

**CLINICAL OUTCOMES OF CHILDREN AGED 6 TO 59
MONTHS WITH SEVERE ACUTE MALNUTRITION
ADMITTED TO MBAGATHI DISTRICT HOSPITAL**

A dissertation presented in partial fulfillment of the requirement for the degree of
Master of Medicine in Paediatrics and Child Health of the University of Nairobi

DR. JOHN KALAMA FONDO

DEPARTMENT OF PAEDIATRICS & CHILD HEALTH

UNIVERSITY OF NAIROBI

April 2013

DECLARATION

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

Signed.....Date.....

Dr John Kalama Fondo

M.B.,Ch.B. University of Nairobi

This dissertation has been presented with our full approval as supervisors

Signed.....Date.....

Professor A.O Wasunna

Consultant Paediatrician & Neonatologist

Associate Professor of Paediatrics and Child Health,

Former Chairman, Department of Paediatrics and Child Health, University of Nairobi

Signed.....Date.....

Dr. Dalton Wamalwa

Consultant Paediatrician & Epidemiologist

Senior Lecturer, Department of Paediatrics & Child Health

University of Nairobi

SignedDate.....

Dr. Ahmed Laving

Consultant Paediatrician & Paediatric Gastroenterologist

Lecturer, Department of Paediatrics & Child Health

University of Nairobi

DEDICATION

I wish to dedicate this work to all the malnourished children who participated in this study whose wellbeing we seek to optimize and to all health workers whose knowledge we endeavor to improve.

ACKNOWLEDGEMENTS

I would like to acknowledge the contribution of the following persons and organizations without whose input this study would not have been realized: PRIME KENYA and its partners for funding this study, my supervisors: Professor A. O. Wasunna, Dr. Dalton Wamalwa and Dr. Ahmed Laving for their invaluable counsel and guidance, all my research assistants for their diligence in data collection and entry.

TABLE OF CONTENTS

DECLARATION.....	II
DEDICATION.....	III
ACKNOWLEDGEMENTS.....	IV
TABLE OF CONTENTS.....	V
LIST OF TABLES.....	VIII
LIST OF FIGURES.....	IX
LIST OF ABBEVIATIONS.....	X
STUDY DEFINITIONS.....	XI
ABSTRACT.....	XIII
CHAPTER ONE: BACKGROUND AND LITERATURE REVIEW	
1.1 BACKGROUND	1
1.2 LITERATURE REVIEW.....	7
CHAPTER TWO: STUDY JUSTIFICATION AND OBJECTIVES	
2.1 STUDY JUSTIFICATION.....	12
2.2 STUDY UTILITY	12
2.3 STUDY OBJECTIVES.....	13
CHAPTER THREE: METHODOLOGY	
3.1 STUDY AREA.....	14
3.2 STUDY POPULATION.....	14
3.3 STUDY DESIGN.....	14
3.4 STUDY PERIOD.....	15
3.5 SAMPLE SIZE.....	15
3.6 SAMPLING METHOD.....	15
3.7 INCLUSION CRITERIA.....	16
3.8 EXCLUSION CRITERIA.....	16
3.9 CASE DEFINITION.....	17
3.10 MEDICAL CARE AND THERAPEUTIC FEEDING.....	17

3.11 ANTHROPOMETRIC MEASUREMENTS AND STUDY EQUIPMENT	
3.11.1 WEIGHT.....	18
3.11.2 HEIGHT/LENGTH.....	18
3.11.3 LEFT MID UPPER ARM CIRCUMFERENCE.....	18
3.12 W.H.O Z SCORE TABLE.....	18
3.13 STUDY PERSONEL.....	19
3.14 STUDY PROCEDURE.....	19
3.15 DATA ANALYSIS.....	21
3.16 STUDY OUTCOMES	
3.16.1 RECOVERY RATE.....	21
3.16.2 MEAN WEIGHT GAIN.....	21
3.16.3 CASE FATALITY RATE.....	22
3.17 ETHICAL CONSIDERATIONS.....	22
CHAPTER FOUR: RESULTS	
4.1 BASELINE CHARACTERISTICS.....	23
4.2 OUTCOMES.....	27
4.2.1 RECOVERY RATE.....	28
4.2.2 MEAN WEIGHT GAIN.....	29
4.2.3 FACTORS ASSOCIATED WITH WEIGHT GAIN.....	30
4.2.4 CASE FATALITY RATE.....	32
4.2.5 FACTORS ASSOCIATED WITH MORTALITY.....	33
4.3 DISCUSSION.....	35
4.4 STUDY LIMITATIONS.....	40
4.5 CONCLUSION.....	41
4.6 RECOMMENDATIONS.....	42

REFERENCES.....43

APPENDICES

APPENDIX I INFORMATION SHEET AND CONSENT FORM.....46

APPENDIX II DATA COLLECTION FORM.....53

APPENDIX III STUDY BUDGET AND BUDGET JUSTIFICATION.....63

APPENDIX IV STUDY TIMELINE.....65

APPENDIX V ETHICAL APPROVAL.....66

LIST OF TABLES

Table 1 Malnutrition Trends among children under five over the past 10 years in Kenya.....	2
Table 2 General principles of routine care: the WHO ten steps.....	4
Table 3 WHO grading of weight gain during the rehabilitation phase of in-patient management of severe acute malnutrition.....	5
Table 4 WHO grading of case fatality rates for hospitalized children with severe malnutrition.....	6
Table 5 Summary of literature review.....	11
Table 6 Baseline characteristics of the 164 children aged 6 to 59 months with severe acute malnutrition admitted to Mbagathi District Hospital.....	25
Table 7 Association between socio-demographic variables, co-morbidity and poor weight gain.....	31
Table 8 Mortality by the child's gender, maternal education and co-morbidity.....	33
Table 9 Study budget.....	63

LIST OF FIGURES

Figure 1 Study Process.....	20
Figure 2 Patient recruitment process.....	23
Figure 3 Prevalence co-morbid conditions among the 164 severely malnourished children aged 6 to 59 months.....	26
Figure 4 Outcomes among severely malnourished children aged 6 to 59 months admitted to Mbagathi district hospital.....	27
Figure 5 Overall recovery rate for severely malnourished children aged 6 to 59 months admitted to Mbagathi district hospital.....	28
Figure 6 Recovery rate at day 21 for severely malnourished children aged 6 to 59 months admitted to Mbagathi district hospital.....	28
Figure 7 Calorie intake in the rehabilitation phase of treatment for the study participants.....	30
Figure 8 Patterns of weight gain for severely malnourished children aged 6 to 59 months admitted to Mbagathi District Hospital.....	30
Figure 9 Case fatality rate among the study participants.....	32
Figure 10 Timing of mortality following admission of severely malnourished children.....	32
Figure 11 Timeline	65

LIST OF ABBREVIATIONS

W.H.O.....	World Health Organization
UNICEF.....	United Nations Children’s Fund
K.N.H.....	Kenyatta National Hospital
WHZ.....	Weight For Height Z score
WAZ.....	Weight for Age Z score
HAZ.....	Height for Age Z score
SD.....	Standard Deviation
MUAC.....	Mid Upper Arm Circumference
SAM.....	Severe Acute Malnutrition
MAM.....	Moderate Acute Malnutrition
WFP.....	World Food Program
UNHCR.....	United Nations High Commission for Refugees
SPHERE.....	Sphere Project
HIV.....	Human Immunodeficiency Virus
DNA.....	Deoxyribonucleic acid
PCR.....	Polymerase Chain Reaction
OR.....	Odds Ratio

STUDY DEFINITIONS

Malnutrition: The World Health Organization (W.H.O) defines malnutrition as the cellular imbalance between the supply of nutrients and energy and the body's demand for them to ensure growth, maintenance and specific functions. Malnutrition generally implies under nutrition and refers to all deviations in nutritional status in infants, children and adults.¹

Under-nutrition: A state of nutritional inadequacy which, in children, manifests as underweight, stunting and wasting with or without oedema²

Acute malnutrition: Malnutrition resulting from a relatively short period of nutritional deficit. It is identified using a weight for height criteria.³

Severe Acute Malnutrition: Is defined as weight for height less than 70% of the median or more than 3SDs below mean of the WHO reference population or presence of visible severe wasting, MUAC of less than 115mm or the presence of bilateral pitting edema of nutritional origin.^{4,5}

Moderate Acute Malnutrition: An intermediate form of acute malnutrition defined as weight for height Z score of- 3SDs to- 2SDs below the mean of the WHO reference population. Children with this grade of acute malnutrition do not have symmetrical edema of nutritional origin.⁴

Chronic malnutrition: Malnutrition due to long term nutritional deprivation and is identified using a height for age indicator. Stunting is defined as height for age less than 95 % of the median of the WHO reference population.³

Underweight: Weight for age Z score more than 2SDs below the mean of the WHO reference population. This is a composite form of malnutrition including elements of both wasting and stunting.³

Z score/standard deviation score: A standard way of saying how far an individual measurement or score is from the group mean, it is negative if the individual measurement is less than the group mean, zero if the individual score is equal to the mean and positive if greater than the mean.

24 hour dietary recall: this is a listing of all foods and beverages and the quantities consumed twenty four hours prior to the interview by a person trained in eliciting a dietary history. It relies on memory and has been found to overestimate energy intakes of children under the age of two years.

Mid upper arm circumference: This is the circumference of the upper arm taken mid way between the olecranon process and the acromion using a special tape. It is usually taken on the **left side for purposes of standardization.**

Odds ratio: this is a measure of effect size describing an association between two binary variables. The odds ratios mentioned in this proposal are adjusted for disease severity and other confounding variables.

ABSTRACT

BACKGROUND: The W.H.O estimates that moderate and severe acute malnutrition contribute to about 3.5 million and 1.5 million preventable childhood deaths every year, respectively. Systematic use of the W.H.O case management guidelines for severe malnutrition has been reported to improve nutritional outcomes, reduce days of hospitalization and reduce case fatality rates to acceptable levels in resource limited environments.

OBJECTIVES: The primary objective was to determine the proportion of children aged 6 to 59 months with severe acute malnutrition achieving a weight for height Z score equal to or greater than -1SD within 21 days of therapeutic feeding or at discharge whichever was earlier. The secondary objectives were to determine the mean weight gain, the case fatality rate, the socio-demographic factors and co-morbid conditions (pneumonia and diarrhea) associated with adverse outcomes.

METHODOLOGY: This study was part of a larger maternal and child malnutrition study that was conducted at the Mbagathi District Hospital. It was a short prospective study involving infants and children aged 6 to 59 months with W.H.O defined severe acute malnutrition admitted at the hospital. Eligible infants and children were consecutively enrolled. Socio-demographic, clinical and anthropometric data as well as nutritional and other medical diagnoses were entered in specially designed forms. Each participant was subsequently weighed on alternate days till discharge, day 21 or death whichever came earlier. Therapeutic feeds intake was monitored using the 24 hour dietary recall method and the emergence of new symptoms, specifically, vomiting, diarrhoea and breathing difficulties was noted at the time of weighing.

RESULTS: Out of the 164 children enrolled 91(55%) were male. The median age was 13.5 months (IQR 9-18.8). For the 142 children who survived to discharge the recovery rate at the time of discharge was 3% (n=4). However, the 21 day recovery rate for the 20 children who were hospitalized for a minimum of 21 days was 20% (n=4). The median duration of hospitalization was 11 days (IQR 8-15). The overall median weight gain was 5.6g/kg/day (IQR 1.7-10.4). The median weight gain for children with edematous SAM was 2.35g/kg/day (IQR 0.0 to 5.95). Forty four children(30%) experienced a weight gain of more than 10g/kg/day, 38(27%) gained 5-10g/kg/ day, 60(43%) gained less than 5g/kg/day categorized by WHO as good, moderate and poor weight gain respectively. The overall case fatality rate was 8% (n=13) with 77% of deaths occurring within the first week of admission. Diarrhoea was significantly associated with increased risk of mortality. (CFR 11% vs. 3%) p=0.04 Pneumonia and HIV infection were not significantly associated with increased risk of death. Mean calorie intake less than 200kcal/kg/day was significantly associated with poor weight gain. (Median weight gain 5.4 g/kg/day vs. 11.7g/kg/day) p=0.015 Socio-demographic characteristics, diarrhoea and pneumonia were not significantly associated with rate of weight gain.

CONCLUSION

The nutritional recovery rate and median weight gain were below international standards and were associated with suboptimal caloric intake in the rehabilitation phase of treatment and a short duration of in-patient nutritional rehabilitation. The case fatality rate of 8% is comparable to international standards. Diarrhoea significantly increased the risk of mortality.

