A COMPARISON OF THE NUTRITIONAL STATUS OF CHILDREN WITH COLONIC STOMAS AND THOSE WITHOUT STOMAS ADMITTED FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

DISSERTATION SUBMITTED IN PART FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF MASTER OF MEDICINE IN PAEDIATRIC SURGERY DEGREE AT THE UNIVERSITY OF NAIROBI.

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DECLARATION

I declare that this is my own original work and has not been presented for a degree in any other University.

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LIST OF ABREVIATIONS AND DEFINITIONS

AC	Arm circumference
ARM	Anorectal Malformation
BMI	Body Mass Index
ERC	Ethics and Research Committee
H/A	Height/Age
Hb	Haemoglobin
HSD	Hirschsprungs Disease
KNH	Kenyatta National Hospital
PSOPC	Paediatric Surgical Outpatient Clinic
RVF	Rectovestibular fistula
SD	Standard Deviation
SGNA	Subjective Global Nutritional Assessment
TSF	Triceps Skin fold
UON	University of Nairobi
W/A	Weight/Age
WHO	World Health Organisation

ABSTRACT

Eighty(80) children aged between thirty days and ten years were enrolled in a descriptive observational case-control study which compared the nutritional status of children with colonic stomas(40/80) to those without stomas(40/80) admitted for elective surgery at Kenyatta National Hospital.

Nutritional status was determined by Subjective Global Nutritional Assessment (SGNA) and anthropometric indicators (height/age, weight/age, and body mass index/age), which were stratified by gender, with World Health Organization standards used as reference.

The average WHZ, HAZ and WAZ scores among cases with colostomies were 1.23, 1.33 and 1.15, respectively compared to mean scores of 1.05, 1.3 and 1.18 among the controls, respectively. 22.5% of the children with colostomies had Wasting compared to 5% among the controls, with colostomies having a five-fold increase in the risk of wasting compared to the controls. There was however, no significant association between stunting or underweight and colostomies. 55% of the children with colostomies had anaemia compared to 32.5% amongst the controls. The mean haemoglobin level in children with colostomies (10.3 ±1.87) was 1 unit lower (95% CI 0.14 – 1.86) compared to the mean levels in controls (11.29±2.06). Similarly the mean MCV in children with colostomies was 61.85 ± 18.15 compared to a mean MCV of 71.14 ± 13.13 among controls. Children with a colostomy due to HSD had significantly lower mean haemoglobin levels (9.66±1.70) compared to those with a colostomy due to ARM (11.36±1.70). The socioeconomic characteristics of caretakers of children with colostomy.

The prevalence of malnutrition in paediatric surgical admissions is high and there exists a significant association between wasting, low haemoglobin, low MCV values and colonic stomas. Therefore, nutritional status screening programs and institution of corrective nutritional care among paediatric surgical patients with colostomies is necessary to prevent the adverse effects on healing, growth and surgical outcome.

1.0 INTRODUCTION

A colostomy is a surgical procedure which involve the fashioning of a stoma from the healthy end of the large intestine or colon through an incision in the anterior abdominal wall and suturing it into place. This opening, in conjunction with the attached stoma appliance, provides an alternative channel for faeces to leave the body. The indications of colonic stomas in paediatric surgical population include Anorectal malformation, Hirchsprungs disease, perineal trauma, acquired recto-urinary fistulas, acquired recto-vaginal fistulas, pelvic tumours amongst others.

The functions of the colonic stomas include decompressing the obstructed colon and/or protecting a future perineal operation. The stoma is associated with several significant complications, which may be related to the technical aspects during the fashioning, recurrent trauma to the exposed mucosa or stool stasis due to dilatation of the bowel. Some of these complications, both early and late, can influence directly or indirectly, the nutritional status of patients.

Protein energy malnutrition has been clearly proven as a major determinant of poor operative outcomes in surgical patients¹. Identification and correction of nutritional deficiencies in a severely malnourished patient helps reduce this risk². The incidence of malnutrition in paediatric surgical patients varies with screening criteria. Nutritional status among paediatric surgical patients in general and specifically those with a colostomy has never been studied at K.N.H

1.2 Literature Review

Malnutrition in paediatric surgical patients has severe adverse effects on healing, growth and surgical outcome, but only limited information is available on its prevalence (in paediatric surgical patients). In addition, only limited published data exists on the nutritional status of paediatric surgical patients with colostomies. There is no published work which has compared the nutritional status of paediatric surgical patients admitted for elective surgery.

Kenyatta National Hospital has a significant number of children with temporary colostomies awaiting definitive corrective surgery and closure of colostomy thereafter. However, the nutritional status among this patient population has never been studied at KNH. Data that is currently available describes the nutritional status of hospitalised patients in general. Ingrid et al did a study at a children's hospital in Germany (on both medical and surgical paediatric patients) and found that some 24.1% of paediatric hospital patients were malnourished, with 17.7% of all patients who were mildly, 4.4% who were moderately and 1.7% who were severely malnourished³.

Paediatric patients undergoing gastrointestinal surgery, which results in the formation of stoma, are at a particular risk of developing malnutrition due to the effects of the underlying disease, the prolonged fasting during pre-and postoperative periods, and possibly due to complications resulting from the surgical procedure^{4, 5}. Santos et al reported that 57.9% of patients had complications related to the stoma⁶. However, in literature there are frequencies that range from 16 to 90%^{7, 8,9}. This studies, however, do not elucidate the level of malnutrition resulting from stoma complications.

A study in Brazil by Emmanuelle et al observed that, in the immediate postoperative period, the most frequent complication was stoma diarrhoea, followed by weight loss and bleeding at the site of the stoma¹⁰. Among these complications, it is known that diarrhoea, so evidenced in this study, can lead to dehydration and electrolyte loss, generating nutritional and systemic repercussions.

According to data from the WHO, only 2.3% of a population has parameters below -2 on the Z score¹¹. Frequency of nutritional deficits of 24.1, 20.0 and 6.9% were observed, according to analysis of anthropometric indicators H/A, W/A and BMI/A, respectively.

Using the mean Z-score as an index of severity for health and nutrition problems results in increased awareness that, if a condition is severe, an intervention is required for the entire community, not just those who are classified as "malnourished" by the cut-off criteria

Silveira et al, when evaluating paediatric patients admitted to a Hospital obtained a frequency of deficit for the indicator H/A similar to that described previously (21 versus 24.1%), however, they found a frequency twice as high for the BMI/A indicator (14.7 versus 6.9%)¹².

Rocha et al, found similar results, in a study of hospitalised children where the prevalence of Z score of less than -2 standard deviations was 18.2, 18.7 and 6.9% for indicators H/A, W/A and W/H, respectively¹³.Studies by Joosten and Hulst, with the indicator W/H or equivalent found a prevalence of acute malnutrition in the last 10 years in hospitalized children in Germany, France, the UK, and the U.S. between 6.1% and 14%, while in Turkey up to 32% of patients had malnutrition¹⁴.

Recently, the prevalence of acute malnutrition has decreased in paediatric patients, however, that of chronic malnutrition has increased. Sigulemet al, found 25% of patients presenting with impaired linear growth¹⁵. In a study involving 749 children and adolescents hospitalized in the paediatric surgery at Hospital São Paulo, there was a percentage of 19% for short stature or risk for short stature.¹⁶

There are no studies in Kenya on malnutrition in hospitalized paediatric or paediatric surgical patients. However, a study by Mwaniki and Makokha in a public school in Kenya found among the children surveyed, 24.5% were stunted, 14.9% underweight and 9.7% were wasted. There were more boys than girls who were stunted¹⁷. Gewa and Yandel in their study found nearly similar results with 30% of younger children stunted, 13% underweight and 8% wasted. 40% of the older children were stunted, 17% were underweight and 4% were wasted¹⁸. In another study by Masibo et al reported in the Kenyan demographic and health survey, the prevalence of stunting decreased by 4·6 percentage points from 39·9% in 1993 to $35 \cdot 3\%$ in 2008-2009, while underweight decreased by 2·7 percentage points from 18·7% in 1993 to $16 \cdot 0\%$ in 2008-2009¹⁹.

