ANTHROPOMETRIC AND BIOCHEMICAL ASSESSMENT OF THE NUTRITIONAL STATUS OF CRITICALLY ILL MECHANICALLY VENTILATED PATIENTS AT THE KENYATTA NATIONAL HOSPITAL CRITICAL CARE UNIT.

A DISSERTATION PRESENTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF MEDICINE IN ANAESTHESIA AT THE UNIVERSITY OF NAIROBI.

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ANTHROPOMETRIC AND BIOCHEMICAL ASSESSMENT OF THE NUTRITIONAL STATUS OF CRITICALLY ILL MECHANICALLY VENTILATED PATIENTS AT THE KENYATTA NATIONAL HOSPITAL CRITICAL CARE UNIT.

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DECLARATION

I declare that this dissertation is my original work and has not been submitted for a Degree award in any university.

Dr James Chitibwi Mumba
MB.Ch.B

SIGNATURE DATE

This dissertation has been submitted for the degree of Masters of Medicine in Anaesthesiology with my approval as a university supervisor.

Prof. Zipporah Ngumi
MB.Ch.B, DA FFARCS

SIGNATURE DATE
DEDICATION

Dedicated to my wife Sophia, my son Ishara and my parents Mr. and Mrs. Albert Chaurembo Mumba for their tremendous support and sacrifice during this period.
ACKNOWLEDGEMENTS

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- Professor Ngumi, my supervisor for her guidance and supervision in writing this dissertation.
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- The Ethical and Research Committee (KNH) for allowing this study to be conducted.
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- The KNH department of Nutrition in particular Anastacia Kariuki and Bertha Ocholla for their tremendous support, guidance and advice during the conduct of the study.
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# TABLE OF CONTENTS

DECLARATION......................................................................................................................ii  
DEDICATION.........................................................................................................................iii  
ACKNOWLEDGEMENTS.........................................................................................................iv  
TABLE OF CONTENTS........................................................................................................v  
LIST OF ABBREVIATION.....................................................................................................vi  
LIST OF FIGURES..............................................................................................................vii  
LIST OF TABLES................................................................................................................vii  
ABSTRACT............................................................................................................................viii  
1.0 INTRODUCTION AND LITERATURE REVIEW ...................................................1  
2.0 STUDY OBJECTIVE..................................................................................................10  
3.0 STUDY JUSTIFICATION..........................................................................................11  
4.0 STUDY METHODOLOGY.........................................................................................12  
4.8 DATA COLLECTION AND MANAGEMENT ...........................................................16  
5.0 RESULTS....................................................................................................................18  
6.0 DISCUSSION..............................................................................................................32  
7.0 CONCLUSION............................................................................................................35  
8.0 RECOMMENDATIONS............................................................................................36  
9.0 LIMITATIONS..........................................................................................................37  
List of References.................................................................................................................38  
Appendix 1: Harris Benedict Equation.............................................................................41  
Appendix 2: Budget..............................................................................................................41  
Appendix 3: Work plan. .....................................................................................................41  
Appendix 4A: Specific Reference Values for MUAC.....................................................42  
Appendix 4B: Specific Reference Values for TSFT.......................................................42  
Appendix 5: Research Instruments...................................................................................43  
Appendix 6: Informed Consent Form...............................................................................45  
Letter of Approval .................................................................................................................49
LIST OF ABBREVIATION

BMI – Basal Mass index

CCU-Critical Care Unit

Kcal-Kilocalories

KNH-Kenyatta National Hospital

MUAC-Mid-upper arm Circumference

R/Q-Respiratory Quotient

TPN-Total Parenteral Nutrition

TSFT-Triceps Skin Fold Thickness
LIST OF FIGURES
Figure 1: Age Distribution ......................................................................................................18
Figure 2: Gender Distribution .................................................................................................19
Figure 3: Distribution of Primary Diagnosis ........................................................................19
Figure 4: Distribution of Co-morbid Disease .....................................................................20
Figure 5: Box Plot of MUAC on Follow-up .........................................................................21
Figure 6: MUAC Trends by age of the Patients ................................................................22
Figure 7: MUAC Distribution by Gender..............................................................................23
Figure 8: MUAC distribution by Gender on Follow-up......................................................24
Figure 9: Albumin Levels over Follow-up Period ...............................................................25
Figure 10: Trend of Prevalence over the Follow-up period ..........................................26
Figure 11: Comparison of mean Gender TSFT at Admission .......................................28
Figure 12: Comparison of mean Gender TSFT after 7 days stay ................................28
Figure 13: Comparison of mean TSFT after 14 days stay .............................................29
Figure 14: TSFT Distribution................................................................................................30
Figure 15: Trend Graph of Incidence of Low TSFT Values............................................31