CHAPTER ONE

1.1 BACKGROUND

The fourth Millennium Development Goal aims to reduce mortality among children aged below 5 years by two thirds between the years 1990 and 2015. To meet this target, efforts to prevent child deaths must be stepped up.⁸

Malnutrition in all its forms remains a major public health problem in the developing world and is an underlying factor in over 50% of the 10 million deaths and increased morbidity among children under 5 years annually. Forty one percent of these preventable deaths occur in sub-Saharan Africa.⁹

According to UNICEF's 'State of the World's Children 2007 Report approximately 9% and 2% of the under 5 population in sub-Saharan Africa suffer from moderate acute and severe acute malnutrition respectively.¹¹

The malnutrition rates among children aged below five years in Kenya has not changed much over the past decade. According to the Kenya Demographic and Health Survey 2008 report (KDHS 2008) 35 % of children under five are stunted while the proportion of severely stunted is 14%. Analysis of stunting by age revealed that it is highest (46%) among children aged 18 to 23 months and lowest among those aged less than 6 months. Overall, 7% and 2% of children aged below five years are wasted and severely wasted respectively. Wasting rates are highest (11%) in children aged 6 to 8 months. The underweight and severely underweight rates are 16% and 4%

respectively.¹² Table 1 below shows the malnutrition trends among children under five over the past ten years in Kenya.

Table 1 Malnutrition trends among children under five over the past 10 years in Kenya.^{13,}

14

INDICATOR	KDHS 1998	KDHS 2003	KDHS 2008
Stunting	33%	31%	35%
Severe stunting	13%	11%	14%
Wasting	6%	5%	7%
Severe wasting	1.4%	1%	2%
Underweight	22%	20	16%
Severe underweight	4.8%	4%	4%

Malnourished children frequently die from diarrheal disease, pneumonia and other common childhood infections. Most nutritional deficiencies impair both innate and adaptive immune responses leading to a cycle of longer lasting and more severe infections and ever worsening nutritional status.¹³

Severe acute malnutrition (SAM) is an unstable condition resulting from a relatively short period of sustained nutritional deficit. It is often complicated by a concurrent infective illness and marked anorexia. Children with severe acute malnutrition undergo physiologic and metabolic changes to conserve energy and preserve essential processes; including a decrease in the functional capacity of organs and slowing of cellular activities. Co-existing infections add to the difficulty of maintaining metabolic control. These children have a limited ability to respond to

stresses (infective and environmental) and are highly vulnerable. They are at risk of death from hypoglycemia, hypothermia, electrolyte imbalance, heart failure and untreated infection. Therefore, they are often admitted for intensive treatment to avert death.^{5, 8, 13, and 15}

The aims of management of severe acute malnutrition are to decrease case fatality rates, to facilitate nutritional recovery and to decrease the length of hospitalization.⁴ The WHO guidelines on case management of severe acute malnutrition offer a standardized treatment protocol which takes into account the pathophysiologic changes that have occurred in the child and have been implemented successfully in resource limited settings. They have been found to produce recovery rates of 61 to 88% within three weeks of inpatient care and reduce case fatality rates by 50% if systematically applied.^{4, 5, 13, 14}

In most developing countries case fatality rates from severe acute malnutrition remain between 20-30%. This is largely caused by faulty case management due to inadequate knowledge among health workers and use of out-dated treatment protocols.³

The WHO published guidelines for the diagnosis and management of severe acute malnutrition and set minimum standards of outcomes. Various studies have demonstrated that these guidelines can be implemented with acceptable outcomes in resource limited settings. The earlier editions of these guidelines recommended hospitalization of all children who met the criteria for severe acute malnutrition.⁵ Recent recommendations are that only those severely malnourished children who are anorexic and those with concurrent medical complications should be admitted. The rest may be managed in the community with ready to use therapeutic foods. These case management guidelines are organized into two phases and ten steps. The initial stabilization phase takes place within the first one week and the rehabilitation phase over the next 5 weeks.

Table 2 General principles of routine care: the ten steps⁵

STEP	AIM	SPECIFIC ACTIONS
1	Treat/prevent hypoglycemia	Do random blood sugar Give 10% dextrose if RBS< 3mmol/l or child not alert Initiate feeds within first hour Feed every 2-3 hours day and night to prevent hypoglycemia/hypothermia
2	Treat/prevent hypothermia	Keep warm
3	Treat/prevent dehydration	Rehydrate with low sodium fluids, monitor for fluid overload, avoid intravenous fluids except in shock
4	Correct electrolyte imbalance	Give potassium and magnesium, restrict sodium
5	Treat/prevent infection	Give broad spectrum antibiotics; infection may be silent
6	Correct micronutrient deficiencies	Give micronutrient supplements, do not give iron in first week
7	Start cautious feeding	Give 100kcal/kg/day and 1g protein/kg/day
8	Achieve catch up growth- rebuild wasted tissues with high energy, high protein diets with micronutrients	Give 150-220kcal/kg/day and 4-6g protein/kg/day, supplement iron, continue giving other micronutrients
9	Provide sensory stimulation and emotional support to enhance mental development	Involve mother in caring for child, provide tender loving care, provide age appropriate play/toys
10	Prepare for continuing care & follow up after recovery	Educate the mother on appropriate feeding, motivate her, ensure she has adequate resources and is available to feed her child

The rehabilitation phase in the treatment of severe acute malnutrition is heralded by the return of appetite and disappearance of edema that generally occurs between the fourth and seventh days of treatment. This phase involves a gradual transition from starter feeds to more energy and protein dense foods which are subsequently given liberally, as much as the child wants, targeting energy intakes of 150- 220kcal/kg/day and protein intake of up to 4-6g/kg/day.⁵ Weight gain in this phase is graded as shown in the table below.

Table 3 W.H.O. grading of weight gain during the rehabilitation phase of treatment of severely malnourished children.⁵

WEIGHT GAIN	GRADING
<5g/kg/day	Poor
5-10g/kg/day	Moderate
>10g/kg/day	Good

The severely malnourished child is considered to have recovered when she attains a weight for height Z score of -1SD of the median of the W.H.O. reference population and has lost all edema for those with edematous acute malnutrition.⁵

Table 4: WHO grading of case fatality rates for severely malnourished children

CASE FATALITY RATE	GRADING
< 1%	Excellent
1-4%	Good
5-10%	Moderate
11-20%	Poor
>20%	Unacceptable

According to the Sphere and World Food Program/United Nations High Commission for Refugees (WFP/UNHCR) standards a recovery rate greater than 75%, mean weight gain equal to or greater than 8g/kg/day, mean duration to nutritional recovery of 3-4 weeks and case fatality rate less than 10% are acceptable for therapeutic programs for children with severe acute malnutrition.^{7, 8} The WHO standards describe a mean weight gain of more than 10g/kg/day as good, treatment effective if the case fatality rate is less than 10% while case fatality rates greater than 20% as unacceptable.⁵

1.2 LITERATURE REVIEW

According to Bejon P. et al malnutrition still underlies half of the inpatient morbidity and mortality rates among children in rural Kenya. Berti A. et al reported a prevalence rate of 30% for severe acute malnutrition among hospitalized children in a retrospective study in Ethiopia.¹⁶

Hossain M. et al in a hospital based prospective study in Bangladesh reported that severe acute malnutrition with complications in children below 5 years of age can be addressed effectively in resource limited settings. In this study 88% of the children achieved a mean weight gain of 10.6g/kg/day and loss of edema fluid at a rate of 1.9g/kg/day. They also reported a recovery rate of 88% and a mean duration of hospitalization of less than 3 weeks for 86 % of children. The children actually lost weight during the stabilization phase. Subsequently 14.7 % demonstrated poor weight gain, 30.9% moderate weight gain and 30.9% good weight gain. Weight gain was observed during days 3 to 7 of the stabilization phase in non edematous children. Nearly 71% of edematous children lost weight and the remaining gained weight. During the rehabilitation phase most children with edema did not gain weight despite adequate food intake. The case fatality rate in this study was 10.8%. Common conditions complicating malnutrition in this study were pneumonia (33%), edema (24%), diarrhea (11%) and pulmonary tuberculosis (9%). The outcomes of this study largely met acceptable international standards. It is worth noting that this study was conducted in a specialized nutrition unit in a teaching hospital. All members of staff had received specific training in managing children with severe acute malnutrition and sufficient resources were available.¹⁷

Bernal C. et al in a 5 year (2001 to 2005) descriptive study in a Colombian primary care hospital reported a 50% decrease in case fatality in severely malnourished children from 8.7% in the first

year to 4 % in the fifth year of the study. The presence of edema and sepsis was associated with increased mortality. Common conditions complicating malnutrition in this study were diarrhea (68.4%) and anemia (51%) with sepsis (9%) being the commonest complication during hospital stay. They reported a recovery rate of 61%, with severely malnourished children attaining weight for height Z score of -1SD within 3 weeks of admission.¹⁸

According to Maitland et al in a retrospective case note review of 920 children in a Kenyan district hospital with WHO defined severe acute malnutrition managed according to WHO guidelines, 176(16%) of them died with 33% of the deaths occurring in the first 48 hours of admission. Bacteraemia complicated more than 40% of these deaths. Having one or more of the following WHO danger signs (lethargy, hypoglycemia and hypothermia) predicted early death with a sensitivity and specificity of 52 and 84% respectively. Four other clinical signs (bradycardia, capillary refill time greater than 2 seconds, weak pulse volume and impaired consciousness level) had high predictive value for early mortality. The presence of two or more of these signs was associated with a 10-fold increase in early case fatality.¹⁹

Moges T and others in a retrospective descriptive data analysis of 164 severely malnourished children admitted to Zewditu Memorial hospital in Ethiopia found marasmus to be more prevalent among infants and kwashiorkor being more prevalent in the second and third years of life. They reported a case fatality rate of 21% which was way above acceptable standards. The presence of diarrhea, edema and stunting was associated with mortality.²⁰

Fergusson P. and others in a prospective cohort of 454 severely malnourished children aged 6 months to five years, of whom 17.4 % were HIV infected, reported that HIV infected children were significantly more wasted and had a higher case fatality rate than uninfected children.

(14.8% vs. 10.4%) Although HIV infected children had significantly longer mean duration of stay (28.8 vs. 24.3) in nutritional rehabilitation units than uninfected children, they actually recorded higher mean weight gains than uninfected children.²¹

Collins S. et al in a prospective cohort study of severely malnourished children in Malawi reported an in-patient mortality of 18% and a recovery rate of 58.1%. Forty nine percent of the known HIV infected children died.²²

In a prospective observational study of 113 severely malnourished children in South Africa, De Maayer et al reported that 51% of these children were HIV infected and that severely wasted children were more likely to be HIV infected. Tuberculosis was strongly suspected and treated in 24% but confirmed in 4% only. Overall case fatality rate was 11.5%. HIV infection conferred a 6 fold increase in mortality risk. (CFR infected 19% vs. CFR uninfected 3.6%). Other significant predictors of death were pallor and shock.²³

Bachou H. in a prospective study of 220 severely malnourished children at the Mulago hospital reported an overall case fatality rate of 24% with 70% of deaths occurring in the first week of admission. Factors associated with increased risk of mortality were the presence of edema, HIV infection, blood transfusion and intravenous fluid infusion. They subsequently conducted another study of severely malnourished children with 220 pre and 230 post adoption of WHO guidelines on intravenous fluids and blood transfusion. They reported that judicious use of blood transfusion and intravenous fluids did not decrease case fatality but greatly reduced infusion and transfusion requirements. The case fatality rates in the pre and post period were 23.6% and 24.8% respectively.²⁴

Ashworth A. et al in a study in two rural hospitals in South Africa demonstrated that the WHO guidelines could be sustainably implemented in resource limited settings with favorable outcomes in case fatality. In a prospective study between April 2000 and April 2001 involving 193 severely malnourished children following implementation of the WHO guidelines, case fatality rates dropped from 46% to 21% and from 25% to 18% at Mary Theresa and Sipeetu hospitals respectively.¹⁸ Rodrigues A.F et al in a 2009 Brazilian study reported a decrease in case fatality from 38% to 16.2 %.²⁶

Nzioki C. reported a case fatality rate of 38% in severely malnourished children in a study done at Kenyatta National Hospital. This study reported poor adherence to the recommended WHO protocols despite the availability of sufficient supplies and well trained medical and nursing staff.²⁷ The median delay in initiating starter feeding was 14.7 hours. F75 was present in 55% of treatment charts among those who needed it. Only 46% of severely malnourished children were provided with warmth and 54% received appropriate rehydration. Proper transition to catch up feeding occurred for only 23.8 % of children. Interestingly there was 90% implementation of step 5, the administration of broad spectrum antibiotics. However, this study did not measure other important clinical outcomes specifically the recovery rate and mean weight gain among children with severe acute malnutrition treated in a hospital setting. The aim of this study is, therefore, to determine nutritional outcomes, particularly the weight gain and recovery of children with severe acute malnutrition.

