OUTCOMES OF SEVERELY MALNOURISHED CHILDREN AGED 6 TO 60 MONTHS ON OUTPATIENT MANAGEMENT IN NAIROBI

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THESIS PREPARED IN PARTIAL FULFILMENT OF THE MMED PAEDIATRICS AND CHILD HEALTH PROGRAMME
THE UNIVERSITY OF NAIROBI, DECEMBER 2012
Declaration

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

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This dissertation is submitted to the University of Nairobi with our approval as supervisors.

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DEDICATION

I dedicate this work to my beloved husband, Wafula Nalwa and our wonderful children Baraka and Amani for their support, prayers, patience and love. God bless you.
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GLOSSARY/DEFINITION OF TERMS

Community based approach/ Community therapeutic centres/Outpatient therapeutic centres
(or program) - in this proposal refer to centres/health facilities used for the outpatient management of carefully selected children with severe malnutrition.

F 75/F100- these are milk-based rehabilitation feeds that are low protein/low calorie (F75-75kcal/100ml) content used in the initial inpatient rehabilitation of severely malnourished children. Once these children have improved their appetite, they are switched to F100, which is a higher protein and calorie content (100kcal/100ml).

RUTF-(Ready to Use Therapeutic food/feed) is a peanut-based spread (eg plumpynut) or biscuit-like food (BP-100) that has a similar nutritional composition to F100. It’s the mainstay of outpatient therapeutic program.

Sphere Standards: The Sphere project was launched in 1997 by a group of non-governmental organisations, Red Cross and Red Cresent Movement. It was set up to come up with a humanitarian charter, guidelines to be followed and minimum standards of response that needed to be achieved by humanitarian agencies in emergencies (41). The stipulated standards are >75% recovery rate, at least a mean weight gain of 8g/kg/d (reduced to 5g/kg/d for outpatient care by WHO), defaulter rate <15%, coverage rate of >50% rural, >70% urban, >90% camp situations.
Supplementary feeding programs- this is different from therapeutic feeding. Supplementary feeding programs mainly target MODERATELY malnourished children before they become severely malnourished. In addition to their regular diets, these children’s diets are supplemented by either enriched corn or soy-based flour. This proposal deals with severely malnourished children.
### LIST OF ABBREVIATIONS (alphabetically)

- **CFR**: case fatality rates
- **CTC**: community-based therapeutic care
- **HIV/AIDS**: Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
- **KDHS**: Kenya Health Demographic Survey
- **MOMS/MOPH**: Ministries of Medical Services/Public Health (Kenya)
- **MUAC**: mid-upper arm circumference
- **NGOs**: non-governmental organizations
- **NCHS**: National Centre for Health Statistics
- **OTP**: outpatient therapeutic programme
- **RCT**: Randomized Control Trial
- **SAM**: severe acute malnutrition
- **UNICEF**: United Nations Children’s Education Fund
- **WHO**: World Health Organisation
- **WHZ**: weight-for-height Z score
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• All the children and their parents/guardians who participated in this study.
ABSTRACT

BACKGROUND AND STUDY RATIONALE

Severe acute malnutrition remains an important underlying cause of morbidity and mortality for children under five years of age globally and locally. This study aims to evaluate the nutritional outcomes of the children on outpatient management, a concept who's adaption to the non-emergency settings has only been recently done.

METHODOLOGY

Objectives: The primary objectives of the study were to determine the mean weight gain (in g/kg/d), mean weight for height (WHZ scores) and mid-upper arm circumference (MUAC) over a 4 week period of severely malnourished children aged 6 to 60 months on outpatient management in Nairobi. Secondary objective was to determine the proportion of children being transferred to inpatient care; who died (mortality); who defaulted and who were discharged home as having been cured.

Study design: a prospective cohort study was carried out at Baraka Medical Clinic (Feeding Programme), Mathare valley in Nairobi between December 2009 and May 2010

Study procedures: A standardized questionnaire was used to collect data. Anthropometric measurements (weight, height, MUAC) and presence of oedema were taken at onset. The children were then started on RUTF, antibiotics, vitamin A as necessary and any other medicine they required. The children were followed up weekly but re-evaluation (clinical and
Anthropometrically) done after four weeks. The data was cleaned using Ms-Excel and analysed using SPSS 17.0. P-value of less than 0.05 was considered significant.

RESULTS: A total of 133 patients were enrolled into the study. The mean age of the study participants was 15.1 months (52.1% between 13-24 months), with 57.1% of them being female. The average weight gain was 3.7 g/kg/d. The mean increase in weight-for-height Z score and MUAC are 0.86 cm and 0.7 cm respectively after 4 weeks of treatment and follow-up. Average weight gain was significantly higher in children who were reported to have consumed the entire RUTF ration. There was an insignificant weight gain difference noted across different levels of education of the caregivers, illness of the child in the prior two weeks, and selected chronic illness (HIV/TB/Rickets).

The majority of patients were discharged from the OTP programme and were thereafter managed as moderately malnourished (57.5%) after four weeks of follow up and treatment. The mortality, transfer inpatient and default rates were 1.6%, 0.8% and 6.5% respectively.

CONCLUSIONS: The mean weight gain, mean increases in height, MUAC and WHZ score were statistically significant. The majority of children were discharged from the OTP programme during the period of follow up (58%). The mortality and default rates met the stipulated Sphere standards for management of severely malnourished children on an outpatient basis.
1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 DEFINITION AND EPIDEMIOLOGY

Severe acute malnutrition remains an important cause of mortality of children under five years of age. It is defined by severe wasting (weight for-height below -3 z-scores or < 70% of the median National Centre for Health Statistics/World Health Organization [NCHS/WHO] reference) with or without oedema, and is a life-threatening condition requiring urgent treatment. [1,2]

Globally, it is estimated that there are nearly 10 million children who are severely acutely malnourished most of whom live in south Asia and in sub-Saharan Africa. [1,2].

Malnutrition, severe or otherwise, is estimated to be a contributing factor in over 50% of the 10-11 million children who die due to preventable causes [3,4]. These children have a limited immunological capacity to respond to infection and environmental stresses and hence die directly due to malnutrition or indirectly due to childhood illnesses such as diarrhoea and pneumonia [5,6]. This is evidenced by their mortality rates being 5-20 times higher than well nourished children. In addition, it is estimated that if malnutrition was eliminated, childhood mortality and morbidity would be reduced by at least one-third [4, 5, 7].

According to the Kenya Health Demographic Survey (KDHS) 2008-2009 report [8] the degree of wasting (weight-for-height) has not changed significantly since the year 2000. Overall, sixteen percent (16%) of children are underweight (low weight for age), with 4% being severely underweight. Underweight is a reflection of both acute and chronic malnutrition. Wasting is defined as weight for height falling below -2 SD and is a sign of severe malnutrition. In the survey, 7% of the
children are wasted, 2% being severely wasted. Wasting is a reflection of recent failure to receive adequate nutrition or recent illness.