LIST OF TABLES
Table 1: Socio-Demographic Factors (n=96) ....................................................................18
Table 2: Distribution of MUAC over Follow-up Period (n=96) .......................................21
Table 3: Distribution of Albumin ...........................................................................................25
Table 4: Prevalence and Incidence of Hypoalbuminaemia ............................................26
Table 5: Gender Specific Incidence over follow-up time ................................................26
Table 6: Prevalence of Hypoalbuminaemia ......................................................................27
Table 7: Mean/Median of TSFT over Follow-up Time (n=96) .......................................27
Table 8: Distribution of TSFT on Follow-up .......................................................................29
Table 9: Prevalence and Incidence of Low TSFT Values ..............................................30
ABSTRACT

Background-Nutritional assessment enhances quality of nutritional care, however, its practice bemuses professionals. Malnutrition prevalence among hospitalised adults is approximately 50% and is correlated with prolonged hospital stays, increased healthcare cost, morbidity and mortality. Nutrition assessment should therefore be an integral part of the clinical evaluation and used as a basis for nutritional support. Most modalities however are cumbersome, time consuming & not routinely performed hence malnutrition goes largely unrecognised.

Objective:-To determine the incidence and prevalence of malnutrition and to monitor changes in nutritional status among the critically ill mechanically ventilated patients admitted at the Kenyatta National Hospital Critical Care unit (KNH CCU).

Study Design-A Prospective cross-sectional observational study.

Study Site- Kenyatta National Hospital Critical Care Unit.

Sampling-Consecutive sampling of adult critically ill mechanically ventilated patients

Study Population-96 critically ill adult patients on mechanical ventilation in KNH CCU.

Main outcome measures- Nutritional status of patients on admission and reassessment at 7 & 14 days.

Methods-The study was approved by the KNH/U.O.N ethics research committee and data collected over a 4 month period (Jan-April 2010). Demographic data was obtained by means of a structured questionnaire. Other relevant details e.g. History, diagnosis and investigation results were obtained from the medical files. Nutritional status was determined from anthropometric (MUAC/TSFT) and biochemical parameters (serum albumin). To determine changes in nutritional status during hospital stay, patients were reassessed at 7 & 14 days respectively or until death or discharge. Data was entered into the computer using Epi-info data entry programme and analysed using SPSS version 17.0. The results are presented in tables and figures where applicable.
Results- 55.2% of the patients were below 40 years of age. 70.8% of patients were male while 29.2% were female. 31.25% of the admissions were for severe head injury. Hypertension was the commonest comorbid illness. Prevalence of hypoalbuminaemia was 63.5%, 85.5% & 86.4% at admission, 7 days & 14 days respectively. Gender had no significant association with degree of changes in albumin levels with a p-value of 0.099. Age showed a significant association with the degree of changes in albumin (p-value-0.041). The incidence of hypoalbuminaemia was 9.4% at 7 days and 14.4% at 14 days. Gender specific incidence was 7.3% at day 7 and 11.4% at day 14 for males but was lower in the females at 2.1% at 7 days and 2.9% at 14 days. High albumin levels of above 5g/dL were noted in 4.2% and 2.4% of the patients at 7 days and 14 days respectively. MUAC values were within normal, but the mean values dropped slightly on follow up. Female patients exhibited higher mean MUAC values (29.9cm) than males (27.5cm) which was statistically significant at a p-value of 0.04. At admission, 27.1% (26) of the patients had TSFT values within normal, 26% (25) had low values indicating depletion of fat stores and therefore some level of undernutrition. Interestingly, 46.9% (45) of the patients were noted to have above normal skin thickness values. The incidence of low TSFT values was 1% at 7 days & 4.8% at 14 days showing a slight increase. The mean TSFT values neither showed significant increase nor decrease over the follow-up period. Female patients were noted to have higher mean TSFT values than males.
1.0 INTRODUCTION AND LITERATURE REVIEW

According to the World Health Organisation, nutrition is the intake of food considered in relation to the body’s dietary needs. The benefits of an optimal nutritional status in critically ill patients include improved wound healing, decreased catabolic response to injury, improved gastrointestinal structure and function and improved clinical outcomes with accompanying cost savings [1, 2].

Malnutrition is a state of nutrition in which a deficiency or excess (or imbalance) of energy, protein and other nutrients cause measurable adverse effects on tissue/body form (body shape, size and composition), function and clinical outcome. Malnutrition in mechanically ventilated patients results in increased risk of infection and pulmonary edema, decreased phosphorus levels needed for cellular energy production, reduced ventilator drive and impaired production of surfactant with eventual prolonged and difficult course of weaning because of muscle fatigue caused by diaphragmatic and skeletal muscle weakness and/or reduced muscle endurance. A survey of 500 patients carried out by McWhiter and Pennington in 1994 found that 40% of patients were undernourished on admission, 34% were overweight while two thirds lost weight during their stay in hospital with only 48 of them having documented nutritional information. This proves that malnutrition remains a largely unrecognized problem in hospitals [3].

Both medical and nursing staff often fail to monitor nutritional status particularly in CCU patients. Malnutrition is prevalent in many ventilated patients and it’s incidence in CCU could be as high as 50% [4].

The commencement of early nutritional support together with ongoing monitoring of nutritional status is therefore now considered a priority.