Table 5 Summary of literature review

INVESTIGATOR/COUNTRY/YEAR	STUDY OBJECTIVE	DESIGN	SAMPLE	RESULTS
Hossain M. et al/ Bangladesh/ 2009	Impact of W.H.O guidelines on outcomes	Prospective	171	Mean weight gain 10.6g/kg/day, Recovery rate 88%, Length of stay 3weeks, Case fatality rate 10.8%
Bernal C. et al/Columbia/2008	Impact of W.H.O guidelines on outcomes	Prospective	335	61% recovery rate within 3 weeks, case fatality rate 5.7%
Maitland K. et al/Kenya/2006	Can those at the highest risk of death be identified with W.H.O protocol?	Retrospective	920	Case fatality rate 19% , 33% deaths within 48 hours of admission, bacteraemia complicated 40% of all deaths
De Maayer et al/South Africa/2010	To determine clinical outcomes of severely malnutrition in high tuberculosis and HIV setting	Prospective	113	51% HIV infected, severely wasted 10 times more likely to be HIV infected, overall CFR 11.5%, CFR increased 6 times among HIV infected (19% vs. 3.6%), HIV infection, pallor and shock significant predictors of death
Collins S et al/Malawi/2008	To assess clinical outcomes of treatment of severe acute malnutrition	Prospective		Overall CFR 18%, recovery rate 58.1%, 49.5% of known HIV infected died
Moges T. et al/Ethiopia/ 2009	To describe the clinical profile and outcomes of severely malnourished cases	Retrospective	164	Case fatality rate 21%, diarrhea (OR 3.5), edema (OR 3.3), stunting(OR 3.3) and short stay(OR 4.4) increased fatality
Bachou H. et al/Uganda/2006	To determine risk factors for hospital deaths for severely malnourished children	Prospective	220	Overall case fatality rate 24%, 70% of deaths in first week, mortality increased by presence of oedema(OR 2.0), HIV infection(OR 2.6), blood transfusion(OR 5.0), intravenous fluid infusion(OR 4.8)
Fergusson P. et al/Malawi/2009	To determine nutritional recovery in HIV infected and uninfected children with severe acute malnutrition	Prospective	454	17.4% were HIV infected and were more wasted, higher case fatality rate among HIV infected (14.8% vs. 10.4%), mean weight gain and nutritional recovery same(8.9g/kg/day for infected and 8.0g/kg/day for uninfected
Nzioki C. et al/Kenya/2009	Audit of care for severe malnutrition at Kenyatta National Hospital	Cross sectional	101	Case fatality rate 38%, overall poor adherence to WHO protocol, F75 prescribed in only 55% of cases, median delay of 14.7 hours in initiation of F75, transition to catch up feeding occurred in only 23.8 % Of cases, 46.5 % kept warm, 54.9% properly rehydrated, 90% given broad spectrum antibiotics
Rodrigues et al/Brazil/2009	Impact of W.H.O guidelines on outcomes	Prospective		Decrease in case fatality rate from 38% to16.2%
Ashworth et al/ South Africa/2004	Impact of W.H.O guidelines on outcomes	Prospective	196	Decrease in case fatality rate from 46% to 21%

CHAPTER TWO

2.1 STUDY JUSTIFICATION

Severe acute malnutrition still contributes significantly to in patient morbidity and mortality in Kenyan hospitals. Locally published studies have determined case fatality rates without describing other clinically important outcomes specifically the mean weight gain and nutritional recovery of the children. This study has contributed data on the outcomes of management of severe acute malnutrition in a district hospital by comparing key clinical outcomes to known international standards. It has also contributed to the knowledge on the risk factors associated with the outcomes of treatment of severe acute malnutrition in our setting. This information will be used to sensitize health workers in the hospital to strive to meet therapeutic feed intake targets in order to improve weight gain and nutritional recovery.

2.2 STUDY UTILITY

The findings of this study will form the basis on which doctors, hospital administrators and policy makers can institute measures to maintain best practices or review practices to further improve outcomes. The findings of this study will prompt health researchers to determine causal associations between various factors and treatment outcomes.

2.3 STUDY OBJECTIVES

2.3.1 Primary objective

To determine the proportion of children aged 6 to 59 months with severe acute malnutrition achieving a weight for height Z score of $\geq -1SD$ by day 21 or at discharge, whichever is earlier.

2.3.2 Secondary objectives

1. To determine the mean weight gain in grams per kilogram per day for the period of hospitalization
2. To determine the case fatality rate for severe acute malnutrition
3. To determine the association between socio-demographic variables, pneumonia and diarrhoeal disease with adverse clinical outcomes.

CHAPTER THREE

METHODOLOGY

3.1 Study Area

The study was part of a larger maternal and child malnutrition study that was conducted at the Mbagathi District Hospital. This is a general hospital located within Nairobi, the Capital City of Kenya. It has a 38 bed capacity children's ward from which study participants were recruited. This ward is managed by two consultant paediatricians, one medical officer, two medical officer interns, sixteen clinical officer interns, sixteen nurses, one nutritionist and four nutrition interns. The average monthly under -5 admissions and outpatient attendance is 340 and 2600, respectively. The proportion of children with severe acute malnutrition is estimated to be 30% translating to 102 children monthly. Mbagathi serves several poor informal settlements including the Kibera slums which have an estimated population of 250,000 persons.

3.2 Study Population

Participants in this study were infants and children aged 6 to 59 months with severe acute malnutrition admitted at the hospital.

3.3 Study Design

This was a hospital based prospective study

3.4 Study period

This study was conducted during the months of August, September and October 2012.

3.5 Sample Size

Fisher's formula for calculating sample size using precision around a proportion

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

N= minimal sample size required for the study.

z= 1.96 (normal deviate corresponding to 95% confidence interval)

d= 0.075 (degree of precision of 7.5%)

P= 0.61 (the recovery rate of 61% reported by Bernal C et al in Columbia)

Thus N= $\frac{1.96^2 \times 0.61 \times 0.39}{0.075^2}$

The minimum sample size N= **163**

3.6 Sampling Method

The consecutive sampling method was used.

3.7 Inclusion Criteria

All infants and children aged 6 to 59 months with severe acute malnutrition as defined by a weight for height Z score < -3 SDs below the mean of the WHO reference population and/or the presence of edema of nutritional origin and/or left mid upper arm circumference of less than 11.5 cm admitted to the hospital were enrolled into the study. Children with severe acute malnutrition superimposed on chronic malnutrition were also included into the study as long as their acute malnutrition met the WHO criteria for severity as outlined above.

3.8 Exclusion Criteria

1. All infants younger than 6 months or children older than 59 months
2. Infants and children with milder forms of acute malnutrition and those with chronic malnutrition (height for age < -2 SD) not complicated by WHO defined severe acute malnutrition
3. Infants and children with malnutrition secondary to chronic diseases such as cerebral palsy, congenital/acquired heart diseases, malignancy, connective tissue diseases, endocrine diseases, severe dermatoses, surgical conditions
4. Those whose parents/guardians declined to consent to their child's participation in the study.

Excluding medical conditions were ascertained by the investigator from the child's medical history, physical findings and review of any relevant investigations that may have been requested by the hospital's doctors.

3.9 Case Definition

Severe acute malnutrition in this study was defined by a weight for height Z score 3SDs below the mean of the WHO reference population and/or the presence of edema of nutritional origin and /or a left mid upper arm circumference of less than 11.5 cm.

3.10 Medical Care and Therapeutic Feeding

The medical care for study participants was provided by the hospital's resident doctors and followed the W.H.O recommendations which form the basis of the Ministry of Health pediatric guidelines for the management of severe acute malnutrition. Another study determining the degree of adherence to the W.H.O treatment protocol for severe acute malnutrition among hospitalized children recruited the same children participating in this study. The adequacy of feeding was assessed by taking a twenty hour dietary recall after every session of weighing. The type of feed prescribed, the amount taken, method of feeding, any other foods and amounts given, presence of vomiting, diarrhea, respiratory difficulty and oedema was recorded on alternate days. Study participants whose feeding did not follow the W.H.O guidelines were analyzed together with those whose feeding adhered to the W.H.O protocol. This was informed by the poor adherence to the W.H.O guidelines as reported by Nzioki C. et al in a Kenyan tertiary hospital. They were expected to adversely affect clinical outcomes; potentially increasing the overall case fatality rate and decreasing overall mean weight gain and nutritional recovery rate. The alternative feed prescribed, the approximate caloric content, the amount taken and feeding frequency was recorded.

3.11 ANTHROPOMETRIC MEASUREMENTS AND STUDY EQUIPMENT

The weight, height/length and mid upper arm circumference were measured thrice and the closest two values averaged. Outliers and implausible measurements were generally not encountered. However, where applicable, they were deleted to avoid distortion of study outcomes.

3.11.1 Weight

Every child was weighed on admission and on alternate days until discharge, day 21 or death. The SECA 354 electronic baby and child weighing scale was used. It has a maximum weighing capacity of twenty kilograms and can detect as little weight change as ten grams.

3.11.2 Height/Length

The Shorr board was used to measure standing height for children older than 2 years and recumbent length for infants and children unable to stand on admission only. This board measures to the nearest 0.1 cm and has maximum capacity of 130 cm.

3.11.3 Left Mid Upper Arm Circumference

UNICEF issued color coded M.U.A.C tapes were used to measure the left mid upper arm circumference on admission only. This is the circumference of the left arm mid way between the acromion and the olecranon process with the M.U.A.C tape fitting snugly.

3.12 W.H.O Z score tables

W.H.O gender specific weight for height, weight for age and height for age Z score tables were used to grade malnutrition after anthropometric measurements were taken.

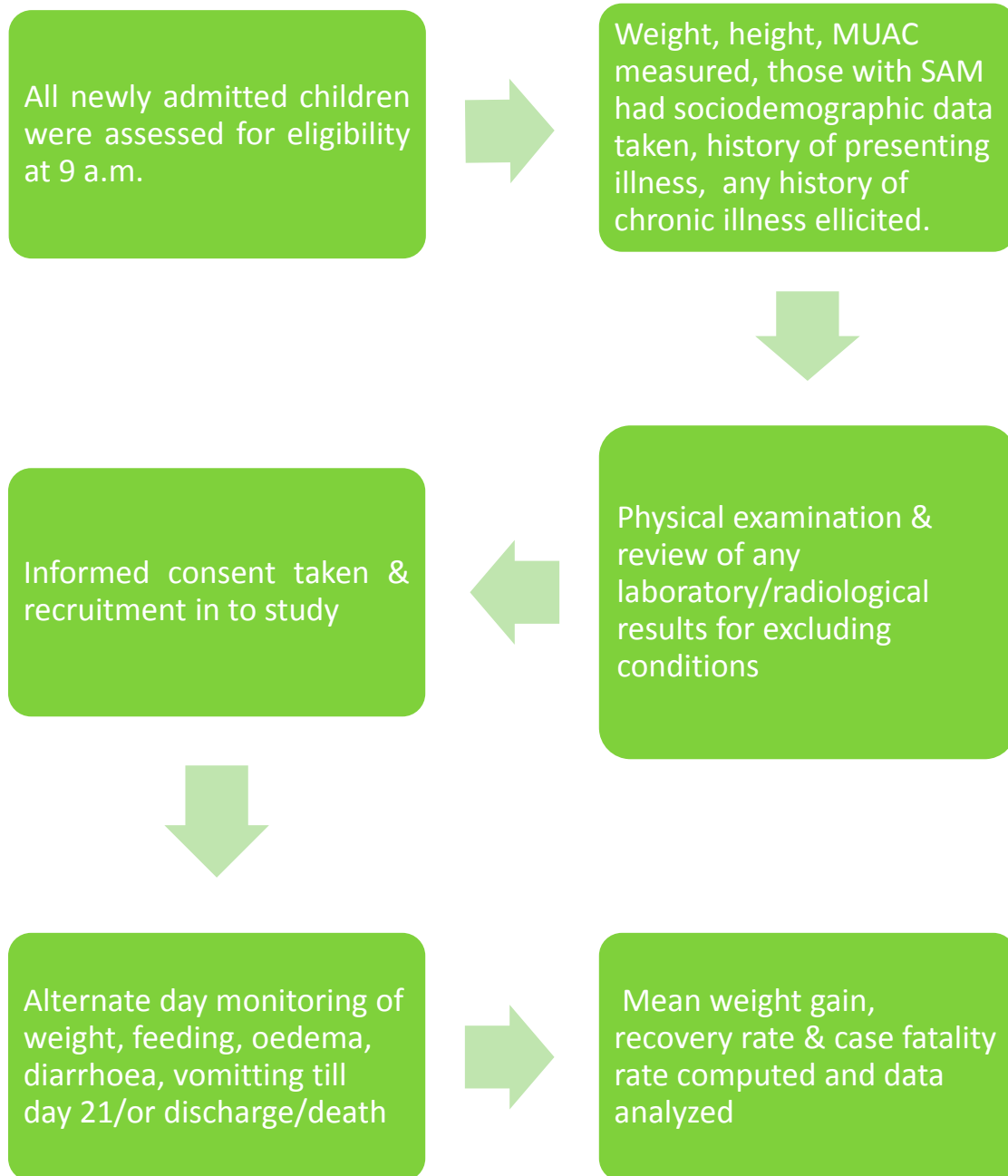
3.13 STUDY PERSONNEL

The principal investigator and research assistants were responsible for recruiting participants, taking anthropometric measurements and collecting data.

