of my research is: **frequency and factors associated with hospitalization of patients with sickle cell disease**

The objectives of the study are:

(a) To determine the frequency of hospitalization of children with sickle cell disease.

(b) To determine the risk factors associated with hospitalization

To assist you in reaching a decision, I have attached to this letter:

(a) A copy of an ethical clearance certificate issued by the University/Kenyatta National Hospital

(b) 3 copies of the research proposal

My supervisors are Prof. Dalton Wamalwa, MB.ChB,M.Med (Paed), MPH an Associate Professor in the Department of Paediatrics and Child Health and a Consultant paeditrician and Dr. Nyambura Kariuki MB ChB M.Med (Paed); Paediatric Haematology & Oncology a Senior consultant at your Haematology Clinic.

Should you require any further information, please do not hesitate to contact me or my supervisor. Our contact details are as follows:

Name: Dr Mahaa Salim

Mobile Number: 0723801060

Email: sahag8686@gmail.com

Name: Prof Dalton Wamalwa

Mobile Number: 0721239493

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Name: Dr Nyambura Kariuki

Mobile Number: 0722679119

Email: kariukin1@yahoo.co.uk

Upon completion of the study, I undertake to provide you with a bound copy of the dissertation.

Your permission to conduct this study will be greatly appreciated.

Yours sincerely,

Dr Mahaa Salim

H58/80670/2015

H58/80670/15

MMed Paediatrics and Child Health

Appendix II: Questionnaire

FREQUENCY OF HOSPITALISATION AND FACTORS ASSOCIATED WITH HOSPITALISATION OF PATIENTS WITH SICKLE CELL ANAEMIA

QUESTIONNAIRE: **Serial Number:** _____

INSTRUCTIONS

1. Please answer all of the questions provided to the best of your ability
2. Answer each question on the space provided and where options are given mark only your intended response
3. The questionnaire will take approximately 15minutes of your time
4. Please answer the questions as truthfully as you can
5. You may ask for any assistance throughout the filling in of the questionnaire

General Information

Please indicate the following information about the patient's participants

Date of Birth: _____

Age: _____

Sex: _____

Current weight: _____

Date: _____

Medical Information

Child factors

1. At what age was the diagnosis of Sickle Cell Anaemia made? _____
2. Was the diagnosis confirmed by Serum electrophoresis? Yes/No
3. How many times in the past one year have you been admitted to hospital
    - 1
    - 2
    - 3
    - 4
    - 5

- Others specify

4. What was the reason for your admissions?
    - Painful crisis
    - Transfusion
    - CVA
    - Acute chest syndrome
    - Vasoocclusive crisis
    - Others specify

5. On your last hospital admission how many days did u stay in hospital?
    - 1
    - 2
    - 3
    - 4
    - 5
    - 6
    - More than a week

6. What is your current (take measurements)

    Weight?

    Height?

    BMI

7. What level are you in school?
    - Primary school
    - Secondary school
    - University/college
    - N/A

7.what type of housing do you live in?
    - Permanent(brick)
    - Semi permanent(mud,curton,mabati)

CARE GIVER FACTORS

1. Who is the primary care taker of the child?
    - Mother
    - Father
    - Both
    - Grandparents
    - Childrens home
    - Aunt/uncle
2. What is your(guardian) level of education?
    - Primary
    - Secondary
    - University
    - None

10.Are you employed? yes/no

If yes what kind?

- Formal
- Informal

11. Approximately how much do you make in a month?
    - <10000
    - 10000-15000
    - 20000
    - 30000
    - >50000

12.Do you know what is sickle cell disease ?yes/no

If yes what do you know

13.Does the patient have other siblings? Yes/No

-if Yes are they known to have sickle cell disease? Yes/No/Not known

14.Has the mother ever done Hb electrophoresis? Yes/No/Not known

15.Has the father ever done Hb electrophoresis? Yes/No/Not known

Quality of health

16. Are you being followed up in any outpatient facility?yes/no

If yes where

How many times in a year?

17.Are you on hydroxyurea?yes/no

If yes since when(indicate age you started)

What dose(mg/kg)

How many times in a day

18.what other medication are you on?