General Goals of Nutritional Support

Critically ill patients are hypermetabolic with increased nutrient requirements [5]. The overall aim of nutritional support is to provide patients with their general nutrient requirements hence treat existing malnutrition and maintain body cell mass, muscle mass, strength and mobility thereby minimizing (but not prevent) the wasting of lean body mass that accompanies critical illness. However, requirements need to be modified according to individual patient needs and specific disease processes.
Total calorie requirements can be either estimated or calculated. More usually used techniques estimate rather than calculate calorie requirement. The Harris-Benedict equation can be used (Appendix 1).

25 Kcal/kg/day is the estimate most often used. Calories can be given in three forms:

1. **Carbohydrate:** Comprise 70-85% of the total non-protein calories that can be given, usually as glucose. Insulin may be required to maintain blood glucose concentration within normal limits, especially since insulin resistance is often seen as part of the stress response [6].

2. **Fat:** 15% - 30% of the total non-protein calories can be given as fat. Critically ill patients often utilize fat better than carbohydrate as an energy source [6]. Including lipids as a component of the TPN formulation is suggested to reduce hepatic complications associated with TPN, reduce carbon dioxide production and improve glycemic control. Provision of fat also provides essential fatty acids required as normal constituents of cells [7].

3. **Protein:** 5% to 20% of the total calories per day can be administered as protein or amino acids depending on route of administration.

Micronutrient requirements should also be considered. Approximately 1mmol/kg of both sodium and potassium are usually given (altered when there are excessive losses e.g. from excess sweating and GI losses). Magnesium, iron, copper, zinc and selenium are also necessary, in much smaller amounts. Muscle weakness associated with a long-term requirement for ventilatory support, and failure in weaning from ventilation is associated with hypophosphataemia [8].

**TYPES OF NUTRITION THERAPIES**

**Enteral Nutrition**

Enteral nutrition refers to feeding via a tube placed into the gut to deliver liquid formulas containing all essential nutrients. It is the preferred route for nutritional support as it is more cost effective than Total Parenteral Nutrition (TPN), the gut barrier and immune functions are preserved and systemic infections reduced [9]. Many studies support the implementation of enteral nutrition as soon as within 24 hours. In critical illness, initiation of nutritional support within 24 hours of injury or CCU admission is associated with an approximate 50% reduction
in mortality [10]. Recent surveys report the use of enteral nutrition ranging between 33% - 39% of patients receiving nutrition support. Enteral feeding requires adequate gastric motility and a gastric residual volume in excess of 150 ml will usually require feeding solutions to be administered slowly. Persistently inadequate gastric emptying may dictate small bowel feeding techniques (duodenal or jejunal) or supplemental TPN.

The main disadvantage with enteral feeding is that feeding is periodically stopped for various reasons hence caloric targets may not be met. An observed prospective study of patients on mechanical ventilation who were receiving enteral nutrition showed that patients received 50% of their caloric needs. Furthermore, enteral nutrition was interrupted 27.5% of the time with a mean of 6 hours/patient/day because of small bore feeding tubes, increased residual volumes, weaning and others [11]. It has recently been suggested that the combination of enteral and parenteral may be appropriate for most critically ill patients, with enteral feeding increasing as tolerance to the feed increases [12].

However, enteral feeding does increase the risk of ventilator associated pneumonia, probably because it increases gastric pH and promotes gastric colonisation. In addition, the gastric tube compromises lower oesophageal sphincter function [13, 14].

**Parenteral Nutrition**

Parenteral nutrition refers to the infusion of complete nutrient solutions into the bloodstream via a peripheral or more commonly by central venous access to meet nutritional needs. This should only be used when the enteral route is either not possible or cannot provide sufficient nutrient input. Catheters used for TPN should be inserted under full aseptic technique and TPN should be delivered through a dedicated catheter.

The European Society for Parenteral and Enteral Nutrition (ESPEN) 2006 guidelines suggest avoidance of parenteral nutrition in patients who tolerate enteral nutrition and can be fed approximately to target values. Recent surveys report use of parenteral nutrition ranging from 12% -21% of all patients receiving nutritional support. Complications are more frequent with the parenteral route and are usually related to catheter insertion and infection [15, 16].
Although it is generally assumed that TPN may provide targeted nutritional support for critically ill patients, it has been shown that in many patients calorie and nitrogen target intakes are not reached, and underfeeding may be a genuine problem in some patients.

The use of TPN in the critically ill has been summarized in a meta-analysis which included 26 randomised trials involving 2211 patients, although only 6 of the studies included were based in CCU. There was no effect on mortality although there was a slight but not statistically significant decrease in major complications in those patients given TPN. The authors suggested that TPN should only be used in those critically ill patients who cannot tolerate enteral nutrition [17].

**Importance of Nutritional Status Monitoring**

Nutritional assessment is a continuous process that involves screening for malnutrition, assessing food and dietary supplement intake, establishing the presence or absence of malnutrition and its possible causes and planning for the most appropriate nutritional intervention. Some degree of malnutrition occurs during most hospitalizations regardless of the type of injury or illness.