3.14 STUDY PROCEDURE

The investigators visited the children's ward every morning at 8 a.m. and assessed all the newly admitted for eligibility for inclusion into the study ascertaining their ages using their well baby clinic card. The weight, height/length, and left mid upper arm circumference were taken for those aged six to fifty nine months. Informed consent for inclusion into the study was taken from parents or guardians of those children meeting the case definition of severe acute malnutrition. The history of the presenting illness was recorded. A physical examination was done. Baseline vital signs and physical findings were recorded. Laboratory data and any radiographs were reviewed. The nutritional diagnosis and all other medical diagnoses were recorded. Comprehensive information on all coexisting disease states was recorded to help provide justification for the diagnosis and rationale for exclusion where the exclusion criterion was met. The tests used to confirm HIV infection was noted as either HIV DNA PCR or HIV rapid tests for children aged below or above 18 months, respectively. Those children with excluding conditions were excluded and explanations were given to the parents for the exclusion. Weight for height, weight for age and height for age Z scores were determined using the W.H.O Z score charts. Subsequently the recruited children were weighed and their food intake monitored using 24 hour dietary recall on alternate days until discharge, death or day 21 of therapeutic feeding whichever came earlier.

Figure 1 The study process



3.15 DATA ANALYSIS

Data were cross-checked for completeness before being entered into a preformed Microsoft Access database and analyzed using SPSS version 17.0 software. Descriptive statistics including proportions, means and medians were calculated. Chi-square or Fisher's exact test were used to compare categorical variables. Comparison of means and medians was done using Student's t test and Mann Whitney U test respectively.

3.16 STUDY OUTOMES

3.16.1 Recovery

The severely malnourished child was considered to have recovered when she/he attained a weight for height Z score of 1SD below the median of the W.H.O. reference population and had lost all edema for those with edematous acute malnutrition.⁵ Recovery was expressed as the number of severely malnourished children attaining WHZ -1SD as a proportion of the total number of children participating in the study.

3.16.2 Mean weight gain

This was calculated using the formula provided in the W.H.O pocket book for hospital care of children. The mean weight gain for oedematous participants was computed separately. The difference between the minimum weight during the rehabilitation phase and the weight at discharge was divided by the number of intervening days; and then by the mid-point of the two weights. The units of mean weight gain were grams per kilogram per day. The proportion of children attaining an average weight gain of more than ten grams per kilogram per day was calculated.

3.16.3 Case fatality rate

The number of enrolled children with severe acute malnutrition who die expressed as a proportion of the total number of severely malnourished children included in the study.

3.17 ETHICAL CONSIDERATIONS

Study approval was sought from the Ethics & Research Committees of the Kenyatta National Hospital/the University of Nairobi and administrative permission from the Mbagathi District Hospital. Participation in the study was voluntary. Informed written consent was sought from the parents or guardians of the children participating in the study. Confidentiality was maintained while handling participants' information. Information useful to the care of the child was shared with the ward doctor.

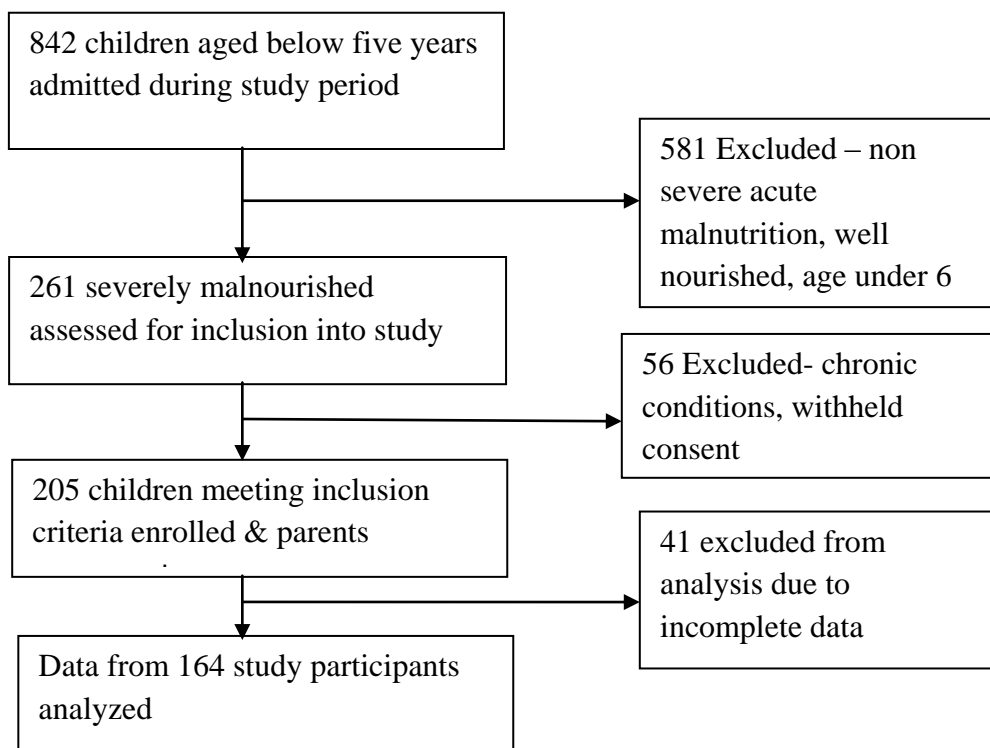
CHAPTER FOUR

RESULTS

4.1 BASELINE CHARACTERISTICS

During the study period a total of 842 children aged below five years were admitted to the paediatric ward of Mbagathi District hospital. Of these, 261 were eligible for the study. However 56 were excluded because of chronic disease and parental withholding of consent. A total of 205 severely malnourished children aged 6 to 59 months were enrolled in to the study. **Figure 2** below shows how the study participants were recruited. Out of the 205 children enrolled into the study, 41 were excluded from analysis due to incomplete data.

Figure 2 Recruitment of study participants



Their characteristics are summarized in table 6 below. One hundred and thirty nine (84.7 %) patients were in the age group 6 to 24 months and the median age was 13.5 months (I.Q.R. 9 to

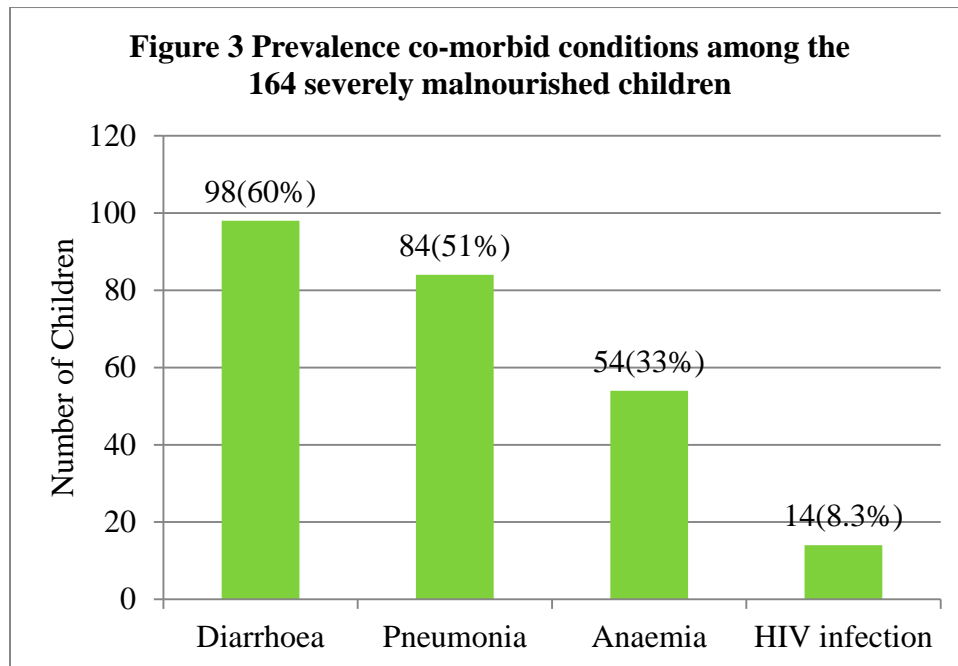
18.8). Out of the 164 children enrolled 91(55%) were male and only 25(15%) had edematous severe acute malnutrition with or without a WHZ of $<-3SD$. The mean maternal age was 27(5.9). Out of the 164 mothers 118(72%) had received at least primary level education only 42(26%) had received secondary and post-secondary education. One hundred and twenty six mothers (76%) were married. One hundred and fifty three families (93%) had a monthly income below KSh.10000 (120 US Dollars) whereas 62(38%) families had between two to four children aged below five years in their households.

Table 6 Baseline characteristics of the 164 children aged 6 to 59 months with severe acute malnutrition admitted to Mbagathi District Hospital.

Characteristics	Frequency (%) Median* (IQR)
Sex Male	91(55)
Age (months) Median	13.5(9-19)*
6 to 11	55(34)
12 to 23	84(51)
24 to 35	14(9)
36 to 47	6(4)
48 to 59	5(3)
Anthropometry	
Median MUAC	11(10.5-11.8)*
Median WHZ	-3.1(-3.5 to -3.0)*
Median WAZ	-3.0(-4.0 to -3.0)*
Median HAZ	-3.0(-3.0 to -2.0)*
Median maternal age(years)	26(22-28)*
Maternal education	
No formal education	4(2)
Primary	118(72)
Secondary	39(24)
Tertiary	3(2)
Maternal marital status	
Married	126(77)
Single	38(23)
Under fives in household	
One	101(62)
two to four	62(38)
Family income Ksh/month	
Less than 5000	71(43)
5000 to 10000	82(50)
10000 to 15000	8(5)
More than 15000	3(2)

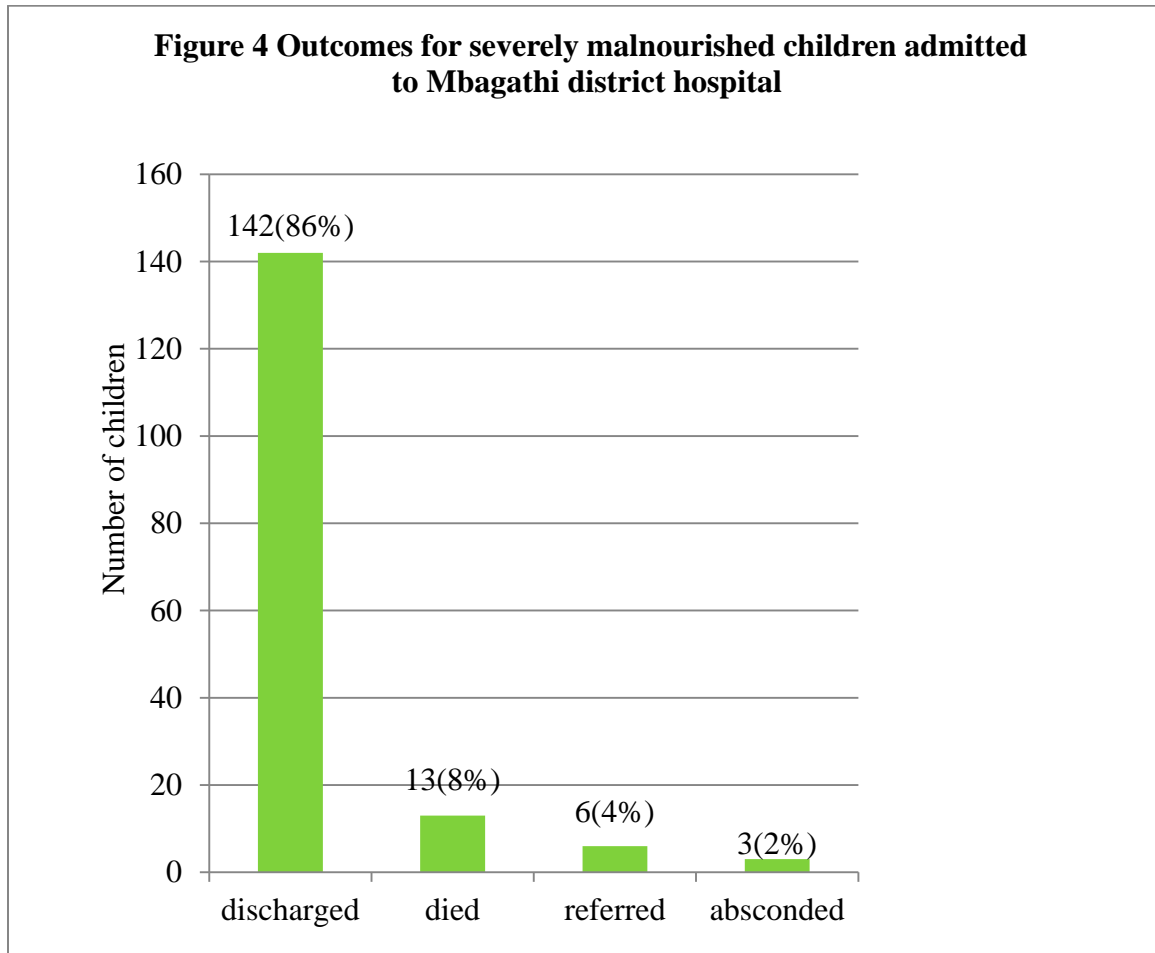
* Median (IQR)

Figure 3 below shows the prevalence of co-morbid conditions in the children studied. Diarrhoea was the most prevalent disease complicating severe acute malnutrition followed closely by pneumonia. Of the 164 children enrolled 98(60%) had diarrhoea, 84(51%) had pneumonia, 54(33%) had anaemia and 14(8.3%) had HIV infection.