- ☐ Folic Acid
- ☐ Penicilin V
- ☐ Anti- malarial drugs
- ☐ None
- ☐ Other

19. Have you received any vaccination since you were diagnosed with sickle cell anaemia?yes/no

If yes which ones

- pneumonia
- H.influenza

Swahili version of the questionnaire

DODOSO **Nambari Maalum:_____**

MAELEKEZO

1. Tafadhali jibu maswali zote kwa umakinifu
2. Jibu kila swali kwenye nafasi iliyopewa na ambapo chaguzi umepewa tia alama pekee kwenye jibu lako
3. Dodoso hii itachukua takriban dakika 15 kuijaza
4. Tafadhali jibu maswali zote kwa ukweli
5. Unaweza kuulizia msaada wowote unapojaza dodoso hii

Habari za Jumla

Tafadhali andika taarifa zifuatazo kuhusu washiriki

Siku ya kuzaliwa: _____

Miaka: _____

Jinsia: _____

Uzito / Kilo: _____

Taarifa kuhusu hali ya afya ya mshiriki

1. Umri kilichokuwa utambuzi wa Ugonjwa wa Selimundu ilipofanywa?

   _____

2. Utambuzi uli thibitishwa na kipimo cha damu cha “Serum Electrophoresis”? Ndiyo / Hapana
3. Ni mara ngapi kwa mwaka umelazwa hospitalini?
   - 1
   - 2
   - 3
   - 4
   - 5
   - Others

4.Ni sababu gani zilizosababisha kulazwa hospitalini?

   - Painful crisis
   - Transfusion

- CVA
- Acute chest syndrome
- Vasoocclusive crisis
- Others specify

5.Mara yako ya mwisho kulazwa hospitalini ulilazwa muda gani?

- 1
- 2
- 3
- 4
- 5
- 6
- Zaidi ya wiki

6 .uko na(vipimo vitachukuliwa)

Kilo ngapi

Urefu

BMI

7 .Uko darasa gani sasa?

- Shule ya msingi
- Shule ya sekondari
- Chuoo kikuu

8 .Una aishi kwa nyumba ya aina gani?

- Nyumba ya mawe
- Nyumba ya udongo/mabati/makuti

9 .Nani anakulea nyumbani

- Mama
- Baba
- Wote pamoja
- Babu and nyanya
- Nyumba za watoto
- Baba mdogo /mama mdogo

10..Mwenye kukulea amefika darasa la ngapi?

- Shule ya msingi
- Shule ya sekondari
- Chuo kikuu
- Hakusoma

11.Umeajiriwa?ndio/hapana

- Kazi rasmi
- Kibarua

12.Kwa mwezi unapata kama pesa ngapi za matumizi?

- <10000
- 10000-15000
- 20000
- 30000
- >50000

13.Uko na ujuzi yeyote kuhusu ugonjwa wa selimundu?ndio/hapana

Kama ni ndiyo unajua nini

14.Uko na ndugu wengine?ndio/hapana

Kama ni ndiyo wanajua kama wako na selimundu?ndio/hapana/sijiu

15.Jee mama mzazi amepimwa ugonjwa wa selimundu?ndio/hapana/sijui

16.Jee baba mzazi amepimwa ugonjwa wa selimundu?ndio/hapana/sijiu

17Jee unafatilizwa katika hospitali yeyote kuhusu ugonjwa wa selimundu?

Kama ndio unafatilizwa wapi

Mara ngapi kwa mwaka

18.Jee unatumia dawa ya hydroxyurea?ndio/hapana

Kama ndio ulianza lini

Kiwango gani cha dawa(mg/kg)

Mara ngapi kwa siku

19.Unatumia dawa gani tena?

- ☐ Folic Acid
- ☐ Penicilin V
- ☐ Anti- malarial drugs
- ☐ hakuna dawa yeyote
- ☐ zingine

20Jee umepata chanjo zezote baada ya kujulikana na ugonjwa wa selimundu?ndio/hapana

Kama ndio gani

- Pneumonia
- H.influenza

Appendix III: Consent form

FREQUENCY AND FACTORS ASSOCIATED WITH HOSPITALISATION OF PATIENTS WITH SICKLE CELL DISEASE

Informed Consent form for _____ _____

The principal investigator is Dr Mahaa Salim under supervision from Prof Dalton Wamalwa and Dr Nyambura Kariuki on a study looking into the frequency of hospitalisation and factors associated with hospitalisation, a study done under the department of Paediatrics and Child Health in the University of Nairobi.

This Informed Consent Form has two parts:

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

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

Introduction

I am a Student currently doing my Masters in Paediatrics and Child health at the University of Nairobi and as such will be doing a study looking at the frequency and factors associated with hospitalisation of patients with sickle cell. Information will be given to you and you may feel free to ask questions before participating in the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me, the study doctor.