1.2 FACTORS ASSOCIATED WITH MALNUTRITION

There are various factors that are associated with malnutrition, either positively or negatively. According to various studies done in Rural China, Zimbabwe and Uganda factors that were studied and found to affect children’s nutrition included: level of education of the mother, duration of exclusive breastfeeding, family income and socioeconomic status, birth weight, household size and child spacing, water and sanitation and rural versus urban residence. In these studies, the factors were statistically regressed against three anthropometric measurements for malnutrition: height for age (stunting), weight for age (underweight) and weight for height (wasting). It was found that children had a greater risk of malnutrition if the following factors were present: mother had a lower level of education; the child had a shorter duration of exclusive breastfeeding; the family had lower socioeconomic standards; there was poorer water supply and the family resided in a rural area [9,10]. Engebretsen IM et al [11] found that the following factors were associated with poor growth among Ugandan infants: suboptimal feeding practices after birth that is, replacement or mixed feeding (OR 2.7, 95% CI 1.0-7.1), lowest household wealth (OR 3.5, 95% CI 1.6-7.8), gender (stunting in male versus female was 58.7% versus 41.3%), family size and age.

These findings were similar to what Mahgoub S.E.O et al reported in Botswana [12].

In addition to the afore mentioned factors, other findings from the Nutritional Collaborative Research Support Program (CRSP) in Kenya, Mexico and Egypt have demonstrated that the aetiology
of stunting has its roots in pre-pregnancy and pregnancy state and in the nutrition of the mother [13]. Other factors that are associated with malnutrition in a child include chronic illness for example HIV/AIDS, Tuberculosis, and other chronic organic diseases [14,15].

### 1.3 MANAGEMENT GUIDELINES FOR SEVERE ACUTE MALNUTRITION

Until recently, it was the guideline of World Health Organisation (WHO) to admit all children with severe malnutrition for inpatient management for a period of at least one month. This inpatient management was based on intensive medical and nutritional protocols administered by highly trained health care professionals in two phases (stabilization and rehabilitation) [16]. These protocols have been shown to be most successful when sufficient skilled staff in addition to other resources is readily available. In selected units in Bangladesh, South Africa and Brazil [17-22] use of these protocols combined with attention to the quality of care has been associated with dramatic decrease in case fatality rates (CFRs). The same is true when the protocols are implemented by well resourced non-governmental organizations (NGOs) during emergency humanitarian interventions.

However, the implementation of these protocols in selected units in most hospitals in the developing world has not led to a significant decrease in CFRs since the 1950’s. To date, CFRs in the vast majority of health facilities in developing countries remain at 20–30% for marasmus and up to 50–60% for kwashiorkor. The persistence of such high mortality rates among the children admitted could be attributed to the shortage of trained staff for implementation of these guidelines, problems in accessing the health facilities, late detection and referral (which increase mortality shortly after admission) and increased risk of nosocomial infections [23-26]. In addition, hospital stays of several weeks for a child and mother are disruptive for families, especially when the mother
has other children at home or when her labour is essential for the economic survival of the household. As a result, hospital-based management of severe malnutrition was perceived as efficacious, but not effective, on a large scale, either as part of routine health services or in emergencies [27-28]. Therefore, during the past 5 years, an increasing number of countries and international relief agencies have adopted a combination of community-based model for the management of acute malnutrition, called community-based therapeutic care (CTC) and inpatient management (for those with medical complications) [29-30]. The community based or outpatient therapeutic management consists of: Measures to mobilize the community in order to encourage early presentation and compliance; Outpatient supplementary feeding protocols for those with moderate acute malnutrition and no serious medical complications; and Outpatient therapeutic protocols for those with severe acute malnutrition and no serious medical complications.

1.4 RESEARCH FINDINGS COMPARING IN AND OUTPATIENT MANAGEMENT OF SAM

Studies have been done to compare the standard inpatient care of children with severe malnutrition with use of ready-to-use therapeutic foods (home-made or commercial).

In a controlled, clinical effectiveness trial done in Malawi by Ciliberto [37], the impact of home-based therapy with ready-to-use therapeutic food was compared with standard therapy in the treatment of 1178 malnourished Malawian children.

The first phase involved giving liquid F75 and parenteral antibiotics to those who were ill. When the children's clinical conditions and appetites improved, the children received the second phase of
treatment, which consists primarily of the feeding of a specially formulated, high-energy, high-protein (100 kcal/100 mL, 2.9 g protein/100 mL) milk-based liquid food (F-100). At home, a flour supplement composed of cereal and legumes is substituted for the milk-based food.

It was found that the children who received home-based therapy with RUTF were more likely to achieve a weight-for-height z score > -2 than were those who received standard therapy (79% compared with 46%; P < 0.001) and were less likely to relapse or die (8.7% compared with 16.7%; P < 0.001). The children who received home-based therapy with RUTF achieved greater rates of weight gain (3.5 compared with 2.0 g/kg/d; difference: 1.5; 95% CI: 1.0, 2.0 g/kg/d) and a lower prevalence of fever, cough, and diarrhoea than did children who received standard therapy (secondary outcomes).

In addition, the outpatient care of the children provided greater satisfaction to the mothers and caregivers. This is more so because there was reduced hospital stay and hence the mothers and caregivers would be available to take care of the other family members and to continue with their income-generating activities or farming.

Even with appropriate guidelines for inpatient management and trained health care workers, inpatient management of severely malnourished children is still not adequate. This is illustrated locally by Nzioki CM (46) who carried out an audit of care of severely malnourished children on inpatient management in KNH. It was found that the quality of care of the children admitted in KNH was below the WHO guidelines.

Additional studies have been done to assess the effectiveness of outpatient therapeutic management (and use of RUTF) of children with severe acute malnutrition are summarised in table
1. Three RCT’s reported weight gains of between 2.0-5.2g/kg/d after an average of 4 weeks of follow up. Two of the RCT’s reported average weight gains of 7.5-13g/kg/d across various groups.

**Table 1: Summary of selected studies on community-based management of malnutrition at home, with or without provision of food. (28,31,45)**

<table>
<thead>
<tr>
<th>Author(s), country and year</th>
<th>Study type</th>
<th>Food</th>
<th>Criteria for admission and age groups</th>
<th>Outcome</th>
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<tr>
<td>Verkley and Jauren (Kenya, 1983,1986) (32,33)</td>
<td>O</td>
<td>Maize, milk and oil premix</td>
<td>≤ 65% Wt/age Mean W/H 80% Sample size 32</td>
<td>1g/kg/d after 6 months</td>
</tr>
<tr>
<td>Ahmed et al (Bangladesh 2002) (34)</td>
<td>RCT</td>
<td>75 inpatient; 75 home visits, 75 clinic visits after discharge; RUTF</td>
<td>6-60 months &lt; -3SD WHZ and/or oedema Sample size 225</td>
<td>Follow up till W/H &gt; 80% weight gain of between 7.5 and 11.9 g/kg/d for the 3 groups</td>
</tr>
<tr>
<td>Diop et al (Senegal, 2004) (35)</td>
<td>RCT</td>
<td>Local vs imported RUTF</td>
<td>6-60 months &lt; -3SD WHZ or oedema Sample size 47</td>
<td>Follow up until W/H was 85%; weight gain range 7.9-8.1 g/kg/d (no significant difference)</td>
</tr>
<tr>
<td>Sandige et al (Malawi 2004) (36)</td>
<td>RCT-S</td>
<td>Local vs imported RUTF</td>
<td>12-60 months; &lt; -2SD or oedema; Sample size 260</td>
<td>After 4 wks: a) 5.2g/kg/d b) 4.8g/kg/d</td>
</tr>
<tr>
<td>Gliberto et al (Malawi 2005) (37)</td>
<td>Non RCT</td>
<td>CSB+MMX and RUTF</td>
<td>10-60 months; &lt; -2SD WHZ or oedema Sample size 1,178</td>
<td>At 4 weeks mean weight gain was 2.0 and 3.5 g/kg/d respectively</td>
</tr>
<tr>
<td>Navarro-Colorado and McKenney (Sierra Leone 2003) (38)</td>
<td>RCT</td>
<td>50 inpatients 40 RUTF at home</td>
<td>12-60 months; W/H &lt; 70% Sample size 95</td>
<td>Weight gain at average of 33 days was 13.4 and 11.9g/kg/d respectively</td>
</tr>
<tr>
<td>Gaboulaud (Niger 2004) (39)</td>
<td>O</td>
<td>794 inpatient; 354 RUTF at home; 1061 mixed</td>
<td>6 - 59 months; WHZ &lt; -3SD or oedema or MUAC &lt;11cm; Sample size 2,209</td>
<td>Weight gain for those on outpatient (354) was 9.8 g/kg/d at average 29 days</td>
</tr>
<tr>
<td>Collins et al (Ethiopia 2001) (40)</td>
<td>Retrospective cohort</td>
<td></td>
<td>170 children; 6-120 months</td>
<td>Median weight gain was 3.16 g/kg/d</td>
</tr>
</tbody>
</table>