Desiree van den Hondel et al conducted a study to Asses growth and development on Nonsyndromal children with anorectal malformations. They prospectively evaluated these children at 0.5, 1, 2, and 5 years using biometric measurements. 108 children (59% male) were included. 49% had a high malformation, and 46% had \geq 1 additional major co morbidity. All growth parameters were below the norm at all ages (p < 0.01), irrespective of type of malformation. Children with \geq 1 additional major anomaly had lower height at all ages; at 5 years, mean (95% CI) height was – 1.83 (– 2.7 to – 1.1) and – 0.70 (– 1.3 to – 0.1) in children with and without co morbidities, respectively (p = 0.019)²⁰

Chronic bleeding from the exposed mucosa of colonic stoma in children is common. This is usually due to recurrent trauma from appliances used in stoma care. Panato et al, studied hospitalized children with bowel stomas less than 5 years observed a high of anaemia of 70.0%, higher than that found in the study by Emmanuelle et al $(59.3\%)^{21}$. It is known that high concentrations of hemoglobin are associated with reduced length of hospital stay and $costs^{22}$. Furthermore, there is some evidence that anaemia is associated with weight loss in hospitalized patients²³.

In paediatric surgical patients comprehensive care should begin at admission, through nutritional assessment; identification of malnourished patients and those at nutritional risk and, thus, optimizing the results of therapy and managing dietary behaviours during admission and after discharge²⁴. Furthermore, the screening and monitoring of the nutritional status of individuals with bowel stomas should be a continuous process, beginning preoperatively and continuing after discharge due to potential repercussions, such as the presence of postoperative complications, modifications in diet, and changes in nutrient absorption capabilities.

Knowledge on the prevalence of malnutrition in paediatric surgical patients with colostomies will aid in developing corrective nutritional protocols for better surgical outcomes after definitive surgery

1.3 Modalities Of Nutritional Assessment

Numerous options are available to assess the nutritional status of paediatric surgical patients, broadly classified into objective and subjective modalities. There are two general classes of objective assessment: anthropometric measurements of body composition and measurement of serum protein levels.

Subjective assessments include questionnaires, which incorporate both subjective data from the patient history, and anthropometric body composition measurements. These include the Subjective Global Nutritional Assessment (SGNA), utilized by Secker et al²⁵, and the Mini Nutrition Assessment (MNA). Both general classes of nutritional assessment are subject to observer error or are influenced by changes in body composition induced by non-nutritional factors²⁶.

Subjective Global Assessment (SGA) evaluates the nutritional status of the patient utilizing history, physical examination, and anthropometric measurements. This assessment tool is validated for use in adults, and has been adapted for the paediatric population and renamed

Subjective Global Nutritional Assessment (SGNA). The focus of this assessment tool is to identify evidence of loss of subcutaneous fat, muscle wasting, or edema. It also incorporates a questionnaire, which identifies other factors associated with malnutrition, such as rate of growth, dietary intake, gastrointestinal symptoms, functional capacity, and metabolic stress. A rating form is used, which takes into account the variables from the history and physical exam, and assigns a rating of normal/well nourished, moderate malnutrition, and severe malnutrition²⁷.

Anthropometric nutritional assessment modalities are objective assessment tool involving measurement of body dimensions and composition to evaluate nutritional status and growth. The most basic are age, sex, height, weight, and head circumference. This is a common and inexpensive method to assess growth and nutritional status, which can also be charted on a standardized growth curve for comparison with normative data. Once patients are over 2 years of age, weight to length (height) ratio can best be reflected using body mass index (BMI), or expression of BMI as a Z-score²⁸

Anthropometric indices can be expressed in relationship to the reference population in two different statistical terms: standard deviations from the median or percentage of the median.

1.4 Standard deviations or Z-scores

It is the difference between the value for an individual and the median value of the reference population for the same age or height, divided by the standard deviation of the reference population

Z-score =<u>measured value - median value of the reference population</u> Standard deviation of reference population

In other words, by using the Z-score, you will be able to describe how far a child's weight is from the median weight of a child at the same height in the reference value

2.0 STUDY JUSTIFICATION

Temporary diverting colonic stomas are highly utilized in the paediatric surgical unit at Kenyatta National hospital especially in the management of congenital diseases such as ARM and HSD before definitive corrective surgery.

Malnutrition is an important predictor of poor surgical outcome. However, it is one of the patient related factors that cause poor wound healing which can be manipulated to the advantage of the patient for better outcomes. Anecdotally, the rate of breakdown of repairs and redo reconstructive surgeries for children who had undergone diverting colonic stomas at the paediatric surgical unit at KNH is high and hence the need to establish a possible cause.

In light of the above, there has been no study conducted locally to assess the nutrition status of children with colonic stomas who are awaiting definitive surgery. In addition, there is no local protocol for nutritional management of these patients as they await definitive corrective surgery. This study aims at establishing the level of malnutrition in this population at K.N.H. This knowledge can be utilised to formulate a Corrective nutritional protocol for better functional outcomes.

2.1 STUDY OBJECTIVES

2.1.1Main objective

To compare the nutritional status of children with colonic stomas to those without stomas admitted for elective surgery at Kenyatta National Hospital.

2.1.2Specific objectives

1. To compare the nutritional status of children with colonic stomas at KNH and controls admitted for elective procedures using Z scores, albumin and haemoglobin level.

2. To characterize the socioeconomic status of the caregivers of children with colonic stomas at KNH.

3.0 METHOD

3.1 Study Design

A descriptive observational case-control study

3.2 Study Area:

Kenyatta National Hospital is a national referral and teaching hospital with a bed capacity of 1800 patients. The study was conducted at the Paediatric Surgical Ward (ward 4A) and at the Paediatric Surgical Outpatient clinic (clinic 24) at this institution.

3.3 Study Population:

The study group included patients, under the age of 10 years with colostomy in situ for more than 30 days and children without bowel stomas admitted at the paediatric surgical ward for elective surgery within the same age limit and who met the inclusion criteria.

3.3.1 Definition of Cases and Control

Cases were defined as paediatric patients under the age of 10 years who had had a colostomy in situ for more than 30 days and also met the inclusion criteria.

Controls were paediatric surgical patients under the age of 10 years admitted for elective surgery without ever having a colostomy fashioned.

3.4 Inclusion Criteria for Cases

All children with colonic stomas seen at KNH paediatric surgical ward or paediatric surgical outpatient clinic, age between 30 days and 10 years, who provided a written consent.

3.5 Inclusion Criteria for Control

Children without colonic stomas admitted at paediatric surgical unit for elective procedures aged between one month and ten years, who provided a written consent.

3.6 Exclusion Criteria

1. Children aged above 10 years. These patients were excluded because the anthropometric parameters have been established to be inaccurate above the age of 10 years.

2. Patients with conditions that impair anthropometric measurements (edema, anasarca, limb amputation).

3. Patients with neurological diseases because these conditions are associated with poor musculoskeletal development hence inaccurate anthropometric measurements.

4. Children with gastrointestinal disorders which impair nutrient absorption: celiac disease, gastro-oesophageal reflux, Crohn's disease and short-gut.

5. Patients with genetic syndromes and likely to experience malnutrition not necessarily related to colonic stomas.

6. Patients with small bowel stomas were excluded because their nutritional challenges were viewed to be different from those patients with colonic stomas.

3.7 Sample Size Calculation

The sample size for the case-control study was calculated using the formula proposed by Fleiss for detecting a standard effect size in two groups:

$$n = (\frac{r+1}{r})\frac{(\vec{p})(1-\vec{p})(Z_{\beta}+Z_{\alpha/2})^2}{(p_1-p_2)}$$

The following assumptions were used in calculating sample size: $Z_{\alpha/2}=1.96$, representing the area under the standard normal curve corresponding to a type I error rate of 0.05

 $Z_{\beta}=0.84$, corresponding to a power of 80% in detecting the stated difference in the prevalence of malnutrition between children with and without stoma

r=1 (equal number of cases and controls)

 p_1 = The mean proportion of children with stoma who have poor nutritional status (WHZ < - 2). This proportion was estimated at 24% based on the reported prevalence of malnutrition in children with stoma by Ingrid *et al*.

 $p_1 - p_2$ = Effect size representing the anticipated difference in prevalence of malnutrition between children with and without stoma (estimated at 0.2 or 20%)

 p_2 = The mean proportion of children without stoma who have poor nutritional status (WHZ < -2). Estimated by subtracting the anticipated effect size from p_1

 $\mathbf{\bar{p}}$ = average of $\mathbf{p_1}$ and $\mathbf{p_2}$

$$n = \left(\frac{1+1}{1}\right) \frac{(0.23)(1-0.23)(0.84+1.96)^2}{(0.24-0.02)^2} = 38$$

Therefore, n = 76 (38 cases and 38 controls)

3.7.1 Sampling Method:

Convenience sampling was used. This strategy allowed the principal investigator to recruit subjects who met the inclusion criteria as they came to the paediatric surgical outpatient clinic or paediatric surgical ward.