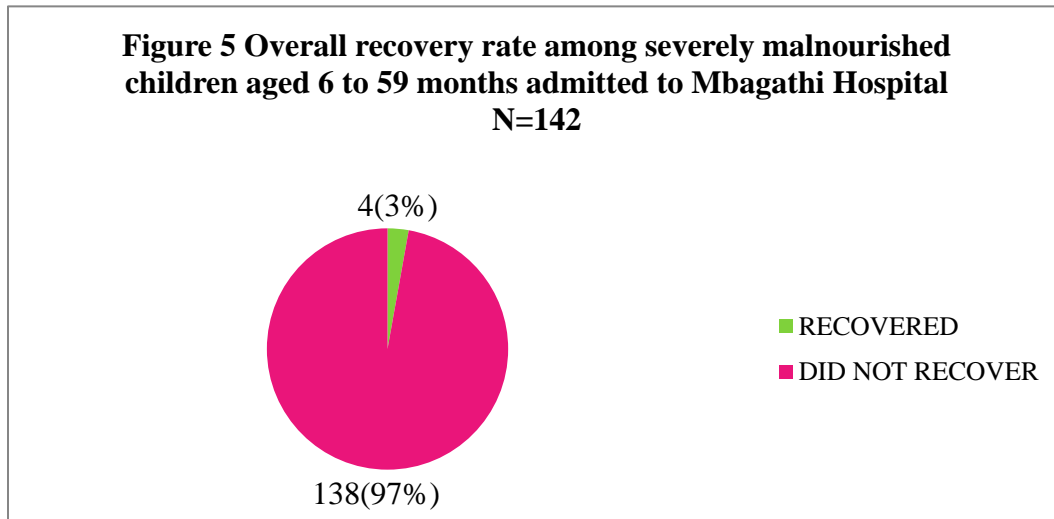
4.2 OUTCOMES

Of the 164 children enrolled into the study 142 (86%) were discharged, 13(8%) died, 6(4%) were referred and 3(2%) absconded. Figure 4 below illustrates the general outcomes of the study participants.

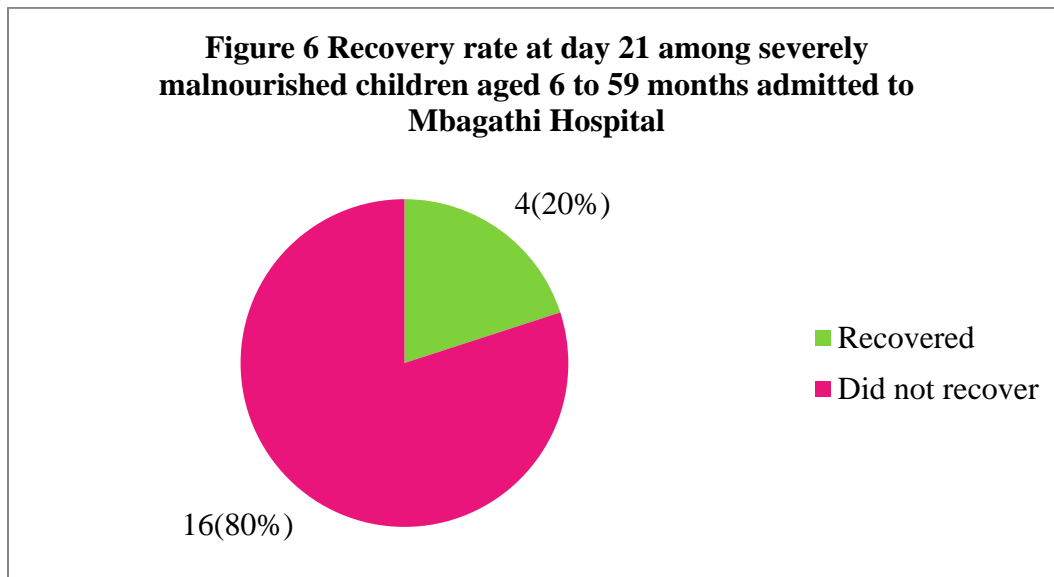


4.2.1 RECOVERY RATE

Out of the 142 children who were discharged only 4 (3%) had attained nutritional recovery (WHZ = or >1SD) by day 21 of admission or at discharge. The median length of hospitalization was 11 days (IQR 8 to 15). The overall recovery rate was 3%.

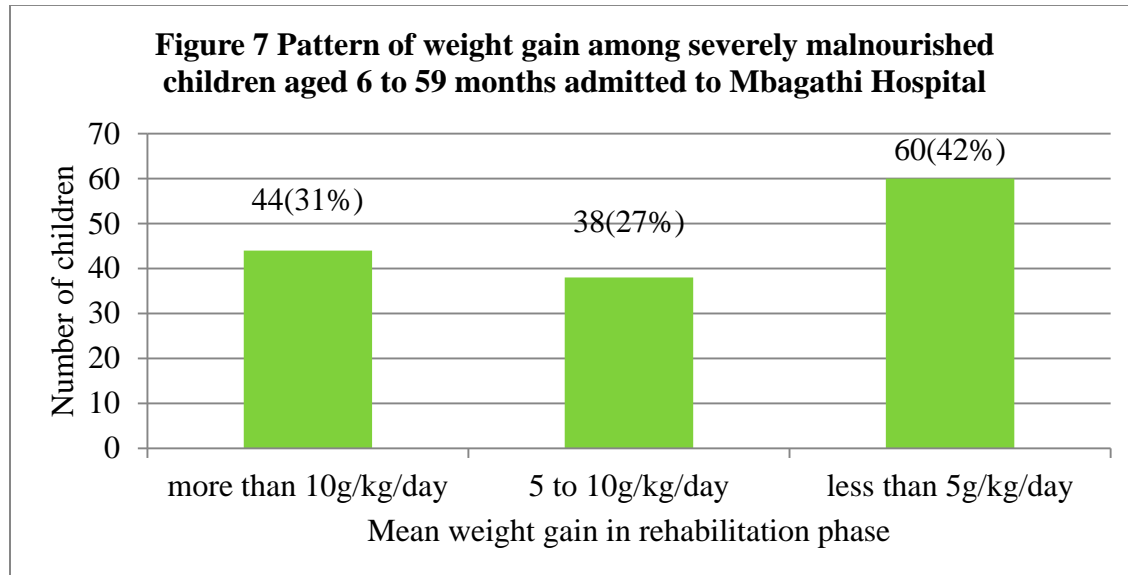


Of the 20 children who took therapeutic feeds for a minimum of 21 days prior to discharge 4(20%) recovered from their severe acute malnutrition. The recovery rate at day 21 was, therefore, 20%.



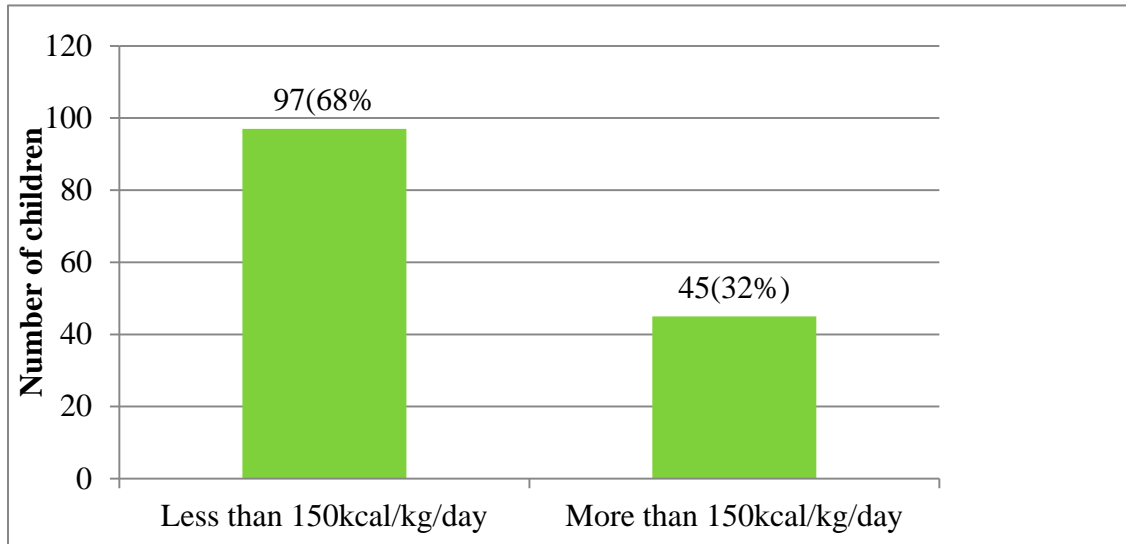
4.2.2 WEIGHT GAIN AND ASSOCIATED FACTORS

The overall median weight gain during hospitalization was 5.6 g/ kg/day (IQR 1.7 to 10.4) with 44(30%) achieving weight gain of more 10 g/kg/ day, 38(27%) gaining between 5 to 10g/kg/day and 60(43%) had a weight gain of less than 5 g/kg/day. The median weight gain for edematous children was 2.35g/kg/day (IQR 0.0 to 5.95).



Ninety seven (68%) of the study participants had a mean calorie intake of less than 150kcal/kg/day during the rehabilitation phase of treatment.

Figure 8 Calorie intake in the rehabilitation phase for the study participants



4.2.3 FACTORS ASSOCIATED WITH WEIGHT GAIN

Socio-demographic characteristics and selected co-morbid conditions namely diarrhea, pneumonia and HIV infection did not have any significant association with the rate of weight gain. Maternal education level did not show any significant association with weight gain. The majority (72%, n=118) of mothers in this study had receive primary education with only 3(2%) having received tertiary education. Therapeutic feed intake in the rehabilitation phase was found to have a strong influence on the rate of weight gain with calorie intake less than 200kcal/kg/day showing a statistically significant association with poor(<5g/kg/day) to moderate(5-10g/kg/day) weight gain. (p=0.015)

Table 7 Association between weight gain, socio-demographic factors and co-morbid conditions

Characteristics	Median weight gain(IQR)	P value
Child's sex		
Male	5.4(2.0-10.6)	
Female	5.8(1.4-10.1)	0.96
Child's age(months)		
6 to 11	5.8(0.0-11.6)	
12 to 23	5.75(2.1-9.8)	0.85
24 to 35	5.75(3.5-7.9)	0.58
36 to 47	9.5(1.7-10.7)	0.62
48 to 59	4.1(2.5-5.0)	0.17
Maternal age(years)		
16 to 20	5.8(1.7-11.9)	
21 to 25	5.7(3.35-8.7)	0.88
26 to 35	5.75(2.0-11.6)	0.91
35 and older	2.55(0.0-7.7)	0.16
Maternal education		
No formal education	5.25(1.05-9.6)	
Primary	5.45(0.0-9.4)	0.95
Secondary	6.8(3.6-12.3)	0.45
Tertiary	4.9(0.0-15.7)	0.86
Pneumonia		
Severe pneumonia	4.7(0.0-11.1)	
Very severe pneumonia	5.4(2.25-10.1)	0.57
Diarrhoea		
Present	5.75(0.0-11.3)	
Absent	5.32(3.4-9.4)	0.89
HIV infection		
Present	5.0(3.0-8.40)	
Absent	5.8(1.7-10.6)	0.85

4.2.4 CASE FATALITY RATE

As illustrated in figure 9 below 13(8%) of the 164 children enrolled died with 5(38%) of deaths occurring within the first 48 hours of admission and 10(77%) within the first week of admission.