RCT(S) - randomized control study (systematic allocation); O-observational study; WHZ-weight for height Z score; W/H or A-weight for height or age; CSB-corn-soy blend; MMX-multimineral mix
The Sphere project set up minimum standards of response that needed to be achieved by humanitarian agencies in emergencies (41). These set standards are one of the bases used in evaluating humanitarian projects.

In a community based therapeutic programme in Dowa district in Malawi between June 2003 and March 2005 over 3000 children were followed up. Recovery, mortality, defaulter, transferred and non-recovered rates were 80.8%, 1.9%, 14.4%, 2.7% and 0.1% respectively [29]. These met the Sphere standards of recovery and defaulter rates.

Case fatality rates among more than 23,000 severely malnourished children on community based treatment in Malawi, Ethiopia and Sudan [29-31] between 2001 and 2005 were 4.1%, recovery rates of 79.4% and default rates of 11%. These also surpassed the set Sphere standards. These indicate that these programmes are effective.

In Kenya, data on OTP from the Division of Nutrition (MOMS/MOPHS, Kenya) records recovery, death and defaulter rates of 82.8%, 0.3% and 8.6% respectively for the OTP in the country (47). These outcomes meet the Sphere standards. The average length of stay of the patients, though, was relatively long (289.6 days).

In view of the emerging evidence, World Health Organisation (WHO), in a consultative meeting [31], reviewed the evidence and recommended use of outpatient therapeutic management for selected severely malnourished children not only in the emergency setting, but also in the routine health care services.
2.0 JUSTIFICATION AND UTILITY OF STUDY

Severe malnutrition remains a major underlying cause of childhood mortality and morbidity in the world and locally. It is largely an unseen problem and yet it claims the lives of many children. In emergency situations, use of the community based approach to manage severe malnutrition has been found to be effective. Potential advantages to use of this approach compared to a wholly inpatient management are multiple. They include availability of the caregiver to the other siblings at home in addition to continuing his/her economic activities; reduced cost to the healthcare worker and system in caring for these children; possible increased health education to the caregiver on how to prevent malnutrition; and increased active case finding in the community of children with severe malnutrition to help get cases early.

Though the community-based approach has been used in the management of children with severe malnutrition in emergency settings in Kenya, it has only been recently expanded to the non-emergency setting. However, to our knowledge there is no published data as to how the program is impacting the health of the severely malnourished children being managed as an outpatient basis in Nairobi, Kenya. Data collected at the national level is based on programmatic outcomes (coverage, cure, default, transfer rates etc) and not on anthropometric measurement changes of the children on follow up. Though the former information is useful on a programmatic level, additional information gathered from this study may be useful in helping to improve and optimize the care of these children in the existing programs in the country. This study gives baseline local data on the nutritional outcomes (anthropometric measures) observed in these children on the outpatient therapeutic programme and perhaps generates other ideas for further research in the field in the future.
3.0 OBJECTIVES

3.1 BROAD OBJECTIVE

To assess the nutritional outcomes of severely malnourished children aged 6 to 60 months on outpatient management in Nairobi over a 4 week period

3.2 SPECIFIC OBJECTIVES

Primary objectives

1. To determine the mean weight gain (in g/kg/d) over a 4 week period of severely malnourished children aged 6 to 60 months on outpatient management in Nairobi

2. To define the mean increase in weight-for-height (WHZ) and Mid-upper arm circumference (MUAC) of over a 4 week period in severely malnourished children aged 6 to 60 months on outpatient management in Nairobi

Secondary objective

To determine the proportion of children being transferred to inpatient care, who die (mortality); who default and who are discharged home as having been cured.
4.0 METHODOLOGY

4.1 Study design: Prospective cohort study

4.2 Study site: Baraka Medical Clinic therapeutic and feeding centre is a faith-based organisation clinic situated in Mathare valley, Nairobi. It is sponsored/run by German Doctors in conjunction with local staff, who are trained and well versed with the Kenyan guidelines on outpatient management of severe malnutrition. The clinic has been running for twelve years but the therapeutic centre has been doing so for two years. The clinic runs daily. The children are identified by community health workers, are referred by other health facilities nearby or by members of the community itself. The children who have complications are referred to Mbagathi District Hospital or Kenyatta National Hospital.

4.3 Study population: children aged 6-60 months who are severely malnourished and meet the criteria for management on an outpatient basis.

4.4 Case definition: children 6-60 months with WHZ below -3 SD (using the WHO growth standards) and/or bilateral oedema, or MUAC <115mm; who have no medical complications and have passed the appetite test (refer to Annex I).

4.5 Inclusion criteria: those who meet case definition as mentioned afore and those children whose parents/guardians give consent.

4.6 Exclusion criteria: children with other chronic organic conditions that may predispose to severe malnutrition eg cerebral palsy, chronic heart or renal disease, malignancy etc

4.7 Study period: the study was carried out from December 2010 to May 2011
4.8 Study procedures

Figure 1: Study Flow diagram

- HEIGHT/LENGTH Z SCORE <-3
  - and/or
  - MUAC <115mm and/or
  - Nutritional oedema
  - No medical complications
  - Pass Appetite test

Clinical evaluation at 4 weeks:
- Medical complications
- Weight/height/MUAC/
  - Oedema
- Appetite test

Outcomes of 125 patients analysed as follows:
- Discharged from OTP
- Still on OTP
- Died
- Transferred to inpatient

N=133

✓ RUTF
✓ Antibiotics (amoxicillin 94%, other 6%)
✓ Other medicine (paracetamol, ORS, Zinc Sulphate)

(-) DEFAULTED
4.9 Sample size: sample size determination was done based on the formula for determining a single mean, a key objective in this study.