3.7.2 Study Period

The study was carried out over a four month period between January 2016 and April 2016.

3.7.3 Recruitment Procedure

All children below 10 years of age who had a diverting colostomy in situ for more than 30 days were recruited during their routine follow up at the Paediatric Surgical Outpatient Clinic or while admitted in the paediatric surgical ward (Ward 4A).

Consecutive enrolment of control subjects who met the inclusion criteria was done as they got admitted into the paediatric surgical ward.

3.7.4 Consenting Procedure

The details and significance of the study was given in written and verbal form to the parent/guardian by the principal investigator or research assistant. Only those willing to provide a written consent were included in this study.

3.7.5 Implementation Plan

Data were collected by a structured questionnaire containing identification, socioeconomic, and clinical data from the parent or guardian of the minor. Additional information was obtained from the patient's medical records. The socioeconomic situation and housing conditions were also recorded.

For the anthropometric assessment, measurements of weight, height, arm circumference (AC), triceps skin fold thickness (TSF), were performed at the time of first contact with the patient. The same weighing scale was used in all the subjects of this study. The length of those below two years was taken while supine and height for those above 2 years was done while erect. The nutritional assessment was performed using anthropometric indicators height/age (H/A), weight/age (W/A) and body mass index/age (BMI/A) according to sex, taking as a basis the standard reference of the World Health Organization (WHO) and using the WHO AnthroPlus® program, version 3.2.2. The results were expressed as Z scores, considering that: children below 2 standard deviations presents nutritional deficits, above 1 standard deviation for the indicator of BMI/age - overweight/obese, and above 2 standard deviations for weight/age, presents high weight for age.

In body composition assessment, to measure AC an inextensible tape measure was used and, for the TSF, a Lange® scientific skin fold calliper with 10gr/mm2 constant pressure. Measurements were taken at the midpoint between the olecranon and the acromion in non-dominant arm. Values below the 5th percentile were considered as indicators of risk of diseases and disorders associated with malnutrition.

Nutrition related history according to Subjective Global Nutritional Assessment (SGNA) protocol was taken for each patient. History taking was conducted by a Surgical Resident who was practicing in the study areas during the study period. Data from the SGNA history was summarized into one of three class groups; A-well nourished, B-moderately (or suspected of being) malnourished and C-severely malnourished

All laboratory procedures were carried out at the phlebotomy room located at K.N.H. clinic 23 while observing sterility. The procedure was explained to the child and parent/guardian. A peripheral vein was identified and the area disinfected with an alcohol swab. 5 millilitres of blood was drawn using a sterile safety syringe and needle, and dispensed into relevant specimen bottles which was then appropriately labelled. The specimen was then transported to the K.N.H. haematology laboratory using blood transport containers. Infection control protocols were observed by gloving and gowning appropriately during sample collection, transport and analysis.

Samples were collected for a haemogram test, whose analysis was performed with an automatic counter. The cut-offs indicative of inadequate levels of haemoglobin and

hematocrit was defined according to age: hemoglobin - <1 year, <10.0g/dL; 1 to 5 years, <11.0g/dL, and > 6 years, with 11.5g/dL; hematocrit - <2 years, <31.0g/dL; 2 to 5 years - <34.0g/dL, and > 6 years, with <36.0g/dL.

Other parameters which were measured from the blood specimen include: magnesium, phosphate, calcium and albumin levels

3.8 Data Analysis

Data were entered in Excel for Windows[®]. Analysis was performed in the Statistical Package for the Social Sciences (SPSS) program, version 21.0. Descriptive analysis was conducted separately for cases and control groups, and comparisons of the two groups conducted. The aim of the analysis was comparison of the nutritional status of children with colonic stomas to those without colonic stomas admitted for surgery. These nutritional status comparison was based on three parameters: nutritional Z-scores, hematological measures (haemoglobin and MCV), and lastly biochemical parameters (serum albumin and micronutrients levels). For Z-scores weight and height measures were used to calculate weight for height Z score (WHZ) standardised for age and sex. The WHZ was then transformed into a binary variable using a cut-off of -2. The primary comparison of nutritional status was based on percentage of patients with WHZ scores < -2. The percentage of cases and controls with WHZ < -2 was compared using logistic regression models to generate Odds Ratios and 95% confidence interval. Weight-for-age and height-for-age Z scores were calculated and reported as secondary measures of nutritional status due to lack of sensitivity for acute nutritional status.

For the secondary objectives involving comparing hematological and biochemical markers of nutritional status comparisons were based on calculating mean measures for children with and without stomas and using two-sample Student's T-test to compare the means. The mean hemoglobin and MCV measures were obtained for each group along with the respective standard deviation. T-test was then be performed assuming unequal variances around the mean. A mean difference in hemoglobin and MCV for children with and without stoma was reported with a 95% CI and p value.

Similarly, mean serum albumin and micronutrients levels was obtained for each group along with the respective standard deviation. T-test was then performed assuming equal variances around the mean. A mean difference in serum albumin and micronutrients levels for children with and without stoma was reported with a 95% CI and p value.

Finally to characterize socioeconomic status of caregivers of children with stoma a comparison of the characteristics of caregivers was done according to case and control status. For variables measured on continuous scale for example age, the mean and standard deviations were reported while categorical variables like patients sex were summarized using frequency distributions. The descriptive statistics of socio-demographic characteristics (such as age and gender) were presented using percentages, frequencies tables, pie charts and graphs. Logistic regression was used to obtain OR (95% CI) and these reported along with P values.

3.9 Limitations

- i. Errors in biochemistry analysis resulting from blood specimen haemolysis
- ii. Selection of a suitable control group that is representative of the population of children without stoma is difficult

3.10 Dissemination Plan of Study Findings

The findings of the study will be disseminated through scientific presentations at the departmental and college level as well as presentations made at national and international scientific conferences. The results of the final analysis will be published in a peer reviewed scientific journal.

4.0 ETHICAL CONSIDERATIONS

Institutional consent was sought from the Department of surgery, University of Nairobi (UON) and Ethics and Research Committee of KNH. Informed consent was also sought from parents/guardian of patients. Confidentiality and privacy was observed.

Patients who were diagnosed with Protein Energy Malnutrition (PEM) during this study were reviewed by a nutritionist attached to the Paediatric Surgical Unit – K.N.H and corrective nutritional measures instituted accordingly.

All questionnaire data will be safely stored during analysis and report writing and be destroyed after concluding the dissertation and publication of scientific peer reviewed manuscripts.

4.1 Safety Considerations

Only patients deemed to be clinically stable by the investigator were subjected to diagnostic procedures. These were patients who by clinician's assessment, were unlikely not suffer health deterioration once subjected to the diagnostic procedures carried out in this study. In this study these investigations included analysis of peripheral blood samples and anthropometric measurements only. The safety of patients included in the study was not interfered with by way of delays caused by waiting for investigation or intervention since the standard of care was not be altered by application of the questionnaire or entry of information to the data sheet. There was no adverse interference on the standard of care.

5.0 RESULTS

A total of 80 paediatric surgical patients were recruited in the study including 40 children with colostomies (cases) and 40 admissions for elective surgery (controls).

5.1 Patient Characteristics

The mean age (\pm SD) of the patients with colostomy was 4.46 years (\pm 3.0) compared to a mean age of 4.58 years (\pm 4.0) in children with no colostomy. The most common age groups among both cases and controls were 2-4 years and 5-8 years (Table 1). There were 15 (37.5%) cases aged 5-8 years and 10 (25%) controls in the same age group while 13 (32.5%) cases and 14 (35%) controls were aged 2-4 years. There was no significant difference in age distribution among cases and controls (p = 0.554), Table 1. Male children accounted for 25 (62.5%) colostomy cases and 28 (70%) controls with no significant association between sex and stoma (p = 0.478).

 Table 1: Demographic characteristics of children with colostomy and without colostomy in KNH

		Cases		Cont	rols	P value
		Ν	(Percent)	Ν	(Percent)	-
Age	< 2 years	9	22.5	10	25	0.554
	2-4 years	13	32.5	14	35	
	5-8 years	15	37.5	10	25	
	9 years and above	3	7.5	6	15	
Gender	Male	25	62.5	28	70	0.478
	Female	15	37.5	12	30	

5.2 Socioeconomic status of the caregivers of children with colonic stomas at KNH

The socioeconomic characteristics of caretakers of children with colostomy were comparable to those of caretakers of children without colostomy (Table 2). Most caretakers in both groups were aged below 30 years (57.5% in cases and 45% in controls, p = 0.104). Among the caretakers of cases 24 (60%) reported that they had secondary level education compared to 26 (65%) caretakers of controls (p = 0.822).