Purpose of the research

Sickle cell anaemia is quite common in the Sub-Saharan region of which Kenya is part of, it is an inherited disease that affects a number of children in our region who spend many days of their lives in hospital if not properly managed. Doing this study will enable us to identify modifiable risk factors and that will predict risk of hospitalisation in SCD that could help in targeting groups at risk and improve quality of life .Interventions may be designed to improve health outcomes.

Objectives of the study

To determine the frequency of hospitalization among under 18 year old children in one year with SCD followed up at KNH and GCCH.

To determine factors associated with frequency of hospitalization of patients with SCD at KNH and GGCH

Risks

The study poses no risk to the participant and all information given will be treated with utmost confidentiality. Participants will only answer questions and no invasive procedure will be done.

Benefits

The study aims in identifying modifiable factors that predict risk of hospitalization in SCD that could help in targeting groups particularly at risk and possibly reduce the frequency of hospitalization and also reduce complications associated with the disease.

Participant selection

We invite all children who are on follow up for Sickle cell anaemia at Kenyatta National Hospital and Gertrude's Garden Children hospital to participate in the research.

Voluntary Participation

Your participation in this research is entirely voluntary as such no remuneration or compensation will be offered to the participants of the study. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will still be offered the treatment that is routinely offered in this clinic/hospital for Sickle cell anaemia.

Procedures and Protocol

Description of the Process

Once consented, a set of questions will be presented to you mainly asking on the general condition and number of hospitalization of the child. Some factors related to the study questions will mainly be targeted. Information will also be extracted from the files available at the clinic to better capture the causes of admission and timing.

Duration

Duration of the study is 90 days. You take part at first contact and only participate once and we will just require 15 minutes of your time gathering information from you. The 90 day duration is to enable us to reach our sample size and you do not need to be part of the study for 90 days.

We will just require 15 minutes of your time gathering information from you. You only participate once.

Confidentiality

With this research, a better understanding of sickle cell disease will be achieved. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you and your child that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up. It will not be shared with or given to anyone except the department of Paediatrics and Child Heath in the University of Nairobi.

Right to Refuse

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. Your treatment at this clinic will not be affected in any way

This proposal has been reviewed and approved by the department of Paediatrics and Child health and the Ethics committee in Kenyatta National Hospital, which is a committee whose task it is to make sure that research participants are protected from any harm. You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent **SerialNumber:**

_____

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I as a guardian/parent to: _____consent voluntarily to participate as a participant in this research.

Name of Participant_____ Researchers Name: DR Mahaa Salim

Signature of Participant _____ Researchers Signature_____

Date _____ **Date _____**

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name: Dr Mahaa Salim (Principal investigator)

Mobile Number: 0723801060

Email: sahag8686@gmail.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Tel. (254-020) 2726300-9 Ext 44355

E-mail: uonknh_erc@uonbi.ac.ke

Gertrude's Garden Children Hospital

ERC/ Director of Clinical services

P. O. Box 42325 Muthaiga road,Nairobi

Tel(254-020)7206000

Swahili Version: IDHINI

Fomu ya Idhini ya _____ _____

Mpelelezi mkuu ni Dr Mahaa Salim chini ya usimamizi wa Profesa Dalton Wamalwa na Dr Nyambura Kariuki katika utafiti wa kuangalia sababu za kusababisha kulazwa kwa hospitali kwa watoto wanayoishi na Ugonjwa wa Selmundu. Utafiti itafanyika chini ya Idara ya Afya ya Watoto katika Chuo Kikuu cha Nairobi.

Hi fomu ya idhini ina sehemu mbili:

- Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)
- Shahada ya Idhini (sahihi ikiwa umekubali kujihusisha na utafiti huu)

Sehemu ya 1: Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi, ninapofanya shahada kuu kwenye Idara ya Afya ya watoto. Ningependa pamoja na wasimaizi wangu kutafiti sababu zinazofanya watoto wenye ugonjwa wa Selimundu kulazwa hospitali mara kadha . Kando na haya utapewa maalezo zaidi kuhusu mada na pia una uhuru wa kuuliza maswali yoyote ili kuelewa uafiti huu zaidi.