Using formula for calculating mean:

\[ N = \frac{Z^2 \sigma^2}{e^2} \]

Z=95% confidence interval=1.96

\( \sigma \)-standard deviation of population mean (Concern Worldwide, S. Wollo Ethiopia) mean, 4.3g/kg/d, SD 2.44

\( e \)-standard error, dependent on how accurate the results are desired, in this case +/- 0.42 g/kg/d

Minimum number \( n = 130 \)

4.10 Sampling technique: Entry into the study was by consecutive sampling

4.11 Outcomes measured after one month:

Primary outcomes: weight gain/loss (in g/kg/d); change in wt for ht index/measurement; change in mid upper arm circumference (MUAC); presence or absence of oedema

Secondary outcomes included: transfer rates to inpatient or otherwise, death while on the programme, discharge from the outpatient therapeutic programme and default rates

4.12 Screening and recruitment

The principal investigator/assistant screened patients daily in the clinic once they are determined to have met the eligibility criteria; got informed written consent and were enrolled into the study. Thereafter a questionnaire was completed (to get information on demographics, care giver
characteristics, medical and diet history) and a clinical evaluation was performed (annex III). This included anthropometric measurements (weight, height, mid upper arm circumference) and presence of oedema as required.

Weight was taken on a calibrated digital scale with minimal clothes and without shoes. It was repeated three times and an average taken and rounded to the nearest 100g. The weighing scale used was recalibrated to zero before each weighing. (ref annex II).

Height/length was taken using a measuring board with the feet flat on the bottom surface, with no shoes and the heels, shoulders, buttocks and head parallel to the length of the board. The child was held firmly but gently in this position with the help of an assistant, in most cases the caretaker. This was done thrice and an average rounded to the nearest 0.1cm done. Height was taken for the child more than 87 cm and length for the child less than 87 cm. A child greater than 87cm is generally expected to be standing with/without support and hence was able to be supported to stand on the height board (32). (ref annex II).

Mid upper arm circumference (MUAC) was taken at the midpoint between the tip of the shoulder and the elbow of the left arm. Any clothing was removed. Using a MUAC tape in the correct position, not too loose or too tight, the reading was made to the nearest 0.1 cm. (ref annex II).

Weight for height/length indices was compounded using the WHO growth charts (2006) to get the Z scores.

The presence or absence of oedema was determined by pressing the feet and/or hands of the patient with the thumbs for 5 seconds and releasing after which the foot and/or hand was observed and felt for any indentation. If present, the extent was determined by checking for oedema in the
legs/hands as well. Oedema was graded as mild, moderate or severe if it involved the hands/feet; up to elbows/knees and if above that (or generalised) respectively.

Appetite test was conducted by following the steps highlighted in Annex I and amount of RUTF given to the child was dependent on their weight. They passed the appetite test if they consumed the minimal amount required for their weight (Refer to Annex I).

The caregiver was then given RUTF (amount depending on weight) and any other medication indicated (eg paracetamol for fever, Oral Rehydration Solution (ORS) and zinc sulphate for diarrhoea). The routine medications given were antibiotics and vitamin A. The ratio of RUTF given is based on the intake requirement of between 150-200kcal/kg/day. RUTF provides about 530kcal per 100gm. Key information that the caregiver needed to know while taking care of the child and in the use of RUTF was given by the nurse or trained community health worker at site (Refer to Annex I). Any other questions and concerns that the caregiver had were addressed.

Though a follow-up visit was done at 4 weeks from the recruitment date, the children were seen at the clinic every week by the nurse at the clinic to assess their progress (weight, appetite) and to check for any complications. At the fourth week information on how the child had consumed the RUTF was taken. This was done by self-report by the caregiver based on the number of RUTF packets that remained at home. The child was determined to have had good consumption of RUTF if they reported that they did not have any sachets of RUTF at home. The child was examined for any complications or signs of illness (anaemia, dehydration, respiratory distress, fever, state of consciousness) and height, weight and mid-upper arm circumference was measured and recorded. Presence or absence of oedema was determined.
4.13 Data Management

Data collection was done using standardized questionnaires and anthropometric measurements.

Analysis of the data was done by use of SPSS version 17.0.

Descriptive statistics was used to summarise continuous data such as age, duration of illness-into frequencies, means, median, standard deviations (SD) and percentages.

A p-valued of less than or equal to 0.05 was defined as statistically significant in reference to mean weight, height, weight for height Z-score and MUAC. This was done by using the single t-test. In addition, comparison of anthropometric values at onset and after 4 weeks of follow up was done using a paired t-test.

Weight gain was computed in grams/kg/day. In addition, mean increases in weight-for-height indices and mid upper arm circumference was computed. Presence or absence of oedema was determined. Reference was made to WHO tables (2006) when determining the weight for height/length Z scores.

Outcomes of the patients at the end of four weeks was assessed by determining weight for height/length Z score, deaths, defaults or transfers to inpatient care after four weeks of treatment and follow up.
5.0 ETHICAL CONSIDERATIONS

Approval was sought from the Department of Paediatrics and Child Health, University of Nairobi, the Ethics Committee of the Kenyatta National Hospital (Annex V) and from the Baraka Medical Clinic Administration.

Written, informed consent and/or use of thumb print was obtained from the caregiver of each child enrolled into the study. Each care giver was counselled on the need of good nutrition for the child and complying with the advice/treatment given at the clinic. Any questions regarding the nutritional status and health of the child were addressed.

Feedback on results was given to the Baraka Medical Clinic administration with appropriate recommendations. As far as was practicable based on study findings, guidance on therapeutic strategies was offered to the patient in conjunction with the paediatrician/nutritionist during study period.
6.0 RESULTS

6.1 DEMOGRAPHIC CHARACTERISTICS

The following table 2 summarises selected demographic characteristics of the sample population studied. There were slightly more females (57.1%) in the study population, with 52.1% of the study population being between 13-24 months of age. The majority of patients were first-borns (50.2%).

Table 2: Age, Gender and Birth order of the patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in months</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>15.1 (9.5)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>12.0 (8.0-18.0)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>57 (42.9)</td>
</tr>
<tr>
<td>Female</td>
<td>76 (57.1)</td>
</tr>
<tr>
<td><strong>Distribution of age groups</strong></td>
<td></td>
</tr>
<tr>
<td>6-12 months</td>
<td>67 (50.4)</td>
</tr>
<tr>
<td>13-24 months</td>
<td>56 (42.1)</td>
</tr>
<tr>
<td>25-60 months</td>
<td>10 (7.5)</td>
</tr>
<tr>
<td><strong>Birth order</strong></td>
<td></td>
</tr>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt;</td>
<td>67 (50.4)</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt;</td>
<td>47 (35.3)</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt;</td>
<td>9 (6.8)</td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
<td>4 (3.0)</td>
</tr>
<tr>
<td>5&lt;sup&gt;th&lt;/sup&gt;</td>
<td>5 (3.8)</td>
</tr>
<tr>
<td>8&lt;sup&gt;th&lt;/sup&gt;</td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>
6.3 SOCIOECONOMIC CHARACTERISTICS