The monthly income for 30 (75%) caregivers of cases and 23 (57.5%) caregivers of controls was less than Kshs 5000 (p = 0.098). There were 24 (60%) cases whose households resided in

semi-permanent housing compared to 23 (57.5%) controls similarly residing in semipermanent houses (p = 0.82).

	Cases		Cont	rols	P value
	Ν	(Percent)	Ν	(Percent)	_
<30 years	23	57.5	18	45	0.104
30-34 years	14	35	12	30	
35 years and above	3	7.5	10	25	
Primary	12	30	10	25	0.822
Secondary	24	60	26	65	
Tertiary	3	7.5	4	10	
<kshs 5000<="" td=""><td>30</td><td>75</td><td>23</td><td>57.5</td><td>0.098</td></kshs>	30	75	23	57.5	0.098
Kshs 5000-20000	10	25	17	42.5	
Permanent	16	40	17	42.5	0.82
Semi-permanent	24	60	23	57.5	
Protected water	20	50	7	17.5	0.845
Surface/					
Unprotected water	10	25	3	7.5	
Not stated					
	<30 years 30-34 years 35 years and above Primary Secondary Tertiary <kshs 5000<br="">Kshs 5000-20000 Permanent Semi-permanent Protected water Surface/ Unprotected water Not stated</kshs>	Cases N <30 years	Cases N (Percent) <30 years	$\begin{tabular}{ c c c c } \hline Cases & Cont \\ \hline N & (Percent) & N \\ \hline <30 years & 23 & 57.5 & 18 \\ 30-34 years & 14 & 35 & 12 \\ 35 years and above & 3 & 7.5 & 10 \\ \hline Primary & 12 & 30 & 10 \\ Secondary & 24 & 60 & 26 \\ \hline Tertiary & 3 & 7.5 & 4 \\ \hline Kshs 5000 & 30 & 75 & 23 \\ \hline Kshs 5000-20000 & 10 & 25 & 17 \\ \hline Permanent & 16 & 40 & 17 \\ \hline Semi-permanent & 24 & 60 & 23 \\ \hline Protected water & 20 & 50 & 7 \\ \hline Surface/ & & & \\ \hline Unprotected water & 10 & 25 & 3 \\ \hline Not stated & & & \\ \hline \end{tabular}$	$\begin{tabular}{ c c c c } \hline Cases & Controls \\ \hline N & (Percent) & N & (Percent) \\ \hline <30 years & 23 & 57.5 & 18 & 45 \\ \hline 30-34 years & 14 & 35 & 12 & 30 \\ \hline 35 years and above & 3 & 7.5 & 10 & 25 \\ \hline Primary & 12 & 30 & 10 & 25 \\ \hline Primary & 12 & 30 & 10 & 25 \\ \hline Secondary & 24 & 60 & 26 & 65 \\ \hline Tertiary & 3 & 7.5 & 4 & 10 \\ \hline $

Table 2: socioeconomic status of caretakers of children with colostomy	and	those
without colostomy in KNH		

Figure 1 presents reported prevalence of gastrointestinal symptoms among children with colostomy in KNH. The most prevalent GI symptom was vomiting (43.2%). Other GI complaints were diarrhoea (38.9%), anorexia (35.9%) and nausea (33.3%).



Figure 1: Gastrointestinal symptoms in children with colostomy in KNH

Table 3 shows the nutritional requirements and history of change in functional capacity among children with colostomies compared to controls. There was no differences in the percentages of cases (75%) and controls (82.5%) reporting history of change in functional capacity (OR = 1.98 [95% CI 0.60-6.57] p = 0.264). A primary diagnosis of change in energy demand was made in 7 (17.5%) cases and 4 (10%) controls. The diagnosis of change in energy demand was not significantly associated with colostomies (OR = 2.10 [95% CI 0.56-7.87], p = 0.271).

 Table 3: Nutritional requirements and energy demands of children with and without colostomies

		Cases	Controls	OR (95% CI)	P
History of change in functional					
capacity	No	30(75.0)	33(82.5)	1.00(Ref)	
	Yes	9(22.5)	5(12.5)	1.98(0.60-6.57)	0.264
Change in energy demand (Primary					
diagnosis)	No	30(75.0)	36(90.0)	1.00(Ref)	
	Yes	7(17.5)	4(10.0)	2.10(0.56-7.87)	0.271

5.3 Nutritional status of children with colonic stomas at KNH and controls admitted for elective procedures

There were three children with any signs of acute severe malnutrition. Of the children with severe malnutrition there were 2 (5%) cases with colostomies and 1 (2.5%) control. There was no significant association between documented clinical signs of severe malnutrition and colostomies (OR = 2.05 [95% CI 0.18-23.59], p = 0.564). All three children had easily plucked hair. The remaining signs of severe malnutrition that were documented were: pallor (cases n = 1 and control n = 1), muscle wasting (control n = 1), ascites (cases n = 1), white band on nailbed and glossitis (n = 1).

		Cases	Controls	OR (95% CI)	Р
Any sign of severe					
acute malnutrition	No	38(95.0)	39(97.5)	1.00(Ref)	
	Yes	2(5.0)	1(2.5)	2.05(0.18-23.59)	0.564
Specific signs of severe					
acute malnutrition					
Pallor	Yes	1(2.5)	1(2.5)	1.00(Ref)	
	No	39(97.5)	39(97.5)	1.00(0.06-16.56)	1
Easily plucked hair	Yes	2(5.0)	1(2.5)	1.00(Ref)	
	No	38(95.0)	39(97.5)	0.49(0.04-5.60)	0.564
Muscle wasting	Yes	0(0.0)	1(2.5)	NA	NA
	No	40(100.0)	39(97.5)		
Ascites	Yes	1(2.5)	0(0.0)	NA	NA
	No	39(97.5)	40(100.0)		
White bands on nailbed	Yes	0(0.0)	1(2.5)	NA	NA
	No	40(100.0)	39(97.5)		
Glossitis	Yes	0(0.0)	1(2.5)	NA	NA
	No	40(100.0)	39(97.5)		

Table 4: Signs of malnutrition in children with and without colostomies

Out of the children with colostomies 12 (30%) had history of weight loss in the last six months compared to 5 (12.5%) controls also reporting a history of weight loss in the same period (Table 5). These differences in reported weight loss during the last 6 months was not statistically significant (OR = 3.0, 95% CI 0.94 - 9.53, p = 0.062). However, considering the past 2 weeks cases were significantly more likely to report weigh loss compared to controls (p = 0.018). Specifically, the risk of reporting weight loss was five-fold higher in children with colostomies compared to controls (OR = 5.19, 95% CI 1.33-20.23).

Table 5.	Uistow	of record	woight	ahanga	in ahi	Idnon	with	and	without	anlact	miaa
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	Cases	Controls	OR (95% CI)	P value
History of weight loss in last 6				
months				
No change	28(70.0)	35(87.5)	1.00(Ref)	
Weight loss	12(30.0)	5(12.5)	3.00(0.94-9.53)	0.062
History of weight change in the				
past 2 weeks				
No change	27(67.5)	35(87.5)	1.00(Ref)	
Increase	1(2.5)	2(5.0)	0.65(0.06-7.53)	0.729
Decrease	12(30.0)	3(7.5)	5.19(1.33-20.23)	0.018

5.4 Anthropometric Assessment

Three different measures of child nutrition were used for the analysis, based on the World Health Organization (WHO) definitions (Table 6). The average WHZ, HAZ and WAZ scores among cases with colostomies were 1.23, 1.33 and 1.15, respectively compared to mean scores of 1.05, 1.3 and 1.18 among the controls, respectively. Wasting was significantly more prevalent among children with colostomies 9 (22.5%) compared to controls 2 (5%) with colostomies having a five-fold increase in the risk of wasting compared to the controls OR = 5.52(95% CI 1.11-27.43), p = 0.037 (Table 6). There was however, no significant association between stunting (p = 0.809) or underweight (p = 0.762) and colostomies as shown in Table 6.