Nia

Ugonjwa wa Selimundu ni ugonjwa moja wapo unaoathiri watoto kweye sehemu yetu bara Afrika. Ugonjwa huu umeadhiri maisha ya watoto hawa hasa wakati wao mwingi hutumiwa hospitalini wanapolazwa ili kupokea matibabu zaidi.Utafiti huu utasaidia kuboresha maisha ya watoto wetu and kupunguza hasara za kifedha zinazoletwa na ugonjwa huu.

Objectives

To determine the frequency of hospitalization among under 18 year old children in one year with SCD followed up at KNH and GCCH.

To determine factors associated with frequency of hospitalization of patients with SCD at KNH and GGCH

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu. Hakuna vipimo viatakavyofanywa isipokuwa kilo and urefu.

Faida ya utafiti

Utafiti huu utasaidia kutambua watoto wenye shida zaidi na kujaribu kupunguza kulazwa hospitalini kwa kutambua sababu ili kuweza kuzitatua.

Waanaoalikwa kujihusisha na utafiti

Mtafiti anawakaribisha watoto wote wanaopokea matibabu ya Ugonjwa wa Selimundu na kufuatiliwa katika Hospitali ya Taifa Ya Kenyatta na Gertrude's Garden Childrens Hospital.

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki ,uamuzi huu hautakuathiri kwa njia yoyote iwe matibabu yako au utakavyiohudumiwa.

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki utapewa fomu ya kujaza iliyo na seti ya maswali hasa kuhusu hali ya afya ya mototo and sababu zinazofanya mototo kulazwa hospitalini mara kadha na idadi ya kulazwa hospitalini. Maswali yatalenga zaidi sababu za kulazwa na wapi walilazwa na mara ngapi wamelazwa hospitalini.

Wakati utakaotumika

Kwa ujumla, utafiti huu utachukua siku tisini (90). Kwa wakati huu, utahitaji dakika kumi na tano tu kujaza fomu na kuchukua maelezo mengine yatakayohitajika.Utashirika mara moja tu na hutokuwa kwa utafiti kwa siku zote hizo tisini.

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika ma utafiti huu. Zaidi ya hayo badala ya jina la mtoto, numbari zitatumiwa kutambuliwa watoto hawa. Matokeo yatazungumziwa na idara ya afya ya watoto pekee wala sio mtu mwingine

Haki ya kutoshiriki

Kushiriki utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki, uamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya afya ya watoto ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa .Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

Sehemu ya 2: Shahada ya Idhini **Nambari Maalum:_____**

Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali ambayo yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha.Kwahio kama mzazi/ mgarini wa : _____ningependa kupeana idhini yangu na pia kujitolea kushiriki kwa utafiti huu.

Jina la mshiriki: _____

Mtafiti mkuu: DR MAHAA SALIM

Sihihi la mshiriki: _____ **Sahihi ya mtafiti mkuu: _____**

Tarehe: _____ **Tarehe: _____**

Kwa maelezo zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

Jina: Dr Mahaa Salim(mtafiti mkuu)

Nambari ya simu: 0721370746

Barua pepe: polielo@yahoo.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Simu. (254-020) 2726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Gertrude's Garden Children Hospital

ERC/ Director of Clinical services

P. O. Box 42325 Muthaiga road, Nairobi

Tel (254-020)7206000

Appendix IV: Assent form

FACTORS ASSOCIATED WITH FREQUENCY OF HOSPITALISATION OF PATIENTS WITH SICKLE CELL DISEASE.

Informed Assent Form for _____

This informed assent form is for children above 7 years of age who attend the Haematology Clinics and wards at Kenyatta National hospital and Gertrude's Garden Children's Hospital and who we are inviting to participate in research to study the factors associated with hospitalization of patients with sickle cell disease.

The principal investigator is Dr Mahaa Salim under supervision from Prof Dalton Wamalwa and Dr Nyambura Kariuki on a study looking into the factors associated with hospitalization of patients with sickle cell disease, a study done under the department of Paediatrics and Child Health in the University of Nairobi.

This Informed Assent Form has two parts:

- Information Sheet (gives you information about the study)
- Certificate of Assent (this is where you sign if you agree to participate)

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

My name is Mahaa Salim and I am a doctor at Kenyatta National Hospital. I am interested in doing a research on Sickle Cell Anaemia that might help the children with Sickle Cell Disease live a better life. We want to know the factors associated with hospitalization of patients with sickle cell disease.knowning this might help us reduce the hospitalization risk.

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately. There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at any time and I will take time to explain.

Purpose: Why are you doing this research?

We want to improve the health outcome for the children with sickle cell anaemia, reduce hospital admission.