A prospective study of 500 patients admitted to an acute care teaching hospital in England determined that 40% of patients were undernourished on presentation, and patients lost an average of 5.4% of their body weight during their hospital stay. 52% of malnourished patients had no nutritional information documented, suggesting that the problem is commonly overlooked by physicians [18]. Furthermore, even when enteral feeding is undertaken in the CCU, inadequate nutrition is frequently delivered because of underestimation of patients' nutritional needs and inappropriate cessation of feedings.

All critically ill patients develop a stress response that results in a hypercatabolic state and increased nutritional demand that eventually results in mucosal atrophy, loss of body tissue, skeletal muscle atrophy and weakness, immunosuppression and delayed wound healing. These effects may even occur within days [19]. A prospective audit of 100 admissions to a general medical unit to determine the relationship between the nutritional statuses of patients to the actual length of stay showed that 45% of the malnourished patients were hospitalized longer compared to 30% for normal patients and 37% for the baseline group [20].
The Downward Spiral of Malnutrition in ICU

MODES OF NUTRITION ASSESSMENT

Nutrition assessment is the process used to evaluate the nutritional status of the body. In the critically ill patient it presents a unique challenge to the practitioner. Traditional methods of assessing nutritional status are of limited value in CCU setting hence the use of any method can be appropriate provided the limitations are clearly understood. There is no gold standard for determining the nutritional status of patients [21]. However, as any one single method can have shortcomings, it is recommended to use two or three methods in parallel to overcome this problem [22,23].

The adaptive changes which occur during starvation and as part of the stress response are now well known and are directed at conserving body protein and maintaining normoglycaemia, whilst ensuring that the body can fight infection and undergo subsequent necessary healing processes. Severe nutritional deficits can result in organ dysfunction, abnormalities in blood biochemistry and reduced body mass, and may also be associated with altered outcome following hospital treatment.

Assessment of the state of nutrition of a patient is clearly the first step in deciding the degree of nutritional support required.
1) Dietetic Techniques

These techniques involve estimating food intake by interview techniques and recording of intake e.g., by completion of food diaries or weighing of food prior to its being eaten. These techniques require the input of trained dietitians. Although they may be valuable in determining the cause of malnutrition or a logical approach to its management, they are in general too complex to be of value in identifying a need for nutritional support [21].

2) Anthropometric Measurements

General loss of body weight associated with a catabolic process leading to loss of muscle mass as a result of protein and calorie deficits provides a gross indicator of inadequate nutritional intake. In an ideal situation, a measure of body mass index (BMI) is a useful indicator of nutritional state. The BMI can be used to calculate the nutritional status of the patient. Unfortunately regular BMI estimations are difficult in critically ill patients.

Body mass index = \( \frac{\text{Weight (kg)}}{\text{Height (m)}^2} \)

Anthropometry uses skin fold thickness and skeletal muscle mass as an index of nutritional state. It helps determine whether nutrition is inadequate and recommended simple measurements include height, weight, mid-upper arm circumference (if low—indicates overall weight loss), triceps skin fold thickness (provides an estimate of body fat reserves), mid-arm muscle circumference (if low—indicates protein depletion)[24].

A prospective study in 2002 by Ravasco et al at the university Hospital of Santa Maria-Portugal aimed at identifying feasible and informative nutritional parameter in intensive care, concluded that MUAC is simple and feasible and if classified by percentiles may prove functional with prognostic value [25].

MUAC and TSFT can be measured with minimal equipment, effort and time. When these parameters are measured it is recommended that they be evaluated to specific standards of reference[Appendix 4A/4B].

3) Calculation of Basal Metabolic Rate (BMR)

The Harris-Benedict equation; used to calculate BMR along with the usual multiplication factors to provide adequate calorie intake (Appendix 1).
However, in critically ill patients baseline calculation errors can occur as the ideal weight and height is rarely known [22].

4) Laboratory Measurements

A) Serum Albumin:

Albumin is the main protein synthesized and secreted by the liver (15 g per day) with a half-life of approximately 18 days. Plasma protein concentrations are used routinely for assessment of nutritional status and the effect of nutritional therapy. Serum albumin is an index often used, although many factors other than energy intake influence the metabolism of albumin and its distribution in the intra- and extravascular fluids.

It may serve as a parameter of chronic protein deficiency because of its relatively long half-life. Measurements of the concentrations of plasma proteins have been extensively studied in the context of nutritional assessment. The most widely used is albumin and less frequently Transferrin, retinol binding protein or prealbumin have also been used to monitor nutritional status. The normal serum or plasma concentration is 35-50 g/L.

A study done by Murray H. Seltzer et al of Nutrition support service and Department of surgery at St. Barnabas Medical center; New Jersey reported nutritional assessment of the critically ill patient using serum albumin level and total lymphocyte count [26]. When a CCU population was compared to the general hospital population a 6-fold increase in albumin level depressions, a 2-fold increase in lymphocyte count depression, and an 11-fold increase in depression of both parameters was noted in the CCU population.