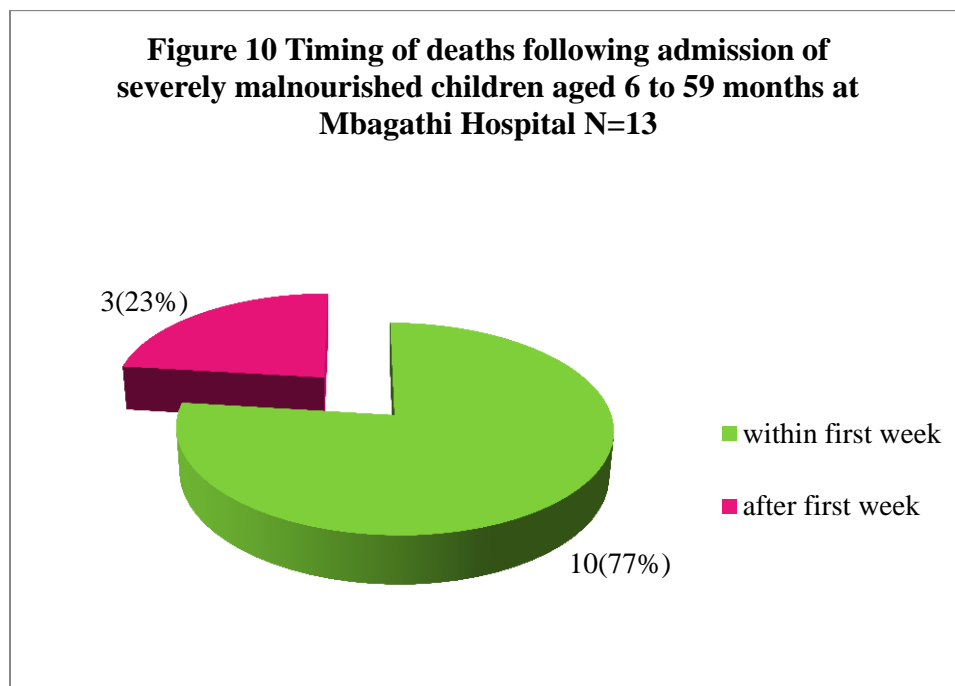
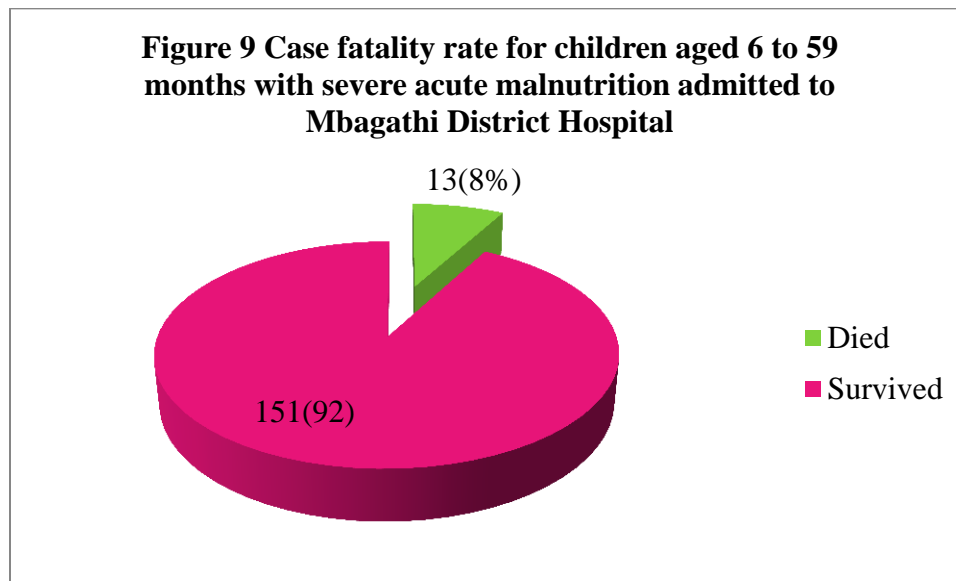


Table 8 Association between mortality and diarrhoea, pneumonia and maternal education

	Dead (n=13)	Alive (n=151)	Unadjusted OR(95% CI)	P value	Adjusted OR*(95% CI)	P value
Diarrhoea						
Present	11	87				
Absent	2	64	0.25(0.05-1.15)	0.07	0.11(0.01-0.96)	0.04**
Pneumonia						
No pneumonia	4	76	1		1	
Pneumonia	5	34	2.79(0.7-11.1)	0.14	2.55(0.45-14.6)	0.28
Severe pneumonia	3	30	1.9(0.4-9.0)	0.42	2.44(0.41-14.2)	0.33
Maternal education						
No formal education	0	4				
Primary	10	108	1		1	
Secondary	1	38	0.28(0.04-2.29)	0.24	0.43(0.05-4.0)	0.47
Tertiary	1	2	21.6(1.8-260)	0.015	223(3.4-14728)	0.01

*Adjusted for age and sex

**Diarrhoea had a statistically significant association with mortality (p=0.04)

4.2.5 FACTORS ASSOCIATED WITH MORTALITY

In this study 11 (11%) out of the 98 children with diarrhoea died as compared to only 2(3%) out of 64 who did not have diarrhoea. Diarrhoea showed a statistically significant increase in risk of death. (p=0.04) Pneumonia and maternal education level did not have statistically significant association with mortality. The odds of dying among those with poor weight gain (<5g/kg/day) was significantly higher compared with those who experienced moderate (5-10g/kg/day) to good

(>10g/kg/day) weight gain. {(OR 8.7(1.2-382) p=0.001} The majority (72%, n=118) of mothers in this study had receive primary education. The number of mothers (n=3) who had received tertiary education was too small to demonstrate any difference in child mortality compared with less educated mothers.

4.4 DISCUSSION

This study was designed to determine the clinical outcomes of severely malnourished children aged 6 to 59 months admitted to Mbagathi district hospital. Out of the 164 children who participated in this study 142(86%) were discharged after variable durations of hospitalization, 13(8%) died, 6(4%) were referred to tertiary hospitals and 3(2%) absconded. The proportion of absconders is lower than the 11.7% reported by Hossain M. et al. and meets the W.F.P/UNICEF/SPHERE standards for defaulter rates of less than 15%.

The common co-morbid conditions reported in this study were diarrhoea (60%), pneumonia (51%), anaemia (33%) and HIV infection (8.3%). These findings were comparable to those reported by other investigators. The prevalence of diarrhoea and pneumonia among severely malnourished children at K.N.H was 70% and 51% respectively according to Nzioki C. et al. Hossain et al in Bangladesh reported lower prevalence for pneumonia (33%) and diarrhoea (11%) among hospitalized severely malnourished children. Bernal C. et al in Columbia reported a prevalence of diarrhea (68%) and anaemia (51%) among severely malnourished children. De Maayer in South Africa reported a much higher prevalence of HIV infection (51%). In summary, two thirds of the hospitalized severely malnourished children in our study had diarrhoea and half of them had pneumonia. Approximately 8 in 100 had HIV infection, which is just slightly higher than the national HIV prevalence for Kenya.

The overall nutritional recovery rate (defined as a WHZ equal to or greater than -1SD) among the 142 children who were discharged was 3% (n=4) at discharge. The recovery rate for the 20 children who received therapeutic feeding for at least 21 days was 20%(n=4). It is apparent that only those children who stayed a minimum of 3 weeks in hospital on catch up feeding recovered.

The 21 day recovery rate of 20 % reported by this Mbagathi study fails to meet the minimum SPHERE/W.F.P/U.N.H.C.R standards of recovery rate of >75% and is much lower than that reported by other investigators. The low recovery rate reported in this study was contributed to by the generally low calorie intake in the rehabilitation phase and shorter duration of hospitalization. The median duration of hospitalization in this study was 11 days (IQR 8-15), which was much shorter than the 3 to 4 week of therapeutic feeding within which nutritional recovery is expected to occur as per the W.H.O/W.F.P/UNICEF standards. Some of the factors that are likely to have contributed to low calorie intake include delayed transition to catch up feeds, failure to appropriately increase feeds and infrequent use of nasogastric tube feeding. The factors that are likely to have contributed to shorter duration of hospitalization include inadequacy of ward space relative to large patient numbers, inadequate knowledge of W.H.O standard discharge criteria for severely malnourished children and preference for outpatient nutritional rehabilitation. Deficiencies of nurses and nutritionists are likely to have contributed to inadequate supervision and monitoring of feeds intake.

Bernal C. et al in Columbia reported a recovery rate of 61% for severely malnourished children with mean duration of hospital stay of 3 weeks. This study was conducted in a first level referral hospital comparable to our district hospitals. Hossain M. et al in Bangladesh reported a recovery rate of 88%, again within a minimum duration of 3 weeks in hospital. This study was conducted in a well resourced specialized nutrition unit of a teaching and referral hospital.

The median weight gain in this study was 5.6g/kg/day, much lower than the 10g/kg/day reported by Hossain M. et al. Only 44(31%) children had good weight gain (greater than 10g/kg/day), 38(27%) had moderate (5 to 10g/kg/day) and 60(42%) had poor weight gain(less than 5g/kg/day). Sixty eight percent of all study participants had a calorie intake of less than

150kcal/kg/day which was significantly associated with poor weight gain during the rehabilitation phase of treatment. ($p < 0.015$) The median duration of hospital stay was 11 days (IQR 8 -15). The nutrient intake was suboptimal in more than two thirds of the children and most were discharged before the W.H.O criteria for discharge could be met. Hossain M reported a good weight gain in 30.9%, moderate weight gain of 30.9% and poor weight gain in 14.7%. The proportion of children experiencing poor weight gain in this study was much higher at 43% whereas the proportion attaining good and moderate weight gain were 30% and 27% respectively, comparable to what was reported by Hossain M.

There was no association between rate of weight gain and the child's age, sex, maternal education, diarrhea, pneumonia and HIV infection. Ferguson P. et al in a 2009 study in Malawi reported that nutritional recovery rate and mean weight gain did not differ between HIV infected (8g/kg/day) and HIV uninfected (8.9g/kg/day).

The overall case fatality rate (CFR) for this cohort was 8%. According to the WHO/SPHERE/UNHCR/WFP grading of case fatality rates for severe malnutrition, a case fatality rate of less than 10% implies treatment was effective. Whereas the in-patient CFR reported by this study may appear comparable to international standards, it is important to note that 86% (n=122) of children were discharged before day 21, largely prior to recovery and 94% (n=153) of parents earned less than Kshs.10, 000 per month. It is possible more could have died at home. In this study 38.5 % of all deaths occurred within the first 48 hours whereas 77% of all deaths occurred within the first week of admission. This is comparable to the findings of Maitland K. et al in a study in East Africa where 33% of deaths occurred within the first 48 hours. Bachou H. et al at the Mulago hospital in Uganda also reported that 70% of mortalities occurred within the first week of admission

The case fatality rate of 8% is comparable to the case fatality rates of 5.7% reported by Bernal C. et al and 11.5% reported by De Maayer et al in Columbian and South African first referral level hospitals respectively. The case fatality rate was much lower than the 38% reported by Nzioki C. et al in a study at Kenyatta National Hospital (KNH). It is likely that selection bias may have influenced the case fatality in this study; the critically ill severely malnourished children may have been omitted due to practical difficulties of regular weight monitoring of such children. The case fatality rate for children with diarrhoea (11%) was higher than that of children without diarrhoea (2%). Diarrhoea was associated with a statistically significant increase in the risk of death among children with severe acute malnutrition ($p=0.04$).

The association between diarrhoea and malnutrition has been known for many decades. Diarrhoea can precipitate or aggravate malnutrition by decreasing nutrient intake, impairing nutrient absorption, increasing nutrient losses and requirements. Protein calorie malnutrition with associated micronutrient deficiencies are known to cause gastrointestinal mucosal atrophy and depletion brush border enzymes which can lead to impaired digestion and absorption of carbohydrates precipitating osmotic diarrhoea. The associated impairment of barrier functions, innate and adaptive immune responses lead to more severe, prolonged and recurrent enteric infections that cause diarrhoea. Diarrhoea, particularly when persistent often leads to loss of micronutrients notably magnesium, phosphorus and zinc. Kimutai D. et al in a cross-sectional study at the Kenyatta National Hospital in 2006 reported statistically significant association between hypophosphatemia among severely malnourished children and mortality, with higher mortality rates among those with more severe degrees of hypophosphatemia.

The increased risk of mortality conferred by pneumonia was not statistically significant. The child's gender, HIV infection status and pneumonia were not significantly associated with

mortality. Only 8.3% of children in this study were HIV infected. HIV infection is associated with nutritional deficiencies secondary to decreased nutrient intake, impaired nutrient absorption, increased nutrient losses and increased nutrient demand. This is due to direct effect of HIV and the myriad of opportunistic infections precipitated by HIV induced immunodeficiency. HIV/AIDS has a significant impact on food security in affected households. Under-nutrition, on the other hand, influences HIV disease progression, increases morbidity and lowers survival of HIV infected persons.²¹ De Maayer, in a prospective study of hospitalized severely malnourished in South Africa reported a six fold increase in mortality risk among HIV infected children. The prevalence of HIV infection in that cohort was 51%. Fergusson P in a prospective cohort study of hospitalized children with severe acute malnutrition where 17.4% were HIV infected reported higher mortality for HIV infected (35.4%) than uninfected (10.4%). All children who survived achieved nutritional recovery (>85%) regardless of HIV status. HIV-infected children (8.9g/kg/day) had similar weight gain to HIV-uninfected (8g/kg/day).²² In our study HIV infection status had no significant influence on the rate of weight gain, thus agreeing with the findings of the other investigators cited above. However, our finding that HIV infection did not significantly increase case fatality differs from the findings of other investigators. It is noteworthy that our cohort had a comparatively lower HIV infection prevalence (8.3%) compared to that reported by De Maayer (51%) and Fergusson P (17.4%) and that we only determined in-hospital case fatality while Fergusson followed up the children for 4 months after discharge from hospital. It is not possible to conclusively assess the impact of HIV infection on the survival of severely malnourished children within a short duration of hospitalization.