The following table 3 summarises aspects of socioeconomic characteristics of the caregivers. Ninety-five percent (95%) of the caregivers who brought the child to the clinic was the mother. In addition, in majority of the caregivers, the mother was reported to be the one who primarily fed the child. Sixty percent of them did not have formal employment and the father was reported as being the main income generator in 67% of the time. It is also evident that more than 50% of the patients lived in premises with permanent walling, with 83.9% with access to toilet and 79% of them purchased water for their use in jelly cans.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
</tr>
<tr>
<td>Not employed</td>
<td>91 (60.1)</td>
</tr>
<tr>
<td>Casual employment</td>
<td>51 (35.7)</td>
</tr>
<tr>
<td>Regular employment</td>
<td>6 (4.2)</td>
</tr>
<tr>
<td><strong>Income generator</strong></td>
<td></td>
</tr>
<tr>
<td>Father</td>
<td>88 (66.1)</td>
</tr>
<tr>
<td>Mother</td>
<td>16 (12.1)</td>
</tr>
<tr>
<td>Others</td>
<td>29 (21.8)</td>
</tr>
<tr>
<td>Mean monthly income (SD)</td>
<td>5398.3 (2693.5)</td>
</tr>
<tr>
<td><strong>Wall materials</strong></td>
<td></td>
</tr>
<tr>
<td>Permanent (brick/wall)</td>
<td>69 (52.4)</td>
</tr>
<tr>
<td>Semi permanent (iron sheets)</td>
<td>57 (42.0)</td>
</tr>
<tr>
<td>Not permanent (mud)</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td>Mean number of rooms (SD)</td>
<td>1.1 (0.3)</td>
</tr>
<tr>
<td><strong>Toilet Access</strong></td>
<td></td>
</tr>
<tr>
<td>Toilet</td>
<td>112 (83.9)</td>
</tr>
<tr>
<td>Pit latrine</td>
<td>21 (16.1)</td>
</tr>
<tr>
<td><strong>Water source</strong></td>
<td></td>
</tr>
<tr>
<td>Community piped (purchased)</td>
<td>105 (79.0)</td>
</tr>
<tr>
<td>Piped water to house</td>
<td>17 (12.6)</td>
</tr>
<tr>
<td>Borehole</td>
<td>11 (8.4)</td>
</tr>
</tbody>
</table>
The greatest percentage of care givers had achieved some level of primary school education (72.7%) with the distribution of the rest as illustrated in figure 2 below.

Figure 2: Level of education of primary care giver

6.4 MEDICAL HISTORY OF THE PATIENTS

Twenty one (17.5%) of the patients had been admitted once time for acute illness during their lifetime. In the previous two weeks prior to admission to the outpatient therapeutic programme, the children had various illnesses: cough (36%), diarrhoea (29%), fever (18%), vomiting and reported poor appetite (17%).

The following table 4 summarises aspects of medical history. Ninety-nine percent of the children received BCG vaccination at birth or shortly after. Approximately seventy percent of the children were fully immunised. Less than fifty percent (46.5%) of the children aged 6 to 24 months are currently breastfeeding. In addition 13.5% and 9.7% of the children were HIV positive and were being managed for tuberculosis respectively.
Table 4: Immunisation Coverage and breastfeeding history of the study participants

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>FREQUENCY (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccination</strong></td>
<td></td>
</tr>
<tr>
<td>BCG</td>
<td>132 (99.3)</td>
</tr>
<tr>
<td>OPV 1,2,3</td>
<td>130 (97.9)</td>
</tr>
<tr>
<td>Pentavalent 1,2,3</td>
<td>127 (95.4)</td>
</tr>
<tr>
<td>Pneumococcal vaccines</td>
<td>56 (83.5 % of those eligible)</td>
</tr>
<tr>
<td>Children fully immunised</td>
<td>93 (69.9)</td>
</tr>
<tr>
<td><strong>Breastfeeding history</strong></td>
<td></td>
</tr>
<tr>
<td>Exclusive breastfeeding for &lt; 6 months</td>
<td>92 (69.2)</td>
</tr>
<tr>
<td>None/information missing</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Those 6 months to 24 months of age still breastfeeding</td>
<td>54 (46.5)</td>
</tr>
</tbody>
</table>
6.5 ANTHROPOMETRIC MEASUREMENTS

The following table 5 illustrates the anthropometric measurements at baseline and at the end of 4 weeks of assessment and that these differences (in mean weight, weight-for-height, MUAC) are statistically significant.

Table 5: Comparison of anthropometric measures as baseline and after 4 weeks of follow up

<table>
<thead>
<tr>
<th>ANTHROPOMETRIC MEASURES</th>
<th>AT BASELINE (N=133)</th>
<th>AFTER 4 WEEKS (N=122)</th>
<th>Mean increase (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean weight in kg (SD)</td>
<td>6.4 (1.4)</td>
<td>7.1 (1.6)</td>
<td>0.68 (0.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean height in cm (SD)</td>
<td>69.2 (7.4)</td>
<td>70.5 (7.1)</td>
<td>0.84 (1.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean MUAC in cm (SD)</td>
<td>11.1 (1.1)</td>
<td>11.8 (1.1)</td>
<td>0.7 (0.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Oedema</td>
<td>12</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Weight for Height Z</td>
<td>-2.9 (1.1)</td>
<td>-2.0 (1.2)</td>
<td>0.86 (0.9)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The mean weight gain was 3.7 g/kg/d.

The majority of the patients [n=70 (57.5%)] of the children on follow up were discharged from the outpatient therapeutic programme (OTP) after 4 weeks of treatment. These are children who had WHZ >/= -3, and/or MUAC >/=11.5cm and had no oedema. They were discharged to the supplementary food programme (SFP) in which they are managed as moderately malnourished children. Other children indicated in the bar graph refer to those still in the OTP [n=52(33.6%)]. The outcome of the other patients after 4 weeks of follow up is illustrated in the following bar graph (fig 5).
Although HIV positive children were included in the study, weight gain stratified by HIV status (Table 6) shows no statistically significant difference between the two.

<table>
<thead>
<tr>
<th>Table 6: Weight gain stratified by HIV status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV NEGATIVE</strong></td>
</tr>
<tr>
<td>N=115 (86.5%)</td>
</tr>
<tr>
<td><strong>Average Weight gain</strong></td>
</tr>
<tr>
<td>(g/d)</td>
</tr>
</tbody>
</table>

There was a greater weight gain in the children who were reported by the caregivers at the fourth week visit to have consumed all the RUTF given compared to those who did not. This difference was statistically significant as illustrated in table 7.
The following table 8 illustrates that though there was greater average weight gain in those who had no fever, no diarrhoea, no oedema and no cough in the preceding two weeks prior to enrolment into OTP, these differences were not statistically significant. In addition, there was no significant difference in average weight gain across the different levels of education of the care givers.
Table 8: Comparative weight gain between children with selected clinical features (fever, diarrhoea, cough and oedema) and level of education of care giver

<table>
<thead>
<tr>
<th>Variable</th>
<th>Average weight gain Mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;37.5</td>
<td>23.2 (11.9)</td>
<td>0.667</td>
</tr>
<tr>
<td>&lt;=37.5</td>
<td>25.5 (19.3)</td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>21.5 (15.4)</td>
<td>0.140</td>
</tr>
<tr>
<td>No</td>
<td>27.1 (19.7)</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>23.9 (20.0)</td>
<td>0.456</td>
</tr>
<tr>
<td>No</td>
<td>26.5 (17.8)</td>
<td></td>
</tr>
<tr>
<td>Oedema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32.7 (17.7)</td>
<td>0.141</td>
</tr>
<tr>
<td>None</td>
<td>24.4 (18.5)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With education</td>
<td>25.2 (18.7)</td>
<td>0.982</td>
</tr>
<tr>
<td>No education</td>
<td>25.0 (12.4)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>25.0 (25.2)</td>
<td>0.473</td>
</tr>
<tr>
<td>Primary</td>
<td>23.7 (41.7)</td>
<td></td>
</tr>
<tr>
<td>Secondary</td>
<td>12.4 (18.3)</td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>18.2 (34.3)</td>
<td></td>
</tr>
</tbody>
</table>
7.0 DISCUSSION

The key findings of this study were that the average increase in weight, weight-for-height and MUAC was 3.7g/kg/d, 0.86cm and 0.7cm respectively over a four week period of outpatient treatment. This indicates a positive impact on the nutritional status of the children.