Surgical CCU patients with depressed albumin levels and total lymphocyte counts had twice the complication rate and 4.5 times the death rate compared to those with normal albumin levels and lymphocyte counts. It was concluded that serum albumin levels and total lymphocyte count determinations are valuable tools for instant nutritional assessment of the critically ill patient [26].

Another study on the utility of serum albumin values in the nutritional assessment of hospitalized patients by Anderson CF et al showed that low serum albumin values were by far the most common abnormal nutrition related findings with associated longer hospital stay of 3-5 days on average [27].
B) Lymphocyte Count:

Nutrition is a critical determinant of immune responses and malnutrition is the commonest cause of immunodeficiency worldwide. Studies have shown that undernutrition impairs cell mediated immunity. The number of lymphocytes and their ability to provide help to B cells in antibody synthesis is decreased. The numerical and functional deficiency of the lymphocytes may be important in the pathogenesis of some of the clinical and immunological manifestations of undernutrition [16, 26, and 29].

Other studies [30, 31, 32], revealed malnutrition resulted in decreased thymic and splenic lymphocytes and shrinkage of lymphoid structures with an eventual decrease in total lymphocytes and decreased cell mediated immunity. The approximate normal value for lymphocytes in humans is 1.3 – 3.5 x 10⁹/L i.e. 20-45% of the total white blood cells.

5) Subjective Global Assessment (SGA)

Because of the limitations with objective means of assessing nutrition status, the SGA was developed. Based on the client’s medical, weight, and diet history and a physical examination, the patient is categorized as well nourished, moderately malnourished, or severely malnourished with physical signs of malnutrition evident. When patients are critically ill, it is often necessary to elicit this information from the patients' family members.

A subjective assessment of nutrition status is made to establish whether a patient will need maintenance therapy or nutrition repletion.

This technique has good interrater agreement, good sensitivity and specificity and predicts nutrition-related complications in certain populations, including surgical patients. The SGA has the most diagnostic value for acute care patients and correlates well with objective measurements and is widely accepted as a practical and reliable tool for nutrition assessment. However, a significant proportion of the instrument requires patient or proxy report and depends on the history being available and accurate [33].

6) Measurement of body composition

Undernutrition leads to a decrease in total body protein, total body fat and various individual elements.
Methods for assessing body composition include: Hydrodensitometry (underwater weighing) to assess total body fat, Isotope dilution (e.g., using deuterium, tritium or assessing total body water (which allows estimation of total body fat and fat-free mass), Bioimpedance analysis (also measuring total body water), Dual-energy x-ray absorptiometry (capable of providing an estimate of fat and muscle mass), CT and MRI (muscle mass and visceral tissue), Whole body counting (for measuring total body potassium by assessing the decay of naturally occurring potassium, which is closely correlated with total cell mass), Neutron activation analysis (capable of measuring various elements, including nitrogen—and thus total body protein).

However, although valuable in research, these techniques are either too complex, or their predictive values in relation to outcome have yet to be determined, or both, to be of value in routine clinical practice.

7) Functional Measurements

Functional measurements that have been used in nutritional assessment include examination of immune status (usually involving measurement of the peripheral lymphocyte count or of delayed cutaneous hypersensitivity to recall antigens), exercise tolerance and tests of the strength of individual muscles or muscle groups. Measurement of delayed cutaneous hypersensitivity for this purpose has poor specificity and sensitivity.

Exercise tolerance and muscle strength are decreased in malnutrition, but are dependent on premorbid status. Grip strength can be measured using a dynamometer, but is demanding on the patient. Electromyography, measuring muscle contraction in response to a standardised stimulus, is more objective but invasive.

8) Calorimetry

Direct calorimetry provides an actual measurement of the energy utilisation of the body, whereas in indirect calorimetry this is derived from measurements of either oxygen consumption or carbon dioxide production. Direct calorimetry is impracticable for clinical purposes. Indirect calorimetry can be performed at the bedside using a "metabolic cart", but these are expensive and require trained staff for their operation [27].
2.0 Study Objective

General objective

To assess the incidence/prevalence of malnutrition among the critically ill patients admitted in the CCU at Kenyatta National Hospital.

Research Question

1) What is the incidence/prevalence of malnutrition and what are the changes in nutritional status over time amongst critically ill patients at KNH CCU?

Specific Objectives

1) To determine the incidence/prevalence of malnutrition among the critically ill mechanically ventilated patients on admission to KNH CCU.

2) To monitor the changes in nutritional status of the critically ill mechanically ventilated patients in KNH CCU over time.
3.0 STUDY JUSTIFICATION

Parenteral and enteral nutrition is not a new concept in our setting yet its effects on patients is not routinely monitored, which is where this study bears its relevance. Good nutrition has benefits all round; to the patient and the healthcare providers in terms reduced morbidity & mortality and to the hospital in terms of reduced healthcare provision costs.

From the foregoing literature review several issues relating to nutrition in the critically ill patients were highlighted. First is the fact that studies have shown that critically ill patients have some degree of malnutrition even at admission with further subsequent loss of weight during their hospital stay, both of which remain largely unrecognized problems in hospitals. Emphasis is now being laid on early commencement of nutritional support while monitoring of nutritional status is now considered a priority. A baseline determination of nutritional status of patients admitted in our CCU is therefore necessary.