	Cases N (%)	Control N (%)	OR (95% CI)	P value
WHZ				
Normal (>-2 SD)	31(77.5)	38(95.0)	1.00(ref)	
Wasting (<-2 SD)	9(22.5)	2(5.0)	5.52(1.11-27.43)	0.037
HAZ				
Normal (>-2 SD)	27(67.5)	28(70.0)	1.00(ref)	
Stunting (<-2 SD)	13(32.5)	12(30.0)	1.12(0.44-2.89)	0.809
WAZ				
Normal (>-2 SD)	34(85.0)	33(82.5)	1.00(ref)	
Underweight (<-2 SD)	6(15.0)	7(17.5)	0.83(0.25-2.74)	0.762

Table 6: Nutritional status of children with and without colostomies in KNH

There were 22 (55%) cases who met the definition of anaemia based on a haemoglobin cut off values of 12g/dl compared to 13 (32.5%) controls. Table 7 shows that haematological measures in children with colostomies were significantly lower compared to controls. The mean haemoglobin level in children with colostomies (10.3 \pm 1.87) was 1 unit lower (95% CI 0.14 – 1.86) compared to the mean levels in controls (11.29 \pm 2.06), p = 0.026. Similarly the

mean MCV in children with colostomies was 61.85±18.15 compared to a mean MCV of 71.14±13.13 among controls (mean difference 9.29, 95% CI 2.35-16.24).

	Cases	Controls	Mean difference	P value
	(n = 40)	(n = 40)	(95% CI)	
Haemoglobin	10.30±1.87	11.29±2.06	1.00(0.14-1.86)	0.026
MCV	61.85±18.15	71.14±13.13	9.29(2.35-16.24)	0.011

 Table 7: Mean haemoglobin and MCV in children with colonic stomas and controls admitted for elective procedures

The mean measures for biochemical parameter in children with colostomies and controls are presented in Table 8. The mean levels of albumin, phosphate, calcium and magnesium in children with colostomies were 27.40, 2.21, 1.77 and 1.23, respectively. These mean levels of biochemical parameters were not significantly different from those of the controls (Table 8).

 Table 8: Mean serum albumin and micronutrients in children with colonic stomas and controls admitted for elective procedures

	Cases	Controls	Mean difference	P value
	(n = 40)	(n = 40)	(95% CI)	
Albumin	27.40±6.44	29.41±5.72	2.00(-1.67-5.68)	0.294
Phosphate	2.21±3.28	1.59±0.40	-0.62(-1.82-0.58)	0.32
Calcium	1.77±1.06	3.36±5.63	1.60(-1.61-4.80)	0.349
Magnesium	1.23±0.38	1.36±0.39	0.13(-0.14-0.40)	0.364

5.5 Anthropometric Measures in Children with Colostomy

5.5.1 Duration of Colostomy

The median duration since fashioning of the colostomy in patients with stoma was 1.9 years (IQR 1 to 3.8), with a range from less than a month to 11.8 years. Most 25 (62.5%) patients reported that the duration with colostomy was more than one year (Figure 2).



Figure 2: Time duration since fashioning of colostomy in children with stoma in KNH

Duration of time with colostomy was not significantly associated with haematological parameters (Table 9). There were no significant differences in mean haematological parameter measurements between cases admitted with colostomy depending on the duration of time spent with the colostomy (Table 9). Mean haemoglobin values were (10.79 versus 10, p = 0.19) and MCV was 64.14 compared to 60.48, p = 0.551).

	Duration since operation			
	< 1 year	>1 year	Difference (95% CI)	P value
Haemoglobin	10.79±1.73	10.00±1.92	0.79(-0.37-1.95)	0.19
MCV	64.14±18.88	60.48±17.95	3.66(-8.21-15.52)	0.551
Albumin	24.27±10.51	28.90±2.28	-4.63(-11.21-1.96)	0.201
Calcium	2.15±1.98	1.62±0.32	0.53(-0.85-1.91)	0.476
Phosphate	4.02±5.76	1.43±0.44	2.59(-1.18-6.36)	0.214
Magnesium	1.19±0.29	1.25±0.42	-0.07(-0.33-0.20)	0.634

Table 9: Mean haematological measures in col	ostomy patients according to duration
since colostomy insertion	

Table 10 presents the anthropometric indices for cases and controls according to duration with colostomy. There were no statistically significant differences in prevalence of stunting (24 versus 16.4%, p = 0.435), wasting (18.2 versus 18.8%, p = 0.292) or underweight (15.4 versus 19.4%, p = 0.819) in children who had had colostomies for less than one year compared to those who has had colostomies for longer time periods (> 1 year).

	V	VHZ		
	< - 2 SD	>= - 2 SD	OR (95% CI)	Р
Duration with				
colostomy				
<= 1 year	2(18.2)	13(18.8)	1.0(ref)	
> 1 year	7(63.6)	18(26.1)	2.53(0.45-14.20)	0.292
	V	VAZ		
<= 1 year	2(15.4)	13(19.4)	1.0(ref)	
>1 year	4(30.8)	21(31.3)	1.24(0.20-7.74)	0.819
	H	IAZ		
<= 1 year	6(24.0)	9(16.4)	1.0(ref)	
> 1 year	7(28.0)	18(32.7)	0.58(0.15-2.26)	0.435

Table 10:Anthropometric assessment of colostomy patients in KNH

5.6 Hematologic Parameters in Children with Colostomies

Out of the 40 cases with colostomies there were 15 (38%) patients with a diagnosis of ARM and 25 (62%) had HSD. HSD disgnosis was associated with a significant reduction in mean hemoglobin levels (9.66 \pm 1.70) compared to ARM (11.36 \pm 1.70), p = 0.005 (Table 11). The remaining hematologic parameters did not show significant differences with primary diagnosis of the children with colostomies.

Table 11: Hematologic parameter	s in children	ı with colostomies in I	KNH
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	ARM	HSD	Difference (95% CI)	P value
Haemoglobin	11.36 ± 1.70	9.66±1.70	-1.70(-2.79 to -0.61)	0.005
MCV	66.44±20.53	59.09±16.38	-7.35(-19.56 to 4.86)	0.249
Albumin	29.67±3.08	26.48±7.25	-3.19(-6.83 to 0.45)	0.096
Calcium	1.62 ± 0.25	$1.81{\pm}1.21$	0.20(-0.34 to 0.73)	0.48
Phosphate	4.26±6.10	1.46±0.49	-2.80(-7.04 to 1.43)	0.235
Magnesium	1.26±0.37	1.23±0.40	-0.03(-0.35 to 0.29)	0.856

Table 12 presents the anthropometric indices of children with colostomies according to the primary diagnosis. There was a significant association between diagnosis and stunting (p = 0.035) but diagnosis was not significantly associated with wasting (p = 0.77) or underweight (p = 0.276). The stunting rate was four-fold higher in children with colostomies and primary diagnosis of ARM (32%) compared to those with colostomies and primary diagnosis of HSD (20%), OR 4.57 (95% CI 1.12-18.73).

	W	VHZ		
	< - 2 SD	>= - 2 SD	OR (95% CI)	Р
Diagnosis				
,HSD	6(54.5)	19(27.5)	1.0(ref)	
ARM	3(27.3)	12(17.4)	0.79(0.17-3.78)	0.77
	V	VAZ		
HSD	5(38.5)	20(29.9)	1.0(ref)	
ARM	1(7.7)	14(20.9)	0.29(0.03-2.72)	0.276
	E	IAZ		
HSD	5(20.0)	20(36.4)	1.0(ref)	
ARM	8(32.0)	7(12.7)	4.57(1.12-18.73)	0.035

Table 12: Anthropometric measures in children with colostomies in KNH

6.0 DISCUSSION

This study conducted within the paediatric surgical unit in KNH aimed to compare the nutritional status of children with colonic stomas to that of controls admitted for elective procedures using anthropometric indices (WHZ, WAZ and HAZ), haematological values and biochemical measures. Of these three measures of nutritional status two measures namely anthropometric and hematologic showed a significant association with colonic stomas. The prevalence of malnutrition ranged between 5 and 22% for wasting among controls and cases, respectively, 15 and 17.5% for underweight, and 30 and 32% for stunting.

At present there are no published studies reporting prevalence of malnutrition in Kenyan paediatric surgical patients. Despite this lack of directly comparable data the estimates from this study are similar to reported prevalence of malnutrition among both paediatric surgical and general inpatient populations in studies from other settings. The prevalence of stunting in two South American studies ranged between 19 and 25%^{15, 16}. In a separate series of hospitalised children the prevalence of Z score of less than -2 standard deviations was 18.2, 18.7 and 6.9% for indicators H/A, W/A and W/H, respectively¹³. Four studies using W/H indicator or equivalent found a prevalence of acute malnutrition in the previous 10 years in hospitalized children in Germany, France, the UK, and the U.S. between 6.1% and 14%, while in Turkey up to 32% of patients had malnutrition¹⁴. The estimates of malnutrition reported in the current study are within the range of those reported in the populations of paediatric inpatient populations in literature. The slight variations in estimates between the current study and existing studies could be explained by underlying prevalence of malnutrition in the general population of Kenyan children compared to populations within which other studies were conducted. More importantly with respect to underlying nutritional status in populations is the observation that the malnutrition prevalence in KNH compares to the national childhood malnutrition prevalence reported in Kenya Demographic Health Survey 35.3% for stunting and 16% for underweight¹⁹. Kenyan school surveys report stunting rates of 24.5%, 14.9% underweight and 9.7% wasting¹⁷. The higher rates of malnutrition in hospitalised Kenyan children compared to those reported in school surveys could be attributed to the effects of the underlying disease, and possibly due to complications resulting from the surgical procedure^{4, 5}.