This weight gain is lower than the stipulated WHO standard (at least 5g/kg/d), (31,42), however studies in this region have found comparable findings.

Studies that reported similar weight gains compared to this study include the following. In Malawi, Sandige et al (36) reported weight gains of 5.2g/kg/d and 4.8g/kg/d in children on RUTF (local and commercial respectively) after 4 weeks of treatment. In addition, there was a reported mean increase in WHZ score of 0.9. Collins et al (40) reported a median weight gain of 3.2g/kg/d. In addition, Ciliberto et al (37) reported similar findings of weight gain of 3.5g/kg/d for children on RUTF after 4 weeks of follow up. In these studies, much of the RUTF ration was thought to have been shared and in Malawi fever was associated with the lower weight gain (28). Although it is possible that the sharing of RUTF ration may have contributed to the less than optimum overall weight gain, we did not formally evaluate this. Rationing of the RUTF was still thought to occur in some cases, considering that at least 50% of the children had other siblings and that caregivers were not given any additional food for the rest of the family.

Other studies have found much higher weight gains than we reported. Navarro-Colorado and McKenney (38) in a randomised control trial reported weight gains (11.9g/kg/d) for those on outpatient follow up comparable to inpatients (13.4g/kg/d). They followed up patients from 12 months of age and with no oedema. These findings are similar to what Gaboulaud et al. (39) in Sierra Leone reported weight gains of 9.8g/kg/d for those children on RUTF. In these studies, the
children were followed up until they were cured (average 30-40 days) after initial stabilization in inpatient facilities.

In our study the patients were followed up for a relatively shorter period and were reviewed at four weeks whether cured or not. Navarro-Colorado and McKenney attributed the higher weight gain they reported in their study to careful training of the caregivers before they went home and effective stabilisation at the inpatient centres (19). In our study we did not significantly influence the implementation of the programme at the clinic. This may have contributed to the relatively lower weight gain.

In this study, children who had fever, diarrhoea or cough in the preceding two weeks prior to enrolment into the OTP had a lower mean weight gain; however this difference was not statistically significant. These illnesses are the factors that may have prompted to care givers to bring them to the health facilities and in turn, the severe malnutrition detected. However, data on additional illness during the period of study was not collected and these would have been thought to affect consumption of the RUTF.

The caregivers gave a self-report of the number of RUTF packets that remained at home, though the ideal would have been for them to bring back the empty packets. However it was demonstrated that children who were reported to have consumed all the RUTF ration had a significantly greater average weight gain compared to those who reported to have had less than optimum intake. These findings validate the self report,
This study included twelve children with oedema at onset. The difference in mean weight gain between those who had oedema and those who did not was not statistically significant. However, the initial weight loss associated with successful treatment was not taken into account and may have contributed to the relatively overall lower weight gains reported. In addition it should be taken into consideration that this subset of patients was small and the study may not have been effectively powered to detect this difference.

In addition, this study used the new WHO standards (2006) compared to studies that were published earlier. Using weight-for-height based on the WHO standards or MUAC less than 115 mm as admission criteria selects younger and less severely wasted beneficiaries compared to using the NCHS reference for weight for height or MUAC less than 110 mm (criteria that were used in many of the older studies). Greater weight gains are usually demonstrated in more severely wasted children and as they approach the median weight-for-height, the weight gain drops to average of 1.2g/kg/d (19). These children selected by the new criteria will have a lower risk of death, and a lower weight gain (43,44). Hence the lower case fatality rates and slower weight gains of children selected by the new WHO standards should be taken into account when monitoring the effectiveness of therapeutic feeding programmes.

More than half of the children (58%) discharged from the outpatient therapeutic program and managed as moderately malnourished children after one month of follow up. Though this study was not powered to look at cure rates, it can be expected that the children on average take 2 months in the programme to cure. The defaulter and mortality rates were lower than the stipulated Sphere standards (6.5 vs <10% and 1.6 vs <15% respectively)(41,44). These findings are similar to the data recorded in the Division of Nutrition in Kenya (47).
The findings of this study are comparable to findings reported in other studies that were looking at cure rates. For example, in South Wollo, Ethiopia 66% of the children were discharged as cured from the programme between January 2003-2004. The average length of stay was 81 days (30). In Dowa district (Malawi) a study over 2 years reported recovery, death, defaulter and transfer rates of children on OTP as 81%, 2%, 14% and 3% respectively. Similar findings were reported by Collins et al (40) with recovery, mortality, transfer and default rates of noteworthy that these studies were mainly done in children being treated as outpatients in emergency (humanitarian crisis) settings.

This study has demonstrated that outpatient management of severely malnourished children on RUTF increases the weight, height and mid upper arm circumference of the children significantly. It also shows that the programme is effective and feasible in a routine health care setting as it has shown similar mortality, default and transfer rates to those studies done in primarily emergency settings. The low default rates means that the programme is acceptable to the caregivers.

This study has also provided valuable baseline data on the impact of the outpatient therapeutic programme on management of severe acute malnutrition in our setting.

**Study strengths**

1. Objective biological measures including weight, height, and MUAC taken serially by ministry of health-trained personnel.

2. Lack of interference by the investigator thus allowing the standard clinic practice to proceed.
Study limitations

1. It was difficult to verify with certainty the amount of RUTF that the child consumed as that information was collected using self-report by the caregivers.

2. Due to the relatively short period of study it was not possible to follow up the children and evaluate how many relapsed, and hence the long term outcomes of these children.

3. Acceptability of the RUTF to the children was not ascertained before its introduction to the children. In addition record of any current illness during the period of follow up was not done and these may have had impact on weight gain recorded.

CONCLUSIONS

1. The mean weight gain in severely malnourished children on outpatient management in Nairobi was 3.7 g/kg/d. The mean increase in height, MUAC and WHZ score were 0.84cm, 0.7cm and 0.86 respectively.

2. The average weight gain was greater in children who were reported to have consumed the entire RUTF ration.

3. The majority of children (58%) were discharged from the OTP programme by four weeks of treatment and follow up. These children were then managed as moderately malnourished.

4. The mortality (6.5%) and default rates (1.5%) met the stipulated Sphere standards for management of severely malnourished children on an outpatient basis.
RECOMMENDATIONS

1. The outpatient therapeutic programme is having a positive impact on the management of children with severe malnutrition. Therefore, more OTP centres need to be set up to help manage SAM. However further studies are required to specifically look at the reasons why the weight gain is less than the WHO recommended rate. (3.5 vs 5g/kg/d).