Choice of participants: Why are you asking me?

We want to get some information from children with Sickle Cell Anaemia.

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes. This is still your clinic, everything stays the same as before.

I have checked with the child and they understand that participation is voluntary _____ (signature)

Procedures: What is going to happen to me?

If you allow us we are going to ask you some questions mostly asking you how well you have been and also how many times you have been admitted to hospital.

I have checked with the child and they understand the procedures _____(signature)

Risks: Is this bad or dangerous for me?

You will not be in any harm when you take part in this research

I have checked with the child and they understand the risks and discomforts _____ (Signature)

Benefits: Is there anything good that happens to me?

Nothing might happen to you, but the information you give us might help us learn more about sickle cell anaemia.

I have checked with the child and they understand the benefits

_____(Signature)

Reimbursements: Do I get anything for being in the research?

Unfortunately there will be no gifts if you choose to participate in the study.

Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study. Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

Sharing the Findings: Will you tell me the results?

When we are finished with the research we will not contact you personally to give you the results but you can come find out about the research at the Department of Paediatrics, University of Nairobi. We will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Assent **Serial Number:**

_____

I understand that this research is about finding factors associated with hospitalization of patients with sickle cell disease and il be asked a set of questions if I choose to participate in the research.

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have NOT signed the assent below

_____ (initialled by child/minor)

Only if child assents:

Print name of child _____

Signature of child: _____

Date:_____

If illiterate:

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

Print name of witness (not a parent) _____ AND Thumb print of participant

Signature of witness _____

Date _____

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

Name of researcher: DR MAHAA SALIM
Signature of researcher_____
Date_____

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands the purpose and procedure of the study. I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.
Name of Researcher: DR MAHAA SALIM
Signature of Researcher _____
Date _____

Copy provided to the participant _____(initialed by researcher)

Parent/Guardian has signed an informed consent: Yes_____ No_____

Who to Contact
If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:
Name: Dr Mahaa Salim (Primary Researcher)
Mobile Number: 0723801060

Email: sahag8686@gmail.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
College of Health Sciences
P. O. Box 19676 00202 Nairobi
Tel. (254-020) 2726300-9 Ext 44355
E-mail: uonknherc@uonbi.ac.ke

Gertrude's Garden Children Hospital
ERC/ Director of Clinical services
P. O. Box 42325 Muthaiga road,Nairobi
Tel(254-020)7206000

Swahili version

Fomu ya kutiwa saini na watoo ya _____

Fomu hii ni ya kutiwa saini na watoto wenye umri wa miaka saba na juu wanao hudumiwa katika Kliniki ya Ugonjwa wa Damu katika Hospitali ya Taifa Ya Kenyatta na Gertrude's Garden Childrens Hospital. Watoto hawa wanakaribishwa na Mpelelezi mkuu ni Dr Mahaa Salim chini ya usimamizi wa Profesa Dalton Wamalwa na Dr Nyambura Kariuki katika utafiti wa kuangalia sababu zinazosababisha kulazwa hospitalini kwa watoto wanayoishi na Ugonjwa wa Selimundu. Utafiti itafanyika chini ya Idara ya Afya ya Watoto katika Chuo Kikuu cha Nairobi.

Hi fomu ya kutiwa saini na watoto ina sehemu mbili:

- Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)
- Shahada ya Kutiwa saini na watoto (sahihi ikiwa umekubali kujihusisha na utafiti huu)

Utapewa nakala ya maalezo ya utafiti huu**.**

Sehemu 1: Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi,ninapofanya shahada kuu kwenye Idara ya Afya ya watoto.Ningependa pamoja na wasimamizi wangu kutafiti sababu za kulazwa hospitalini kwa watoto wenye ugonjwa wa Selimundu. Kando na haya utapewa maalezo zaidi kuhusu mada na pia, wazazi wako na mgarini wako ameelezewa kuhusu utafiti huu na wamekubali kijihusisha nayo, lakini una uhuru wa kukataa kujihusicha na utafiti huu na pia una uhuru wa kuuliza maswali yoyote ili kuelewa uafiti huu zaidi.