Wasting was more prevalent among patients with colonic stomas compared to controls while the prevalence of stunting and underweight was not significantly different among cases and controls. A possible explanation is the fact that wasting is a measure of acute malnutrition and the stunting and underweight indices measure chronic malnutrition.

The hematologic measures of malnutrition were significantly associated with insertion of colostomies. Children with stomas had significantly lower mean haemoglobin and MCV levels. Chronic bleeding from the exposed mucosa of colonic stoma in children is common due to recurrent trauma from appliances used in stoma care. Studies have reported high prevalence of anaemia in hospitalised children with bowel stomas in the range of 59 to $70\%^{21}$, ²². In the current study the overall prevalence of anaemia was 43.8% with a higher prevalence in children with colostomies (55%). However, this study did not find an association between the duration of time with a colostomy and haematological parameters. The type of stoma care appliances used could possibly have an impact on the level of haematological parameters. Poor stoma site care could explain high prevalence of anaemia, possibly associated with poor socioeconomic status coupled with the prohibitive costs of colostomy bags and other site care materials. In this study between 57.5 and 75% of caregivers reported monthly incomes less than Ksh 5000, which can barely cover for the costs of colostomy bags. Further studies are needed to determine whether the stoma site appliances or dressings have an association with haematological parameter levels. There was a significant association between indications for a colostomy(HSD or ARM) and hematologic parameters with HSD patients having lower levels of hematologic parameters compared to ARM. This observation requires further work to elucidate whether the difference is due mere bleeding from stoma site or the pathophysiology of the disease.

The third measure of nutritional status namely laboratory biochemical investigation was not significantly associated with case-control status. The biochemical markers included albumin, magnesium, phosphate and calcium levels. This finding was unexpected because biochemical markers are commonly deranged in the presence of malnutrition and poorer nutritional status among cases was therefore expected to have corresponding changes in biochemical parameters. In light of this finding it is noteworthy that the study was powered to determine differences in the primary comparison of anthropometric changes in nutritional status and not the secondary endpoints of hematologic and biochemical parameters. Future studies are needed that are specifically designed and adequately powered to explore hematologic and

biochemical parameters on surgical paediatric patients and particularly those with abdominal stomas.

Specific signs of severe malnutrition occurred in only 2.5 to 5% of the cases and controls, implying that dependence on clinical manifestation of severe malnutrition in childhood to identify patients requiring nutritional intervention would result in considerable underestimation of the burden of malnutrition in paediatric surgical patients. These findings are in line with studies that report relatively low prevalence of severe malnutrition verified using anthropometric indices in comparison to moderate and mild malnutrition. The rates of severe malnutrition in hospitalised children in previous studies are in the range of 1.7% ³. As such clinical signs of malnutrition have a high false negative rate and should not be relied on for nutritional screening of paediatric surgical patients. Instead anthropometric measures should be applied in nutritional screening of all surgical patients because of the high prevalence of malnutrition in admission to this surgical unit in Kenya.

6.1 Study Strengths and Limitations

The comprehensiveness of nutritional assessment of paediatric surgical patients with colonic stomas spanning anthropometry, hematologic and biochemical investigations and inclusion of a suitable control group of surgical patients admitted for elective surgery are major strengths of the current study. However, considering the time and resource constraints in conducting the study the case-control study design was ideally suited for investigating nutritional status of children with colonic stomas.

A potential limitation of the findings reported here are the use of a subjective measure of recent changes in nutritional status in children. However, this limitation was overcome by including additional standardised anthropometry measures that in addition to assessing recent changes in nutritional status also measure chronic nutritional status of the subjects.

6.2 RECOMMENDATIONS

6.2.1 Comparison of Nutritional Status of Colonic Stoma and Elective Surgical Patients

Based on the findings of high prevalence of malnutrition and anaemia in children with colonic stomas the study recommends nutritional screening of all paediatric surgical admissions followed by nutritional intervention in children with malnutrition or at risk of malnutrition.

6.2.3 Screening tools

Subjective assessment tools were found to significantly underestimate the prevalence of malnutrition in the population studied. Therefore, this study recommends the use of anthropometric measurements for screening of malnutrition in children aged below 10 years.

6.2.4 Caregiver socioeconomic status

Caregivers of children with colonic stomas in KNH were predominantly from low socioeconomic status and might benefit from dietary counselling and health information on the vulnerabilities and nutritional requirements of colonic stoma patients. This group could also benefit from well organised and coordinated care provided by surgical teams with the intention of optimising wound healing in view of the observed resource constraints e.g. inability to afford colostomy bags.

6.3 CONCLUSION

The prevalence of malnutrition in paediatric surgical admissions is high and there exists a significant association between wasting, low haemoglobin, low MCV values and colonic stomas. Therefore, there is need to conduct nutritional status screening followed by institution of corrective nutritional care among paediatric surgical admissions considering malnutrition has adverse effects on healing, growth and surgical outcome.

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APPENDICES

APPENDIX I: CONSENT FORM

A COMPARISON OF THE NUTRITIONAL STATUS OF CHILDREN WITH COLONIC STOMAS AND THOSE WITHOUT STOMAS ADMITTED FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

English version

This Informed Consent form is for parents/Guardians with children participating in this study at KNH.

We are requesting these patients to participate in this research project whose title is "a comparison of the nutritional status of children with colonic stomas and those without stomas admitted for elective surgery at the Kenyatta National Hospital"

Principal investigator: Dr.Mwika MwirichiaInstitution: School of Medicine, Department of surgery- University of NairobiSupervisors: Dr F. Osawa, Dr. J. Ndung'u

This informed consent has three parts:

- 1. Information sheet (to share information about the research with you)
- 2. Certificate of Consent (for signatures if you agree to take part)
- 3. Statement by the researcher

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

Part I: Information sheet

My name is Dr. Mwika Mwirichia, a post graduate student at the University of Nairobi's School of Medicine. I am carrying out a study to determine the nutritional status of pediatric surgical patients with colonic stomas and those without stomas at the Kenyatta National Hospital. This will be determined by data collection through filling a questionnaire, patient examination and laboratory tests.

Purpose of the study

The purpose for this study is to improve the care provided to children at the paediatric surgical unit. The findings may form a useful baseline to assess and improve care of children with colonic stomas and paediatric surgical patients in general.

Voluntariness of participation

I am inviting you to participate in my study and you are free to either agree immediately after receiving this information or later after thinking about it. You will be given the opportunity to ask questions before you decide and you may talk to anyone you are comfortable with about the research before making a decision. After receiving this information concerning the study, please seek for clarification from either myself or my assistant (Dr.FarihaFazal) if there are words or details which you do not understand.

Confidentiality

If you agree to participate, you will be asked to provide personal information and other details related to your child's condition as well as examination and laboratory tests. All the information which you provide will be kept confidential and no one but the researchers will see it.

Your name will not appear in any document. The information about you will be identified by a number and only the researchers can relate the number to you as a person. Your information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi - Ethics and Research Committee (KNH/UoN-ERC).

Risks

Your child's involvement in this research will be through an interview and clinical evaluation and you will not expose him/her to any risks if you consent to participate. There will be no extra cost incurred for participating in the study.

Right to withdraw from the study

Participation in this study is out of your own free will, you will not be denied medical care in case you refuse to participate in the study .You may stop participating at any time with no consequences whatsoever. All the information that you give us will be used for this research only.