2. Further studies looking at effect of illness during period of follow up and exploring other factors that influence consumption of RUTF should be done.
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ANNEXES

ANNEX I: Use of RUTF

The Appetite test

A poor appetite is often the only sign of severe metabolic disturbances in a child with severe malnutrition. It may indicate significant infection, major metabolic abnormalities eg liver dysfunction, electrolyte imbalance, cell membrane damage or damaged biochemical pathways. Furthermore, a child with poor appetite will not take the RUTF at home and is likely to deteriorate and die.

The following were the steps that are followed when conducting an appetite test:

1. The appetite test was conducted in a separate quiet area

2. Explanation was given to the care giver on the purpose of the appetite test and how it will be carried out.

3. The caregiver washed their hands and the child’s hands and face with soap and water that was available at the site.

4. The caregiver was asked to sit comfortably with the child on his/her laps and offer the RUTF from the packet or put a small amount on his/her finger and give it to the child.

5. The caregiver offered the child the RUTF gently, encouraging the child all the time. This usually took a short time, but it may last one hour. The child was not forced to take the RUTF

6. The child was offered plenty of water to drink from a cup while he/she was taking the RUTF
Table 9: Minimum amount of RUTF that needs to be consumed per weight to have passed the appetite test

<table>
<thead>
<tr>
<th>Body weight (kg)</th>
<th>Sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 4kg</td>
<td>1/8 to ¼</td>
</tr>
<tr>
<td>4 to 6.9</td>
<td>⅓ to 1/3</td>
</tr>
<tr>
<td>7 to 9.9</td>
<td>1/3 to ½</td>
</tr>
<tr>
<td>10 to 14.9</td>
<td>½ to ¾</td>
</tr>
<tr>
<td>15 to 29</td>
<td>¾ to 1</td>
</tr>
<tr>
<td>Over 30</td>
<td>&gt; 1</td>
</tr>
</tbody>
</table>

Note that the appetite test was carried out at every visit.

Medical complications

Medical complications that if found in a child with severe malnutrition at any visit warranted admission of the child to an inpatient facility.

Severe vomiting; Hypothermia with temperature <35°C (axillary) or 35.5°C (rectal); Fever more than 39°C; Pneumonia; Extensive Infection; Not alert/coma/convulsions; Severe dehydration based on history and clinical signs; Severe anaemia; Any condition requiring infusion or NG tube feeding

Key messages given to caregivers whose children are on OTP

- RUTF is a food and medicine for very thin children only. It should not be shared.

- Sick children often do not like to eat. Give small regular meals of RUTF and encourage the child to eat often (if possible 8 times/day).

- RUTF is the only food sick/thin children need to recover during their time in OTP.
• For young children, continue to put them on the breast regularly.

• Always offer plenty of clean water to drink while he/she is eating RUTF.

• Use soap for children’s face and hands before feeding if possible.

• Keep food clean and covered.

• Sick children get cold quickly. Always keep the child covered and warm.

• When a child has diarrhoea, don’t stop feeding. Give extra fluids and extra food.

• Play, sing and talk with your child as this helps with their recovery.

Table 10: Quantity of RUTF per class of body weight, daily and weekly

<table>
<thead>
<tr>
<th>Class of weight (kg)</th>
<th>RUTF (sachet/day)</th>
<th>RUTF (sachet/wk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5-3.9</td>
<td>1.5</td>
<td>11</td>
</tr>
<tr>
<td>4.0-5.4</td>
<td>2</td>
<td>14</td>
</tr>
<tr>
<td>5.5-6.9</td>
<td>2.5</td>
<td>18</td>
</tr>
<tr>
<td>7.0-8.4</td>
<td>3</td>
<td>21</td>
</tr>
<tr>
<td>8.5-9.4</td>
<td>3.5</td>
<td>25</td>
</tr>
<tr>
<td>9.5-10.4</td>
<td>4</td>
<td>28</td>
</tr>
<tr>
<td>10.5-11.9</td>
<td>4.5</td>
<td>32</td>
</tr>
<tr>
<td>12 and above</td>
<td>5</td>
<td>35</td>
</tr>
</tbody>
</table>

(Adapted from Kenyan National Guideline for Integrated Management of Acute Malnutrition, version 1, June 2009)
ANNEX II: METHODOLOGY OF TAKING ANTHROPOMETRIC MEASUREMENTS

**Height/length**

- Measuring board was used. For children less than two years and those above and unable to stand, length is taken.

- Measuring board put flat on the floor.

- Child gently placed on the board, made to lie straight looking directly up.

- Soles of the feet made to lie flat against the fixed vertical bar.

- Assistant on his/her knees holds the feet firmly against the fixed bar and places one hand on the child's knees.

- The measurer moves the sliding bar gently against the crown of the head.

- The measurer reads out loudly the reading at the base of sliding bar to the nearest 0.1cm.

- Since length is 0.5cm more than height due to gravity effect, 0.5 cm is subtracted from all lengths before recording.

- For children two years and above and able to stand, height is taken.

- Measuring board placed vertically up.

- Child stands on the fixed flat surface of the board.

- The sliding bar is lowered gently against crown of the head.

- The measurer reads out loudly the correct measurement to the nearest 0.1cm.
**Weight**

- A digital weighing scale was used.
- Calibration to zero was done before each weighing.
- A child sat on the scale and the measurement taken.
- The measurer makes the reading perpendicular to the pointer to the nearest 0.1 kg and announces loudly.
- Three readings were made and average taken

**Mid upper arm circumference**

- An arm circumference tape was used.
- A child sat on the stool or on the caregiver's lap with the arm dropped down and flexed at right angle at the elbow.
- The shoulder tip (acromion) and elbow tip (radial tuberosity) are identified.
- The tape is placed from the tip of the shoulder to the elbow and the length noted and the midpoint thereby determined and marked.
- The arm circumference tape is applied round the arm at the marked midpoint.
- The reading is made and recorded in millimetres and converted to centimetres.
AFFEX III: INFORMED CONSENT FORM

Title of Study:

OUTCOMES OF SEVERELY MALNOURISHED CHILDREN AGED 6 MONTHS TO 60 MONTHS ON OUTPATIENT MANAGEMENT IN NAIROBI

Author: Dr Grace Nalwa, Department of Child health and Paediatrics,

University of Nairobi,

P.O Box 19676

Nairobi.

Mobile Telephone no: 0722-263041

Supervisors (all University of Nairobi, Department of Child Health and Paediatrics Lecturers)

Dr Daniel Njai

Dr Dalton Wamalwa

Dr Ahmed Laving

I, Dr Grace Nalwa, am a postgraduate student at the University of Nairobi, Department of Paediatrics. I am undertaking a study looking at how the children with severe malnutrition respond to care as an outpatient basis.

Severe malnutrition remains a major underlying cause of sickness and death among children, more so in developing countries.
Procedure: if you accept to be involved in this study, it will involve the study investigator (or assistant) asking you questions in a pre-prepared questionnaire and examining your child for any medical complications, weight, height, mid upper arm circumference and edema.