Nia

Ugonjwa wa Selimundu ni ugonjwa moja wapo unaoathiri watoto kweye sehemu yetu bara Afrika. Ugonjwa huu umeadhiri maisha ya watoto hawa hasa wakati wao mwingi hutumiwa hospitalini wanapolazwa ili kupokea matibabu zaidi. Utafiti huu haujafanywa sana katika bara la Afrika. Kwa hio utafiti huu utasaidia kuelewa zaidi sababu za kulazwa hospitalini kwa watoto wenye ugonjwa wa selimundu.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Nimethibitisha kuwa mtoto ameelewa ya kwamba hakuna hatari yoyote ile itayomkabili _____ (saini)

Faida ya utafiti

Utafiti hii utasaidia kueleza sababu za kulazwa hospitalini kwa watoto wenye ugonjwa wa selimundu. Itasaidia kupunguza hasara za kifedha.

Nimethibitisha kuwa mtoto ameelewa faida ya utafiti _____ (saini)

Waanaoalikwa kujihusisha na utafiti

Mtafitii anawakaribisha watoto wote wanaopokea matibabu ya Ugonjwa wa Selimundu na kufutiliwa katika Hospitali ya Taifa Ya Kenyatta na Gertrude's Garden Childrens Hospital

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki, uamuzi huu hautaathiri kwa njia yoyote matibabu yako au utakavyiohudumiwa.

Nimethibitisha kuwa mtoto ameelewa ya kwamba kujihusisha na hii utafiti ni kwa njia ya kujitolea _____ (saini)

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki utapewa fomu ya kujaza iliyo na seti ya maswali hasa kuhusu hali ya afya ya watoto hawa na idadi ya nyakati za kulazwa hospitalini kwa muda wa mwaka moja.sababu ya kulazwa. Maelezo zaidi pia yatatolewa kwenye file yako kliniki ili kuboresha utafiti.

Nimethibitisha kuwa mtoto ameelewa maelezo kuhusu mchakato_____ (saini)

Wakati utakaotumika

Kwa ujumla,utafiti huu utachukua siku tisini (90).Kwa wakati huu,tutahitaji dakika kumi na tan tu kujaza fomu na kuchukua maelezo mengine yatakayohitajika

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. zaidi ya hayo badala ya jina la mtoto, numbari zitatumiwa kutambuliwa watoto hawa.Matokeo yatazungumziwa na idara ya afya ya watoto pekee wala sio mtu mwingine.

Haki ya kutoshiriki

Kushiriki kwa utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki,uoamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya afya ya watoto ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa .
Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

Sehemu ya 2: Shahada ya Kutiwa Saini na Watoto **Nambari Maalum:_____**

Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali ambayo yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha.Kwahio ningependa kupeana saini langu na pia kujitolea kushiriki kwa utafiti huu .

Nakubali kujihusisha na utafiti huu.

AMA

Si kubali kujuhusisha na utafiti huu na sijatia saini lolote._____ (alama ya mshiriki)

Mtoto akikubali:

Jina la mtoto: _____

Saini la mtoto: _____

Tarehe:_____

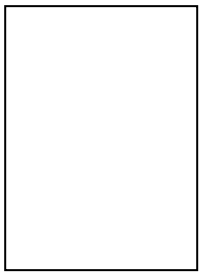
Iwapo mtato awezi akasoma:

Nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la shahidi (isiwe mzazi): _____ NA Alama ya Kidole ya Mshiriki

Saini la shahidi:_____

Tarehe: _____



Nimemsomea ama nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la mpelelezi: DR .MAHAA SALIM

Saini ya mpelelezi: _____

Tarahe: _____

Nakala imepewa kwake mshiriki _____(alama ya mpelelezi)

Mzazi/Mgarini amaitia saini Shahada ya Idhini : Ndiyo_____ Hapana_____

Kwa maelezo Zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

Jina: Dr MAHAA SALIM (mtafiti mkuu)

Nambari ya simu: 0723801060

Barua pepe: sahag8686@gmail.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Simu. (254-020) 2726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

P. O. Box 42325 Muthaiga road,Nairobi

Gertrude's Garden Children Hospital

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Tel(254-020)7206000

Appendix V: Budget

	Ksh
Printing, photocopying and binding of both research booklets and questionnaires	8,000
Travel costs during data collection to Gertrude's Children's Hospital estimated at 100kshs per return trip for 5 clinic days	500
Payment to Statistician/Analyst to enable appropriate analysis	30000
Research assistants 2@ 8000mper month	32000
Total Costs	70,500

Appendix VI: Work schedule

	May	June	August	September-Dec	jan-feb	march 2018
Presentation of proposal to the department						
Presentation of proposal to the ethics committee						
Data collection						
Data analysis						
Presentation of final report						