4.3 STUDY LIMITATIONS

A multiplicity of factors could potentially have influenced the outcomes of hospitalized severely malnourished children in this study. These included, but were not limited to, the availability and competence of health workers, availability and use of guidelines, availability of essential supplies and equipment, laboratory services, clinical severity of the malnutrition at admission, co-morbidity, hematological and biochemical derangements. Due to financial and time constraints this study could not assess the potential impact of all these factors on outcomes. It determined clinical outcomes and assessed the impact of a few clinical and socio-demographic variables and co-morbid states on those outcomes. The quantity of therapeutic feeds and other food intake was obtained from the mother using the 24 hour dietary recall method. Therefore, recall bias may have occurred.

4.5 CONCLUSION

1. The 21 day nutritional recovery rate in this study was 20%.
2. The median weight gain during the rehabilitation phase of treatment was 5.6g/kg/day with 31% of study participants achieving mean weight gain of 10g/kg/day.
3. The case fatality rate was 8%.
4. Diarrhoea was significantly associated with increased risk of mortality.

4.6 RECOMMENDATIONS

1. Goal directed nutritional rehabilitation of children with severe acute malnutrition and W.H.O criteria be attained prior to discharge
2. Severely malnourished children with diarrhoea should be sub-triaged for more intensive care to further decrease case fatality
3. Studies to determine factors contributing to suboptimal feed intake, poor weight gain and to describe long term outcomes

REFERENCES

1. W.H.O. Malnutrition- The Global Picture. World Health Organization, Geneva.
Available at [http:// www.who.int/home-page/](http://www.who.int/home-page/)
2. Antwi S. Malnutrition: Missed diagnosis, Ghana med J 2008 Sept.; 42(3):101-104
3. Collins S. Global Child Health: Treating severe acute malnutrition seriously. Arch Dis Child 2007; 92:453-461
4. W.H.O. Management of severe malnutrition: a manual for physicians and other senior health workers. W.H.O. Geneva,1999; p10-12
5. W.H.O. Pocket book of hospital care for children. W.H.O. Geneva, 2005; p188-195
6. The Sphere project. Humanitarian charter and minimum standards in disaster response- severe malnutrition. The Sphere Project. Geneva. Available at <http://www.sphereproject.org/content/view/66/83/lang,english>
7. U.N.H.C.R/W.F.P. Guidelines for selective feeding programs in emergency situations. Geneva. U.N.H.C.R .1999; p20
8. Horton R. The coming decade for global action on child health. Lancet 2006; 367(9504): 3-5.
9. Black R.E., Morris S.S., Bryce J. et al. Where and why 10 million children are dying every year? Lancet child survival series 1, 2003; 361: p2226-2234
10. UNICEF's State of the World's Children 2007 Report. UNICEF, New York. 2007
11. UNICEF. Global Database on Child Nutrition. UNICEF, New York. 2001

- 12.** Kenya National Bureau of Statistics (KNBS): Kenya Demographic and Health Survey 2008/2009. KNBS, Nairobi. June 2010; p142- 146
- 13.** Ashworth A., Jackson A. and Uauy R. et al. Editorial. Focusing on malnutrition management to improve child survival in India. *Ind. Ped.* 2007 June; 44: 413
- 14.** Hossain M.I, Dodd N.S, Ahmed T. et al. Experience in managing severe malnutrition in a government tertiary treatment facility in Bangladesh. *J Health Popul Nutr* 2009 Feb; 27(1):72-80
- 15.** Pelletier D, Frongillo EJ, Shroeder D et al. Effect of malnutrition on child mortality in developing countries; *Bul WHO.*1995; 73:443-448
- 16.** The African Union and UNICEF. A snapshot of the Nutrition Situation in Africa 2009 report. African Union, Addis Ababa 2009; p12.
- 17.** Bernal, C., Velasquez, C., Alcaraz, G. et al. Treatment of severe malnutrition in children: experience in implementing the WHO guidelines in Turbo, Colombia. *J Ped Gastr Nutr*, 2008 March; 46(3):322-328.
- 18.** Ashworth A., Chopra M., Mc Coy D. et al. WHO guidelines for management of severe malnutrition in rural South African hospitals: effect on case fatality and influence of operational factors. *Lancet* 2004; 363(9415):1110-1115.
- 19.** Rodrigues A., Alves B., Filho B. et al. Decline in Mortality after use of WHO protocol for management of Severe Malnutrition. *Trop Doc* 2009; 39 (2): 71-72.
- 20.** Nzioki C., Irimu G., Musoke R. et al. Audit of care for severely malnourished children aged 6-59 months admitted at K.N.H. *Inter Health.* 2009 Sept; 1(1): 91-96.

- 21.** Kimani-Murage E.W, Norris S.A, Pettifor J.M et al. Nutritional status in rural South African children. *BMC Paediatrics* 2011;11:23 doi:10.1186/1471-2431-11-23
- 22.** Fergusson P, Chinkhumba J, Grijalva-Eternod C et al. Nutritional recovery in HIV-infected and HIV-uninfected children with severe acute malnutrition. *Arch Dis Child.* 2009 Jul;94(7):512-6

APPENDIX I

INFORMATION AND CONSENT FORM: THE CHILD MALNUTRITION STUDY

PART A: PARENT/GUARDIAN INFORMATION SHEET

The following information is to help you understand what this study is about so that you give informed consent for your child to participate in this study. Please read the information carefully before signing the consent form. (Part B)

Who is doing this study?

My name is DR. JOHN K. FONDO and I am the principal investigator in this study. I am currently undertaking postgraduate training at the University of Nairobi, based at the College of Health Sciences, Kenyatta National Hospital. I am doing the study with other doctors from the University of Nairobi and Mbagathi District Hospital.

What is this study about?

This study is looking at the effectiveness of hospital care for malnourished children who are admitted. We want to find out how good or bad is the outcome of the way malnourished children are cared for in order to help the hospital and doctors improve care.

Why am I doing this study?

I am doing this study because we do not have the latest information about our outcomes of care for children admitted with severe forms of malnutrition. Reports from other studies indicate that too many children are dying unnecessarily. We want to get the clear picture so that we can improve care for better results.

Why am I requesting to include your child?

I am requesting to include your child because your child has been diagnosed with malnutrition and has been admitted. He /she is eligible for the study and I want to give all children a chance to participate in the study.

What will be done to my child if I agree?

If you are happy for your child to participate we will ask you a few questions about your child, examine him/her, take his weight and height and record the information in a form. We will also record the child's weight same time every other day until the day of discharge.

Are there any risks to my child?

There is no risk at all.

Are there any benefits if my child participates?

There is no major benefit to your child except that information will be shared with your hospital doctors that may be useful in the day to day care of your child.

What happens if I refuse to participate?

Participation is voluntary. You are free to decide if you want your child to participate. If you agree you can still change your mind at any time and withdraw from the study. This will not affect your child's care now and in the future.

Who will have information about my child in this study?

Information will be shared with your doctors. Your child's medical records will be kept confidentially and securely without your child's name on it.

Who has allowed this study to take place?

The ethics and research committees of University of Nairobi/Kenyatta National Hospital and Mbagathi District Hospital have studied the proposed study carefully and given permission for it to be done.

What if I have questions to ask about this study?

Feel free to ask me any questions now and at any other time. You can contact me for any further clarifications.

DR. JOHN K. FONDO

DEPARTMENT OF PEDIATRICS & CHILD HEALTH

UNIVERSITY OF NAIROBI

P.O.BOX 19676-00200, NAIROBI

MOBILE: 0714 680 433

Email: jhnfondo@gmail.com

OR

THE SECRETARY

KNH/UON ETHICS & RESEARCH COMMITTEE

P.O.BOX 20723-00202, NAIROBI

TEL. 020 2726300-9

EMAIL: KNHplan@ken.Healthnet.org

PART B: CONSENT FORM

I , being the guardian ofhave understood the information in **part A** above on what the study entails. I have had a chance to ask questions and they have been answered satisfactorily. I understand that I can withdraw from the study at any stage and that this will not affect me/ my child in any way.

I hereby consent to my child’s participation in this study.

Parent/guardian’s signature: Date:

Parent/ guardian’s name: Time:

Doctor’s Signature: Date:

.....

Doctor’s Name: Time:

.....

SEHEMU A : MAELEZO KUHUSU UTAFITI

TAFADHALI SOMA KWA MAKINI MAELEZO YAFUATAYO KABLA YA KUJAZA NA KUTIYA SAHIHI SEHEMU B

Utafiti huu unafanywa na nani?

Jina langu ni Dkt. JOHN FONDO. Mimi ni mwanafunzi anaye somea shahada ya udaktari wa watoto katika chuo kikuu cha Nairobi iliyopo hospitali kuu ya Kenyatta. Ninafanya utafiti huu pamoja na madaktari wengine kutoka chuo kikuu cha Nairobi na hapa hospitali ya Mbagathi.

Utafiti huu unahusu nini?

Utafiti huu unahusu watoto wenye umri kuanzia miezi sita hadi miaka mitano waliolazwa hospitalini kwa sababu ya ugonjwa unaoletwa na upungufu wa vyakula. Tunataka kujua matokeo yao baada ya kutibiwa na kupewa maziwa na vyakula maalum hospitalini.

Kwanini unafanya utafiti huu?

Ninafanya utafiti huu kwa sababu kwa wakati huu hatujui kwa hakika matokeo ya matibabu ya watoto wenye ugonjwa huu yanakuwa namna gani. Ningependa kujua ni wangapi wanaolazwa hospitalini manapona, wangapi wanapata nafuu, wangapi wanafariki na ni mambo gani yanachangiza matokeo mazuri au mabaya. Tukijua hayo yote tutaweza kuleta mabadiliko ili kuboresha matibabu na pia matokeo.

Kwanini unataka kumhusisha mtoto wangu?

Nataka kumhusisha mwanao kwa sababu yeye ako nao ule ugonjwa unaoletwa na upungufu wa chakula ninaopendelea kuuelewa zaidi napia umri wake unafaa kulengana na sheria za utafiti huu. Matokeo yatakuwa mazuri zaidi nikiwahusisha watoto wengi wenye ugonjwa huu. Kwa hivyo nataka kumpa mwanao nafasi ya kushiriki.

Nikikubali mtoto wangu atafanywa nini?

Ukikubali mtoto wako ahusike katika utafiti huu wewe mzazi utaulizwa maswali machache kuhusu wewe mwenyewe, familia yako, na mtoto mwenyewe. Mtoto atapimwa kikamilifu halafu mambo yote yanayomhusu yataandikwa kwenye makartasi maalum. Atapewa matibabu na

chakula halafu atapimwa kilo baada ya siku moja mpaka wakati atakapo pona au kupewa ruhusa ya kuenda nyumbani.

Je kuna madhara katika utafiti huu?

La. Utafiti huu hauna madhara yoyote.

Je kuna manufaa maalum kwa mtoto wangu akihusika katika utafiti huu?

Watoto watakao shiriki katika utafiti huu watapewa matibabu wanayohitaji na hakutakuwa na nyongeza yoyote.

Je nisipokubali mtoto wangu ahusishwe nitapata shida yoyote?

Ni haki yako kukubali au kukataa. Hutapata shida iwapo hutakubali mtoto wako ahusiswe.

Ni watu wapi watakuwa na ruhusa ya kusoma mambo yanayohusu mtoto wangu?

Jina la mtoto wako halitaandikwa katika makaratasi ya utafiti na pia mambo yote yanayo husu wahusika yatawekwa vyema. Ni madaktari wanaomtibu mtoto wako pekee ambao wanaweza kuelezewa yale mambo yenye manufaa katika matibabu ya mtoto wako.

Ni nani aliyeruhusu utafiti huu ufanyike?

Utafiti huu umeruhusiwa na kamati ya haki na usalama katika utafiti ya chuo kikuu cha Nairobi, hospitali kuu ya Kenyatta na hospitali ya Mbagathi baada ya kusoma na kuona ni utafiti unaofaa.

Je nitaruhusiwa niulize maswali juu ya utafiti huu?

Ndio. Ukiwa na maswali yoyote unaweza kuniuliza saa hii au wakati wowote ukitumia anwani na nambari yangu ya simu ya rununu iliyopo hapa chini. Pia unaweza kuwasiliana na ofisi ya Chuo Kikuu cha Nairobi ukitumia nambari iliyopo hapa chini.

DR. JOHN K. FONDO

TAALUMA YA MAGONJWA YA WATOTO

CHUO KIKUU CHA NAIROBI

SANDUKU LA POSTA 19676-00200, NAIROBI

MOBILE: 0714 680 433

Email: jhnfondo@gmail.com

AU

KATIBU

KAMATI YA HAKI/USALAMA KATIKA UTAFITI
CHUO KIKUU CHA NAIROBI/HOSPITALI KUU YA KENYATTA
SANDUKU LA POSTA 20723-00202, NAIROBI
NABARI YA SIMU 020 2726300-9

EMAIL: KNHplan@ken.Healthnet.org

SEHEMU B: KIBALI

Mimi, nikiwa mzazi/mlezi wa.....nimeelewa maelezo yaliyo
kwenye sehemu A kuhusu utafiti huu. Nimepewa nafasi ya kutosha ya kuuliza maswali ambayo
yamejibiwa kikamilifu. Ninaelewa ya kwamba naweza kumtoa mtoto wangu kwa utafiti huu
wakati wowote bila athari yoyote kwangu na kwa mtoto wangu.