This proposal has been reviewed and approved by the KNH/UoN-ERC, for the duration of one year, which is a committee whose work is to make sure research participants like you are protected from harm. It was submitted to them through the Chairman of the Department of Surgery at the School of Medicine of the University of Nairobi with the approval of the three university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason;

Secretary, KNH/UoN-ERC

P.O. Box 20723 KNH, Nairobi 00202
Tel 726300-9
Email: KNHplan@Ken.Healthnet.org
University of Nairobi research supervisors
Dr. F. Osawa
Department of Surgery, School of Medicine, University of Nairobi
P.O. Box 19676 KNH, Nairobi 00202
Tel # 0202726300

Mr. James Ndung'u

Department of Surgery, School of Medicine, University of Nairobi P.O. Box 19676 KNH, Nairobi 00202 Tel # 0202726300

Principle researcher: Dr.MwikaMwirichia Department of Surgery, School of Medicine, University of Nairobi P.O. Box 20890 KNH, Nairobi 00202 Mobile phone 0721514477

Research Assistant

Dr.Fariha Fazal

Department of Surgery, School of Medicine, University Of Nairobi P.O. Box 20890 KNH, Nairobi 00202 Mobile No. 0727507961

Part II: Consent certificate by patient

Ifreely give consent for my child Name......to take part in the study conducted by Dr.Mwika Mwirichia, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my child's participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care given to my child. The results of the study may directly be of benefit to my child or other patients and more significantly to the Medical professionals to better understand the nutritional status of pediatric surgical patients with colonic stomas and those without stomas at the Kenyatta National Hospital.

.....

Signature/left thumb print (Parent/Guardian)

Date.....

Day/Month/Year



Statement by the witness if participant is illiterate

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

Name of witness.....

Signature of witness.....

Date.....

Day/Month/Year

Part III: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands the following:

- Refusal to participate or withdrawal from the study will not in any ways compromise the quality of care and treatment given to the patient.
- All information given will be treated with confidentiality.
- The results of this study might be published to enhance the knowledge of the nutritional status of paediatric surgical patients with colonic stomas and those without stomas at the Kenyatta National Hospital. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent
Signature of researcher taking the consent
Date
Day/Month/Year

SWAHILI VERSION

FOMU YA IDHINI

(i) Sehemu ya kwanza – Maelezo ya Daktari mtafiti.

Mimi ni Dkt. Mwika Mwirichia, kutoka chuo kikuu cha Nairobi, kitivo cha Utabibu, idara ya upasuaji. Ninafanya utafiti wa kuangalia "Nutritional status of pediatric surgical patients with colonic stomas and those without stomas at the Kenyatta National Hospital". Ningependa kumchagua motto wako katika utafiti huu wangu. Nitafanya hivyo kwa kukuuliza maswali Fulani kuhusu afya ya mtoto wako na kufanya vipimo vya uzani pamoja na damu.

Habari zote zitakazo kusanywa zitashughulikiwa kwa siri na hazita sambazwa ila tu kwa ruhusa kutoka kwa mkurugenzi mkuu wa utafiti wa chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta.

Umuhimu wa utafiti huu

Utafiti huu utawasaidia madaktari kuelewa ni watoto wangapi hupata shida hizi baada ya upasuaji wao na utawasaidia katika kutengeneza njia za kusuluhisha shida hizi katika hospitali kuu ya Kenyatta.

Uhuru wa kujihusisha na kujitoa kutoka kwa utafiti

Kuhusika kwako kwenye utafiti huu hakuna malipo yoyote ila ni kwa hiari yako mwenyewe na pia unaweza kujiondoa kwa utafiti wakati wowote bila kuhatarisha matibabu yako katika Hospitali Kuu ya Kenyatta. Naomba mimi ama wasaidizi wangu wakuulize maswali ambayo yatajibiwa kwa fomu maalum.

Siri ya habari utatupatia

Habari yote ambayo utatuarifu ni ya siri kati yako nasi watafiti na haitaenezwa kwa watu wengine. Jina lako halitaandikwa kwenye fomu yoyote.

Unaweza kuuliza maswali yoyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu ya mtafiti mkuu ama mkuu wa idara ya upasuaji katika chuo kikuu cha Nairobi ama walimu wasimamizi wa utafiti ukitumia nambari za simu zifuatazo;

Katibu wa utafiti , Hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi.

Sanduku la Posta 20723 KNH, Nairobi 00202.

Nambari ya simu 726300-9.

Walimu wasimamizi wa Chuo kikuu cha Nairobi: Dkt. F. Osawa,

Sanduku la Posta 19676 KNH, Nairobi 00202. Nambari ya simu:0202726300

Dkt J. Ndungu

Sanduku la Posta 19676 KNH, Nairobi 00202. Nambari ya simu:0202726300

Mtafiti Mkuu: Dkt. Mwika Peter,

Idara ya Upasuaji , shule ya Tiba- Chuo kikuu cha Nairobi, Sanduku la Posta 20890 KNH Nairobi 00202. Nambari ya simu ya rununu 0721514477. Mtafiti Msaidizi: Daktari Fariha Fazal

P.O. Box 20890 KNH, Nairobi 00202 Nambari ya simu ya rununu: 0727507961

(ii) Sehemu ya pili – Idhini ya mgonjwa.

Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu anayo yapata mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na hata madaktari wenyewe.



(iii) Sehemu ya tatu - Dhibitisho la mtafiti

Hii ni kuidhinisha ya kwamba nimemueleza mzazi au mchungaji kuhusu utafiti huu na pia nimempa nafasi ya kuuliza maswali. Nimemueleza ya fuatayo;

- Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.
- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayoyapata katika hospital kuu ya Kenyatta.
- Habari ambazo atapeana hazitatangazwa hadharani bila ruhusa kutoka kwake (mshiriki) na pia kutoka kwa mwenyekiti wa idara kuu ya utafiti wa hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi.

Jina la mtafiti ama msimamizi wake..... Sahihi..... Tarehe...

(Siku / Mwezi/ Mwaka)

A COMPARISON OF THE NUTRITIONAL STATUS OF CHILDREN WITH COLONIC STOMAS AND THOSE WITHOUT STOMAS ADMITTED FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

ASSENT FORM FOR CHILDREN 7 YEARS TO 10 YEARS

My name is Dr. Mwika Peter. I am doing a study about nutritional status of pediatric surgical patients with colonic stomas and those without stomas at the Kenyatta National Hospital.

Purpose of study

This may help us understand the burden of such problems and enable us improve our outcomes and hence change our patient care, if any improvement on our part, is necessary. If you would like, you can participate in this study.

Voluntariness of participation

Participation into this study is voluntary and no one can force you to participate. If you decide you want to participate in my study, you will be asked some personal questions and required to go through a questionnaire with me or my research assistant.

Risks

There are no risks involved in this study; you will not incur any extra costs for participating in this study.

Right to withdraw from the study

You can withdraw from the study at any point in time and this will not affect your management at KNH. You will not be denied any service due to your withdrawal

Confidentiality

Other people will not know if you are participating in this study. Your answers and your progress will be kept private. When I tell other people about my research, I will not use your name, so no one can tell who I am talking about.

Your parents or guardian have to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, you will not get into any trouble. You can stop being in the study at any time.

My telephone number is 0721514477. You can call me if you have questions about the study or if you decide you do not want to be in the study any more.

I will give you a copy of this form in case you want to ask questions later.

Sign this form only if you:

- have understood what you will be doing for this study,
- have had all your questions answered,
- have talked to your parent(s)/legal guardian about this project, and
- agree to take part in this research

Your Signature	Name	Date	
Name of Parent(s) or Legal G	buardian(s)		
Researcher explaining study			
Signature	Name	Date	

<u>ASSENT FORM (SWAHILI)</u> ULINGANISHO WA HALI YA AFYA KATIKA WATOTO WALIOFANYIWA UPASUAJI MPANGILIO WA TUMBO NA KUTIWA MFUNGUO WA UTUMBO NA WASIO, KATIKA HOSPITALI KUU YA KENYATTA.

FOMU YA IDHINI YA WATOTO WALIO NA UMRI WA MIAKA KATI YA SABA NA KUMI.

Jina langu ni Dkt. Peter Mwika. Ninafanya uchunguzi wa hali ya afya katika watoto walio fanyiwa upasuaji wa tumbo na kutiwa mfunguo w tumbo na wale wasio nao, katika hospitali kuu ya Kenyatta.

Dhamira ya utafiti.

Matokeo ya utafiti huu yanaweza saidia kuelewa shida zitokonazo na aina hii ya utabibu na kusaidia kuboresha matokeo na huduma kwa wagonjwa wanaofanyiwa aina hii ya upasuaji. Ikiwa ungependa kushiriki katika utafiti huu, nakusihii ujiandikishe kwa mkataba wa uwiano.

Hiari ya kushiriki.

Kushiriki katika utafiti huu ni kwa hiari na hamna masharti yeyote ya lazima. Unapo kubali kushiriki katika utafiti huu, utaulizwa maswali ya kukuhusu kupitia dodoso hili, aidha nami au mtafiti msaidizi wangu.

Je, kuna hatari ya kushiriki?