Secondly, despite recent advances in modes of nutrition assessment, the process still presents a unique challenge to healthcare providers and most traditional methods of assessment are of limited value in the critically ill patient population. This study thus focuses on a combination of anthropometric and biochemical methods of assessment because unlike the other methods, these are simple, less complex, cheap and readily available in our setting with excellent utility in routine clinical practice.

Indeed no previous studies have been done locally with regards to assessment and monitoring of nutritional status of the critically ill mechanically ventilated patients admitted in the CCU’s. This study will therefore set a base upon which other studies on nutrition can be formulated.

In addition, this area of nutrition has largely been left to the nutritionists and nurses with doctors giving it a wide berth. This audit therefore aims to trigger interest in this area of nutrition amongst doctors.

The findings of this study may also go a long way in helping improve the overall management and outcomes of critically ill in patients in KNH CCU.
4.0 STUDY METHODOLOGY

4.1 Study Design
A Prospective cross-sectional observational study design was followed.

4.2 Study Site
Kenyatta National Hospital Critical Care Unit. KNH is a teaching and referral hospital located in Nairobi, the capital city of Kenya. Its CCU is the oldest in the country and has a 21 bed capacity.

4.3 Study Population
Critically ill patients in KNH CCU who met the inclusion criteria.

4.4 Sampling
Consecutive sampling of adult critically ill mechanically ventilated patients admitted at Kenyatta National Hospital CCU during the study period. The sample size was determined by the using the following formulae to achieve an adequate sample to accurately estimate the incidence of malnutrition in mechanically ventilated critically ill patient in the study population.

\[ n = \frac{Z^2 \cdot \alpha^2 \cdot P(1-P)}{D^2} \]

**KEY**

\( n \) = required sample size

\( P \) = prevalence of mechanically ventilated (50%), since there is no study done in a similar setting in the developing world.

\( D \) = Precision with which to measure prevalence, set at plus or minus 10%. 
$Z_{\alpha/2}$ is the cut off points along the x-axis of the standard normal probability distribution that represents probability matching the 95% confidence interval (1.96).

Substituting the above in the formulae we get:

$$n \approx 96.04$$

$$= 96 \text{ patients}$$
4.6 Inclusion/Exclusion Criteria

✓ Inclusion criteria

The following selection criteria were used in selecting patients for the study;

1. Patients over 13 years of age (considered adults in KNH) admitted at the KNH CCU and on mechanical ventilation.

2. Patients from whom consent for participation in the study is obtained

✓ Exclusion Criteria

1. Patients from whom consent was not obtained.

2. Patients below 13 years of age.

3. Patients not on mechanical ventilation.

4. Patients transferred to KNH CCU from neighboring CCUs where they have been admitted for more than 48 hours.

4.7 Data Collection Instruments

Demographic data i.e. age, gender, marital status and occupation was obtained by means of a structured questionnaire (Appendix 5).

The medical history, primary diagnosis, investigation results, treatment plans and other relevant details were obtained from the patient’s medical files. Each patient’s nutritional status was determined from anthropometric (MUAC/TSFT) and biochemical parameters (serum albumin) all taken within 48 hours of admission. To determine changes in nutritional status during hospital stay, patients were reassessed at 7 days and 14 days where possible.

1) Anthropometric data

The researcher will obtain MUAC and TSFT measurements using standard equipment and standardized techniques.

A) MUAC Measurement

It is measured using a non-stretchable flexible tape. The patient is positioned such that the right arm is hanging freely to the side. The midpoint is located by measuring from the acromion to the olecranon and marking the midpoint. The tape is placed around the upper arm, directly over the initial pencil mark, at the midpoint on the posterior aspect of the upper arm and pulled just snugly enough to ensure contact with the medial side of the arm.
The measurements are taken thrice, recorded to the nearest 0.1 cm and the average calculated.

**Location of MUAC/TSFT Measurement**

Age and sex specific standards of reference are as shown below [Appendix 4A].

**B) TSFT Measurement**

Done using the Happened skinfold caliper which is a precision instrument designed for use in measuring skinfold thickness from which estimates of body fat can be derived. This is taken with the patients shoulders relaxed, arms hanging freely at the sides. The posterior surface of the upper arm is located (same area as midpoint for MUAC). The fold of skin is gently grasped together with the subcutaneous adipose tissue using the forefingers approximately 1 centimeter above the marked point. With the jaws of the harpenden calipers perpendicular to the length of the fold, the thickness is measured to the nearest 0.2 mm. Two seconds later, the calipers are released. The measurements will be taken thrice and the average calculated. Age and sex specific standards of reference are as shown below [Appendix 4B].
4.8 Data Collection and Management

A statistician appointed by the principle investigator was consulted for data analysis. Completed questionnaires were coded and sorted out for completeness and data entered into the computer using Epi-info data entry programme. Data cleaning was done before analysis and analysed using SPSS version 17.0.