Nimekubali mtoto wangu ashiriki katika utafiti huu.

Sahihi ya mzazi/mlezi:x.....Tarehe:

.....

Jina la mzazi/mlezi:Saa:

Sahihi ya daktari:Tarehe:

Jina la daktari:Saa:

APPENDIX II

Fill in the spaces and tick inside the box appropriately.

SOCIO-DEMOGRAPHIC DATA

Child's InitialsAge:in months Sex:

Admission Date..... Admission No.....

Mother's age.....

Mother's education

- No formal education
- Primary
- Secondary
- College

PRESENTING ILLNESS

1. Diarrhoea
 - Present (.....acute < 14 days/..... chronic>14 days/..... blood stained)
 - absent
2. Vomiting
 - Present(.....vomits everything/.....not everything)
 - absent
3. Cough
 - Present (.....acute < 14 days/..... chronic>14 days)
 - absent
4. Difficulty in breathing
 - Present
 - Absent
5. Ability to drink/ breast feed
 - Able
 - Unable
6. Level of consciousness
 - Alert
 - Not alert
7. Convulsions
 - Present
 - absent
8. Fever
 - Present (record temperature.....)
 - Absent

PAST MEDICAL HISTORY

Has the child been admitted in the past?

- Yes (specify when/where/ why.....)
- No

Has the child been diagnosed with a chronic illness?

- Yes (specify disease...../when diagnosed.....)
- No

ANTHROPOMETRY

Weight (kg) Height/Length (cm)Left mid upper arm circumference (cm).....

Weight for Height Z (WHZ) score on admission.....

Weight for Age Z score on admission.....

Height for Age Z score on admission.....

PHYSICAL EXAMINATION

GENERAL EXAMINATION

1. Visible severe wasting
 - present
 - absent
2. Bilateral pitting oedema of lower limbs
 - present
 - absent
3. Pallor
 - present
 - absent
4. Jaundice
 - present
 - absent
5. Generalized lymphadenopathy
 - present
 - absent
6. Digital clubbing
 - present
 - absent
7. Oral thrush
 - present
 - absent

8. Dimorphic facies
 - present
 - absent
9. Obvious gross malformations
 - present
 - absent

CENTRAL NERVOUS SYSTEM

1. Head circumference.....centimetres
2. Level of Consciousness
 - Alert
 - Responds to **V**oice
 - Responds to **P**ain
 - U**nresponsive
3. Pupillary signs
 - Normal
 - abnormal
4. Neck stiffness
 - Present
 - absent
5. Kernig's sign
 - Positive
 - negative
6. Posture
 - Normal
 - abnormal
7. Muscle tone
 - normal
 - abnormal (specify – hypertonia/hypotonia)
8. Muscle power
 - Normal
 - reduced
9. Deep tendon reflexes
 - Normal
 - Abnormal(.....brisk/.....depressed)
10. Abnormal movement
 - Present
 - absent
11. Neural tube defects
 - Present
 - Absent

RESPIRATORY SYSTEM

1. Chest deformity
 - Present
 - Absent
2. Respiratory rate breaths per minute
3. Respiratory distress
 - Present
 - Absent
4. Percussion note
 - Normal
 - Abnormal (.....hyper-resonant/.....dull/.....stony dull)
5. Breath sounds
 - Normal
 - Abnormal (.....bronchial...../decreased)
6. Added sounds
 - Present (.....rhonchi/.....crepitations/.....pleural rub)
 - Absent

CARDIOVASCULAR SYSTEM

1. Temperature of extremities
 - warm
 - cold
2. Capillary refill time
 - <3 seconds
 - > 3 seconds)
3. Peripheral pulses
 - normal
 - absent/weak/irregular/bounding/collapsing
4. Visible neck pulsations
 - present
 - absent
5. Central cyanosis
 - present
 - absent
6. precordium
 - normal
 - prominent/hyperactive
7. Heart sounds
 - normal
 - abnormal- specify- loud P2, palpable P2
8. Pathological heart murmurs
 - Present
 - Absent

ABDOMINAL EXAMINATION

1. Fullness
 - Normal
 - Distended
2. Movement with respiration
 - Present
 - Absent
3. Rigidity/guarding
 - present
 - absent
4. Tenderness
 - Present
 - absent
5. Splenomegaly
 - Present.....cm
 - absent
6. Hepatomegaly
 - Present.....cm
 - Absent
7. Abdominal masses
 - Present
 - Absent
8. Fresh surgical incision wounds
 - Present
 - Absent

MUSCULOSKELETAL EXAMINATION

1. Any gross abnormality of the spine (kyphosis, scoliosis)
 - present
 - absent
2. Any bone deformities/ lesions
 - Present
 - absent
3. Joint swelling
 - Present
 - absent

SKIN

1. Severe skin disease (Psoriasis, eczema, exfoliative erythroderma, Steven Johnson Syndrome, Toxic Epidermal Necrolysis)
 - Present
 - Absent

- 2. Burns
 - Present
 - Absent

NUTRITIONAL DIAGNOSIS (tick in the box appropriately, child may have one in each of 1, 2, 3)

- 1. Acute Malnutrition
 - Severe (weight for height z score <-3SD or MUAC <115mm or bilateral edema feet)
 - Moderate(weight for height z score -3SD to -2SD, no edema)
- 2. Chronic malnutrition
 - Severe (height for age z score < -3SD)
 - Moderate (height for age z score -3SD to -2SD)
- 3. Underweight
 - Severe (weight for age z score <-3 SD)
 - Moderate (weight for age z score -3SD to -2SD)

OTHER MEDICAL DIAGNOSES

- 1. Diarrhea disease
 - Acute
 - Persistent
 - bloody
- 2. Pneumonia
 - Pneumonia
 - Severe pneumonia
 - Very severe pneumonia
- 3. Tuberculosis
 - Pulmonary
 - Extra-pulmonary
- 4. Anemia
 - Mild (Hb 8-10)
 - Moderate (Hb 6-7)
 - Severe (Hb< 6)
- 5. Sepsis
 - Yes (specify organism)
- 6. Urinary tract infection
 - Yes
 - No
 - Not tested

7. HIV

- Positive(.....rapid test/.....DNA PCR)
- Negative

LABORATORY TESTS

Random blood sugar

Blood Smear for Malaria

- Positive
- Negative
- Not done

Haemoglobin level

Urinalysis/culture & sensitivity

- Normal
- Abnormal- specify.....
- Not done

Blood culture

- Normal
- Abnormal – specify.....
- Not done

Stool microscopy

- Normal
- Abnormal- specify.....
- Not done

Chest radiography

- Normal
- Abnormal-specify.....
- Not done

TREATMENT GIVEN

1. 10% dextrose

- Yes (specify dose and route.....)
- No

2. Kept warm(room heating)

- Yes
- No

3. Rehydration
 - Oral-Resomal/....ORS.....
 - Intravenous fluids.....0.9 % Saline.....Ringers Lactate.....Half Strength Darrows/5% D
4. electrolyte correction
 - Potassium
 - Other (specify.....)
5. Antimicrobial(if given specify dose and route)
 - Crystalline penicillin.....
 - Gentamicin.....
 - Flucloxacillin.....
 - Septrin.....
 - Rocephine.....
 - Metronidazole.....
 - Chloramphenicol.....
 - coartem.....
 - quinine.....
6. Micronutrients
 - Zinc
 - Vitamin A
7. Transfusion
 - Yes- specify amount- packed RBCs..... / whole blood.....
 - No

DOES THE CHILD HAVE ANY OF THE FOLLOWING CONDITIONS? MARK IF YES

- Congenital/acquired heart diseases
- Chronic pulmonary diseases
- Chronic kidney disease
- Neurological disorders e.g. Cerebral palsy
- Congenital or acquired neuromascular disorders
- Neural tube defects
- Severe Burns
- Chromosomal abnormalities/ genetic syndromes
- Hematological diseases: Sickle cell disease, aplastic anemia, thalassemia, hemophilia
- Endocrinopathies- hypothyroidism, hyperthyroidism, diabetes mellitus, dwarfism
- Malignancies
- Connective tissue disorders- systemic lupus erythematosus
- Massive splenomegaly
- Surgical conditions
- Severe congenital anomalies

MONITORING CHART

Child’s Initial’s..... AgeWeight

Date of Admission.....Date of Discharge/Death.....Adm. No.....

date	Feed type & Method	Amount prescribed	Amount taken	Caloric content	Weight	oedema	Diarrhea	Vomiting	Respiratory distress

The investigator will ask the mother the following questions on alternate days before weighing the child and then record her responses in the monitoring table against the appropriate date.

1. Is there any problem about the baby you would like to tell me? (vomiting feeds/ poor appetite/diarrhea/ breathing difficulty/fever)
2. What type of milk or food have you been advised to give the baby? (F75, F100, Lactose free milk, plumpy nut, mashed food)

3. How much and how frequently have you been advised to give by the doctors?(record volume in millilitres)
4. How much of each food type has the baby taken in the past 24 hours? (millilitres, ¼ cup, ½ cup, 1 cup). Ask to see cup to estimate its capacityml.

FINAL OUTCOME

- Alive
- Dead(on.....day of admission)

Mean Weight Gain.....g/kg/day

WHZ on day 21 or at discharge.....

Recovery (WHZ \geq -1SD)

- Yes (Days to Recovery.....)
- No

APPENDIX III

Table 9 the study budget

ITEM	QUANTITY	UNIT PRICE	TOTAL
EQUIPMENT			
SECA mechanical infant weighing scale(accuracy 10g)	1	24,000	24000
Child weighing scale(accuracy 10grams)	1	17000	17000
SHORR board	1	12000	12000
PRINTING/STATIONERY			
Questionnaires	200	15	3000
Pens	6	10	60
Box file	1	240	240
Note book	1	35	35
Final manuscripts	4	400	1600
Poster presentation	1	2000	2000
COMMUNICATION	3	1000	3000
TRANSPORT	90	80	7200
R. ASSISSTANT	1	9000	9000
DATA ANALYSIS	1	10000	10000
TOTAL	-	-	89135

BUDGET JUSTIFICATION

Anthropometry

This included provision for purchase of infant and child weighing scales and a measuring board which were adapted to measure recumbent length and standing height. This equipment was returned to the financiers upon completion of the study.

Transport

An estimate of KSh.80 per day for ninety days transport expenses for the principal investigator was budgeted to ensure that the investigator and assistant investigators could access the study site under all possible weather conditions.

Stationery/Printing

This included cost of printing and photocopying of the questionnaires and printing and binding of at least four copies of the final dissertation. It also included the purchase of pens, a note book and a box file. The final presentation of the executive summary in a colorful poster has also been included.

Personnel

The study required at least one research assistant who assisted the principal investigator in data collection and data entry.

Communication

One thousand shillings in air time per month was budgeted to facilitate communication amongst the principal investigator, his supervisors, research assistant and research subjects.

Data Analysis

This provided for the professional fee for the medical statistician who was engaged to advise on study methodology and analyze the data.

Figure 11 Timeline

Event	Oct. 2011	Nov- Dec 2011	Jan 2012	Feb- June 2012	Jul- Oct 2012	Nov 2012- Jan 2013	Feb 2013	Mar 2013	Apr 2013
Research question									
Research proposal									
Faculty approval									
Ethical approval									
Data collection									
Data analysis									
Thesis writing									
Poster presentation									
Stakeholder Feedback									



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

KNH/UON-ERC
Email: uonknh_ere@uonbi.ac.ke
Website: www.uonbi.ac.ke
Link: www.uonbi.ac.ke/activities/KNHUoN



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

Ref: KNH-ERC/A/80

17th April 2012

Dr. John Kalama Fondo
Dept. of Paediatrics & Child Health
School of Medicine
University of Nairobi

Dear Dr. Fondo

RESEARCH PROPOSAL: "CLINICAL OUTCOMES OF CHILDREN AGED 6 TO 59 MONTHS WITH SEVERE ACUTE MALNUTRITION ADMITTED TO MBAGATHI DISTRICT HOSPITAL" (P54/02/2012)

This is to inform you that the KNH/UoN-Ethics & Research Committee (ERC) has reviewed and **approved** your above revised research proposal. The approval periods are 17th April 2012 to 16th April 2013.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN -ERC website www.uonbi.ac.ke/activities/KNHUoN



Yours sincerely

A. N. Guantai

PROF A.N. GUANTAI
SECRETARY, KNH/UON-ERC

- c.c. The Deputy Director CS, KNH
- The Principal, College of Health Sciences, UON
- The Dean, School of Medicine, UON
- The Chairman, Dept. of Paediatrics & Child Health, UON
- The HOD, Records, KNH

Supervisors: Prof. A.O. Wasunna, Dept. of Paediatrics & Child Health, UON
 Dr. Dalton Wamalwa, Dept. of Paediatrics & Child Health, UON
 Dr. Ahmed Laving, Dept. of Paediatrics & Child Health, UON

(Faint, mostly illegible text, likely bleed-through from the reverse side of the page)