Benefits: you and your child will have the benefit of being followed closely by the principal investigator (and assistants) and any complication found will be dealt with promptly. Feedback on how your child is responding to treatment and any advice required will be given to you as any of your questions are answered.

Risks: Your child may feel some discomfort when being examined. In addition, the filling of the questionnaire will take some of your time.

However, if at any time you would like to withdraw out of the study, you are free to do so without any compromise to the care of your child or any penalty to you. Confidentiality will be maintained at all times. Only information that is relevant to the care of your child will be given to your primary care givers.

This study has been approved by the Kenyatta National Hospital Ethics committee and you are free to contact the Secretary through the following address if you have any concerns.

The Secretary,

Ethics, Research and Standards Committee,

Kenyatta National Hospital and University of Nairobi,

P.O Box 20723,

Nairobi.
(________________________) of (____________________) and parent/guardian of (________________________) have been explained to the nature and procedure of the study. I have understood the benefits and risks of the study to me and my child as explained to me by (________________________). I therefore give my consent, on behalf of my child, to be involved in this study.

Signed __________________________

Investigator’s/assistant’s signature __________________________

Thank you for your participation.
ANNEX IV: QUESTIONNAIRE

PART ONE

DEMOGRAPHIC DATA

a. Study no/identification no. __________________________

b. Age of patient (in months) __________________________

c. Birth order __________________________

d. Gender: 1. Male □

2. Female □

e. Residence __________________________

SOCIO-ECONOMIC HISTORY

a. Relationship with the patient: 1. Mother □

2. Father □

3. Other □ specify relation __________________________

b. Level of formal education- 1. None □

2. Primary (state years) □

3. Secondary (state years) □

4. Tertiary □

c. Occupation/source of income 1. Regular employment □

2. Casual employment □

3. Not employed □

d. Who is the main income generator __________________________

c. What is the estimate monthly income (Ksh)? ________

f. How many people live in the house on a regular basis? □
g. What material is used to make the walls of the house?

1. Not permanent (grass/mud) □
2. Semi permanent (iron sheets) □
3. Permanent (stone/brick) □

h. How many rooms are there in the house? __________

i. Do you have access to any of the following? 1. Toilet □
   2. Pit latrine □
   3. Other □

j. What is the main source of water for the family? 1. Piped water to house □
   2. Borehole □
   3. Shallow well □
   4. River/stream □
   5. Other □

MEDICAL HISTORY

a. Any prior admission in hospital? 1. Yes □
   2. No □

b. If yes, how many times? __________

c. Reason for admission? 1. Acute illness (in the last 2wks) □
   2. Chronic illness (please specify) □

d. Immunization status BCG □ OPV (Birth) □
   OPV1 □ OPV 2 □ OPV 3 □
   Pentavalent 1 □ □ 3 □
   Measles □
Booster vaccinations (specify)

e. History of illness in the last two weeks?
   1. Diarrhea □
   2. Fever □
   3. Cough □
   4. Anorexia □
   5. Other (specify) □

f. How has the weight of the child been in the last 3 months? (check card if available)
   1. Gaining weight □
   2. Loosing weight □
   3. No change □

h. Any history of chronic illness?
   1. HIV/AIDS □
   2. Tuberculosis □
   3. Other (specify) □

DIET

a. Period of exclusive breastfeeding
   1. 6 months □
   2. Less than 6 months □
   3. None □

b. Is the child still currently breastfeeding?
   1. Yes □
   2. No □

c. How many times did the child feed yesterday?
   1. Once □
   2. Twice □
   3. Thrice □
4. More frequently □

d. List the foods given yesterday at each meal:

meal one __________________________
m. meal two ________________________
meal three _________________________
onother meals ________________________

CLINICAL EVALUATION

a. Weight (in kg) Reading 1 _____ 2 _____ 3 _____ Average: _______ (plot on graph)
b. Height (in cm) Reading 1 _____ 2 _____ 3 _____ Average: _______
c. Weight for height (z score)
d. Mid upper Arm circumference (MUAC) in cm Reading 1 _____ 2 _____ 3 _____

Average: _______
e. Appetite good □ poor □ none □
f. Systemic exam

Severe palmar pallor 1. Yes □ 2. No □

Respiratory rate ____________

Temperature ______________

Severe Dehydration (history of diarrhea/vomiting and associated weight loss)

1. Yes □ 0 □

State of consciousness Alert □ Not alert □

Edema none □ mild □ moderate/severe □

Open Skin lesion none □ scabies □ peeling ulcers/abscess
TREATMENT GIVEN

a. How much Ready to use therapeutic foods (RUTF) given (packets) □

b. Antibiotics? 1. Amoxicillin □ 2. Other □ specify_____________

c. Vitamin A? 1. Yes □ 2. No □

d. Measles vaccine 1. Yes □ 2. No □

e. Other medicine given

PART II

How much of the RUTF has the child consumed since the last visit? Evidenced by amount of empty sachets brought back

Well (all) □ average (50-100%) □ poorly (less than 50%) □

Reasons ____________________________________________________________

CLINICAL EVALUATION

a. Weight (in kg) Reading 1__ 2__ 3__ Average: ____ (plot on graph)

b. Height (in cm) Reading 1__ 2__ 3__ Average: ____

c. Weight for height (z score)

d. Mid upper Arm circumference (MUAC) in cm Reading 1__ 2__ 3__

Average: ____

e. Appetite good □ poor □ none □

f. Systemic exam

Severe palmar pallor 1. Yes □ 2. No □
Respiratory rate ____________

Temperature ____________

Severe Dehydration (history of diarrhea/vomiting and associated weight loss)

1. Yes ☐

State of consciousness Alert ☐ Not alert ☐

Edema none ☐ mild ☐ moderate/severe ☐

Skin lesion none ☐ scabies ☐ peeling ☐ ulcers/abscess ☐

Outcome of patient

Cured ☐

Died ☐

Defaulted ☐

Transferred to inpatient ☐ Reason ____________________________
Dr. Grace M. Nalwa  
Dept. of Paediatrics & Child Health  
School of Medicine  
University of Nairobi  

Dear Dr. Nalwa  

RESEARCH PROPOSAL: "OUTCOMES OF OUTPATIENT MANAGEMENT OF CHILDREN AGED 6 MONTHS TO 5 YEARS WITH SEVERE MALNUTRITION IN NAIROBI" (P87/03/2010)  

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and **approved** your above cited research proposal for the period 5th May, 2010 to 4th May, 2011.  

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.  

On behalf of the Committee, I wish you a fruitful research and look forward to receiving a summary of the research findings upon completion of the study.  

This information will form part of the database that will be consulted in future when processing related research study so as to minimize chances of study duplication.  

Yours sincerely  

PROF AN GUANTAI  
SECRETARY, KNH/UON-ERC  

**c.c.** Prof. K. M. Bhatt, Chairperson, KNH/UON-ERC  
The Deputy Director CS, KNH  
The Dean, School of Medicine, UON  
The Chairman, Dept. of Paediatrics & Child Health, UON  
The HOD, Records, KNH  
Supervisors: Dr. Daniel Njai, Dept.of Paediatrics & Child Health, UON  
Dr. D. Wamalwa, Dept.of Paediatrics & Child Health, UON  
Dr. Ahmed Laving, Dept.of Paediatrics & Child Health, UON