Hakuna hatari wala gharama ya ziada yeyote itakayo kukumba kutokana na kushiriki katika utafiti huu.

Uhuru wa kujiondoa kutoka utafiti.

Una haki ya kujiondoa kutoka ushiriki wa huu utafiti wakati wowote upendapo na uamuzi huo hauwezi dhuru matibabu yako kwa vyovyote vile.

Hifadhi ya siri.

Hakuna yeyote mwingine atakayejuzwa ushiriki wako katika utafiti huu. Majibu yako na mwelekeo wa matibabu yako yatakuwa ni siri na hifadhi yako. Ninapojuza watu kuhusu utafiti wangu, hakuna popote nitataja jina lako, hivyo basi hamna atakaye tambua kwa majina walioshiriki.

Itawabidi pia wazazi au wadhamini wako kukubali ushiriki wako katika utafiti huu. Watakopo amua, utakuwa nawe huru kukubali kwa kushiriki pia. Ijapo hautakubali, hakuna madhara yoyote utapata. Una uhuru wa kujiondoa katika utafiti.

Nambari yangu ya rukononi 0721 51 44 77. Waweza kunipigia simu wakati wowote kuulizia zaidi kuhusu utafiti huu au ikiwa ungependa kujiondoa.

Nitaku panaka laya fomuhii iki wa ungependaku uli zamaswa li zaidi baada ye.

Tia sahihi iwapo;

- Umeelewa ushiriki wako katika utafiti huu
- Maswali yako yote yamejibiwa vilivyo
- Umejadili na wazazi au wadhamini wako kuihusu
- Umekubali kushiriki katika utafiti

Jina lako	. Sahihi	yako
Tarehe		
Jina la mzazi au mdhamini		
Mtafiti aliyekupa maelezo ya utafiti Jina	Sahihi	
Tarehe		

APPENDIX II: QUESTIONNAIRE FOR CHILDREN WITH COLOSTOMY

A COMPARISON OF THE NUTRITIONAL STATUS OF CHILDREN WITH COLONIC STOMAS AND THOSE WITHOUT STOMAS ADMITTED FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

QUESTIONNAIRE FOR CHILDREN WITH COLOSTOMY

Questionnaire No.

1. Demographic data

a) Residence
b)Sex
c) Current age
d)Age at the time of fashioning of the colostomy (months):
e)Date of fashioning of the colostomy:
f)Duration with a colostomy:
2. SGNA DATA COLLECTION TOOL
A. History of weight change
I. History of weight loss in last 6 months. Yes No

a) _____ (grams/kilograms)

b) ____% of previous weight]

II. History of weight change in the past 2 weeks (tick as appropriate)

a) No change in weight in the past 2 weeks

b) Increase in weight in the past 2 weeks
c) Decrease in weight in the past 2 weeks
III. History of dietary change
a) Usual diet (specify name and quantity)
b) Supplementary diet: meals /day; specify type
c) Regular diet: meals/day; specify type
d) History of change in type and/or quantity of diet. Yes No
Details:
IV. Has any of the following gastrointestinal symptoms listed below occurred in the past two weeks (indicate "Yes" or "No")
a) Nausea. Yes No
b) Vomiting. Yes No
c) Anorexia. Yes No
d) Diarrhoea. Yes No
V. History of reduction in the child's normal activity:YesNo
If Yes, duration in weeks

VI. Disease and its relationship to nutritional requirements. Primary diagnosis (Change in energy demand)*Yes* No

VII. Signs of malnutrition (state "Yes" or "NO" as per the signs of malnutrition listed below)

A). pale

b). Easy pluck- ability of hair.....

c). muscle wasting
d). Ascites
e). White bands at nails
f). Angular stomatitis
g) Glossitis.....
h). Pellagrous dermatitis

3. Anthropometric measurements:

Weight (Kg)	Height (cm)	AC(cm)	W/H	W/A	H/A	$BMI(W/H^2)$

4. CLINICAL EXAMINATION DATA:

A. Diagnosis ($$):	ARM	HSD	Other	

B. Has any of the Stoma complications listed below ever occurred? (tick where appropriate):

- 1. Bleeding.....
- 2. Stoma diarrhoea.....
- 3. Stoma Prolapsed.....
- 4. Stoma stenosis.....
- 5. Stoma Retraction.....
- 6. Bridge breakdown.....

C. Haematological Parameters:

Haemoglobin	Haematocrit (%)	MCV	MCHV

D. Blood biochemistry

Albumin	Calcium	Phosphate	Magnesium

5. Parent/Guardian Data:

A. Age. _____

B. Level of education ($\sqrt{}$):

Primary	Secondary	Tertiary	No formal education

C. Income per month (Kenyan currency) $\sqrt{}$

<2500	2500 - 5000	5001 - 10000	10001-20000	≥20000

D. Housing:

Type of housing material (Tick where appropriate)

Bricks	wooden	palm/lattice/mud	Others

APPENDIX III: QUESTIONAIRE FOR CHILDREN WITHOUT A COLOSTOMY

Title: A COMPARISON OF THE NUTRITIONAL STATUS OF CHILDREN WITH COLONIC STOMAS AND THOSE WITHOUT STOMAS ADMITTED FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

QUESTIONAIRE FOR CHILDREN WITHOUT A COLOSTOMY

Date: _____

Questionnaire No.

1. Demographic data

- a) Residence
- b)Sex
- c)Current age
- d) Diagnosis.....

2. SGNA DATA COLLECTION TOOL

A. History of weight change

I. History of weight loss in last 6 months. Yes No

- a) _____ (grams/kilograms)
- b) ____% of previous weight]
- II. History of weight change in the past 2 weeks (tick as appropriate)

a) No change in weight in the past 2 weeks

b) Increase in weight in the past 2 weeks

c) Decrease in weight in the past 2 weeks

III. History of dietary change

a) Usual diet (specify name and quantity) _____

b) Supplementary diet: meals /day; specify type _____

c) Regular diet: meals/day; specify type _____

d) History of change in type and/or quantity of diet. Yes No

Details:

IV. Has any of the following gastrointestinal symptoms listed below occurred in the past two weeks (indicate "Yes" or "No")

- a) Nausea. Yes No
- b) Vomiting. Yes No
- c) Anorexia. Yes No
- d) Diarrhoea. Yes No

V. History of reduction in the child's normal activity: Yes No

If Yes, duration in weeks _____

VI. Disease and its relationship to nutritional requirements. Primary diagnosis (Change in energy demand)Yes No

VII. Signs of malnutrition (state "Yes" or "NO" as per the signs of malnutrition listed below)

A). pale

b). Easy pluck-ability of hair.....

c). muscle wasting

d). Ascites

- e). White bands at nails
- f). Angular stomatitis
- g) Glossitis.....
- h). Pellagrous dermatitis
- i). Other; specify _____

3. Anthropometric measurements:

Weight (Kg)	Height (cm)	AC(cm)	W/H	W/A	H/A	BMI(W/H ²)

4. CLINICAL EXAMINATION DATA:

a. Diagnosis:

b. Haematological Parameters:

Haemoglobin	Haematocrit (%)	MCV	MCHV

c. Blood biochemistry

A 11	•
Alhi	ımın
Alu	

Calcium

Phosphate

Magnesium

5. Parent/Guardian Data:

A. Age. _____

B. Level of education ($\sqrt{}$):

Primary	Secondary	Tertiary	No formal education	

C. Income per month (Kenyan currency) $\sqrt{}$

<2500	2500 - 5000	5001 - 10000	10001-20000	≥20000

D. Housing:

Type of housing material($\sqrt{}$)

Bricks	wooden	palm/lattice/mud	Others

APPENDIX IV: SCREENING TOOL:

Title: A COMPARISON OF THE NUTRITIONAL STATUS OF CHILDREN WITH COLONIC STOMAS AND THOSE WITHOUT STOMAS ADMITTED FOR ELECTIVE SURGERY AT THE KENYATTA NATIONAL HOSPITAL

Screening tool:

This tool shall be utilised to screen patients (both cases and control) for any parameter listed in the exclusion criteria. Any patient found to have any of the parameters listed below shall not be included in this study.

- 1. Is the patient above 10 years? Yes No......
- 2. Does the Patient have any condition that impair anthropometric measurements such as edema, anasarca, or limb amputation? Yes No
- 3. Is the Patients suffering from any neurological diseases which could impair musculoskeletal development? Yes No
- Does the patient have gastrointestinal disorders which impair nutrient absorption such as celiac disease, gastro-oesophageal reflux, Crohn's disease and short-gut? Yes No
- 5. Is the Patient suffering from any genetic syndromes likely to cause malnutrition? Yes No