The results are presented in tables and figures where applicable. Non-Parametric tests (Mann Whitney U test) will be used to examine whether there is any significant association between the continuous variables (factor at enrolment and after 7 days) e.g. age and MUAC, while chi-square will be used to establish the significant associations between the categorical variables.

Odds Ratios (OR) and associated 95% Confidence interval (CI) will be calculated to identify the factors that are more likely to explain the explanatory variable (likelihood to have developed malnutrition at ICU).

P-value of less than 5% (P<0.05) were considered statistically significant.
4.9 ETHICS CONSIDERATIONS
The protocol was submitted to the Kenyatta National Hospital/University of Nairobi Ethics Review Committee approved.

Informed Consent
A written informed consent was obtained from the patient or the patient’s next of kin.

Patient Confidentiality
The patient’s identification information was omitted from the study related material to ensure participants confidentiality.
5.0 RESULTS

Table 1: Socio-Demographic Factors (n=96)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Factor level</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in Year</td>
<td>&lt; 30</td>
<td>27</td>
<td>28.1</td>
</tr>
<tr>
<td></td>
<td>30-39</td>
<td>26</td>
<td>27.1</td>
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<td></td>
<td>40-49</td>
<td>17</td>
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<td></td>
<td>50-59</td>
<td>11</td>
<td>11.5</td>
</tr>
<tr>
<td></td>
<td>60+</td>
<td>15</td>
<td>15.6</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>68</td>
<td>70.8</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>28</td>
<td>29.2</td>
</tr>
</tbody>
</table>

Figure 1: Age Distribution

The mean age of patients was 41.3 (±1.6) and a 95% CI of between 37.9 to 44.5 years, which ranged between 13 to 74 years. Majority of the patients recruited in the study were aged below 30 years (28.1%) followed by those between 30-39 years of age (27.1%). This shows that over 50% of our CCU population is comprised of the youth below 40 years of age.
70.8% of the patients were male while females comprised of 29.2% of the study subjects.
81 (84.38%) of the patients recruited into the study had no co-morbid illnesses. 10 (10.42%) had hypertension, 2 (2.08%) had renal failure, 2 (2.08%) had diabetes and 1 patient (1.04%) had pulmonary tuberculosis.
Table 2: Distribution of MUAC over Follow-up Period (n=96)

<table>
<thead>
<tr>
<th>Statistics</th>
<th>MUAC initial</th>
<th>MUAC After 7 days</th>
<th>MUAC After 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean MUAC</td>
<td>28.2</td>
<td>28.9</td>
<td>27.2</td>
</tr>
<tr>
<td>Median</td>
<td>28.0</td>
<td>28.0</td>
<td>27.0</td>
</tr>
<tr>
<td>Minimum</td>
<td>18</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Maximum</td>
<td>38</td>
<td>38</td>
<td>34</td>
</tr>
</tbody>
</table>

Figure 5: Box Plot of MUAC on Follow-up

On follow up at 14 days, the mean MUAC was lower than the initial; the MUAC was decreasing with time.
From the figure above it can be deduced that mean MUAC for patients with less than 30 years of age was decreasing on follow-up. The same applied for ages between 30 and 39 years, 60+. For ages 50 and 59 years, MUAC increased after 7 days then dropped at 14 days.
Female patients had higher MUAC values compared to male patients, 27.5cm and 29.9cm respectively. MUAC which was significantly at a p-value of 0.04.
The mean MUAC of male was decreasing with time while for female it increased at 7 days and dropped at 14 days.
Table 3: Distribution of Albumin

<table>
<thead>
<tr>
<th>Level</th>
<th>Initial, n (%)</th>
<th>Second, n (%)</th>
<th>Third, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>61 (63.5)</td>
<td>35 (85.4)</td>
<td>19 (86.4)</td>
</tr>
<tr>
<td>Normal</td>
<td>31 (32.3)</td>
<td>5 (12.2)</td>
<td>3 (13.6)</td>
</tr>
<tr>
<td>High</td>
<td>4 (4.2)</td>
<td>1 (2.4)</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 9: Albumin Levels over Follow-up Period

- **LOW**
- **NORMAL**
- **HIGH**
Table 4: Prevalence and Incidence of Hypoalbuminaemia

<table>
<thead>
<tr>
<th>Level</th>
<th>Initially</th>
<th>At 7 days</th>
<th>At 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td>63.5</td>
<td>85.5</td>
<td>86.4</td>
</tr>
<tr>
<td>Incidence</td>
<td>-</td>
<td>9/96=9.4%</td>
<td>5/35=14.4%</td>
</tr>
</tbody>
</table>

The incidence increased with time from 9.4% to 14.4% at the last follow-up.

Figure 10: Trend of Prevalence over the Follow-up period

The prevalence of low albumin levels increased with time from 63.5% to 86.4%.

Table 5: Gender Specific Incidence over follow-up time

<table>
<thead>
<tr>
<th>Incidence</th>
<th>At 7 days</th>
<th>At 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>7/96=7.3%</td>
<td>4/35=11.4%</td>
</tr>
<tr>
<td>female</td>
<td>2/96=2.1%</td>
<td>1/35=2.9%</td>
</tr>
</tbody>
</table>
Table 6: Prevalence of Hypoalbuminaemia

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Prevalence (after 14 days)</th>
<th>OR 95%CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes, n (%)</td>
<td>No, n (%)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• male</td>
<td>15 (78.9)</td>
<td>1 (33.3)</td>
<td>7.5 (0.5 to 10.5)</td>
</tr>
<tr>
<td>• female</td>
<td>4 (21.1)</td>
<td>2 (66.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt; 40</td>
<td>7 (36.8)</td>
<td>3 (100.0)</td>
<td>-</td>
</tr>
<tr>
<td>• 40+</td>
<td>12 (63.2)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

TRICEP SKINFOLD THICKNESS

Table 7: Mean/Median of TSFT over Follow-up Time (n=96)

<table>
<thead>
<tr>
<th>Statistics</th>
<th>TSFT Initial</th>
<th>TSFT After 7 days</th>
<th>TSFT After 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean TSFT</td>
<td>13.8</td>
<td>15.0</td>
<td>14.5</td>
</tr>
<tr>
<td>Median</td>
<td>12.0</td>
<td>15.5</td>
<td>13.5</td>
</tr>
<tr>
<td>Minimum</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Maximum</td>
<td>37</td>
<td>37</td>
<td>37</td>
</tr>
</tbody>
</table>
Males had lower TSFT values compared to females at admission to the CCU.

Males had lower TSFT values compared to females after 7 days of follow-up.
Male still had lower TSFT values compared to females at 14 days of follow-up.

Table 8: Distribution of TSFT on Follow-up

<table>
<thead>
<tr>
<th>Level</th>
<th>Initial, n (%)</th>
<th>Second, n (%)</th>
<th>Third, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>25 (26.0)</td>
<td>5 (11.9)</td>
<td>4 (18.2)</td>
</tr>
<tr>
<td>Normal</td>
<td>26 (27.1)</td>
<td>14 (33.3)</td>
<td>9 (40.9)</td>
</tr>
<tr>
<td>High</td>
<td>45 (46.9)</td>
<td>23 (54.8)</td>
<td>9 (40.9)</td>
</tr>
</tbody>
</table>
Figure 14: TSFT Distribution

Table 9: Prevalence and Incidence of Low TSFT Values

<table>
<thead>
<tr>
<th>Level</th>
<th>Initially</th>
<th>At 7 days</th>
<th>At 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td>72.9</td>
<td>66.7</td>
<td>69.1</td>
</tr>
<tr>
<td>Incidence</td>
<td>-</td>
<td>1/96=1.0%</td>
<td>2/42=4.8%</td>
</tr>
</tbody>
</table>
Figure 15: Trend Graph of Incidence of Low TSFT Values

- Column 1
- Series 2
- Column 2

Day 7: 1%
Day 14: 4.80%
DISCUSSION

The prevalence of malnutrition is a common problem in critically ill patients who are being ventilated mechanically and commonly goes unnoticed as most patients lack documented nutritional information [3, 18]. As there is no gold standard for determining the nutritional status of patients [21] and any one single method can have shortcomings, it is recommended to use two or three methods in parallel to overcome this problem [22,23] hence the choice of a combination of anthropometric and biochemical methods in this study.

The main aim of the study was to determine the incidence and prevalence of malnutrition while at the same time monitoring the changes in nutritional status of the critically ill mechanically ventilated patients in KNH CCU. The study identified some level of malnutrition in CCU patients with a variety of disease states. The criteria used to determine malnutrition were derived from previously published studies. Measurement of TSFT is indicative of body fat stores, MUAC measurements reflect skeletal protein muscle mass and the serum albumin level provides an index of visceral and somatic protein stores. KNH was chosen as the study site because its CCU is the largest in the country and also because it is affiliated to the college of Medicine, University of Nairobi, where training in critical care medicine is undertaken.

Majority of the patients recruited in the study were aged below 30 years (28.1%) followed by those between 30-39 years of age (27.1%). This shows that over 50% of our CCU population is mainly comprised of the youth below 40 years of age as opposed to CCU’s in the Western world where the greater proportion of critically ill patients are those of the geriatric age group.

The patients selected for the study were a heterogeneous group with a wide array of diagnoses. 70.8% of them were male while females comprised of 29.2%. 30 of the patients (31.25%) had a diagnosis of severe head injury which accounts for the most common indication for admission in the KNH CCU. Of the 30 patients with severe head injury, only 1 of them was female and this would probably indicate that the male gender may be involved in activities that expose them to the risk of trauma than their female counterparts.

In as far as co-morbidities are concerned, 81 (84.38%) of the patients recruited into the study had no co-morbid illnesses.
This is probably because of the fact that majority of the patients in the study were young and thus had no risk factors for development of comorbid illnesses. 10 (10.42%) had hypertension, 2 (2.08%) renal failure, 2 (2.08%) diabetes mellitus and 1 patient (1.04%) had pulmonary tuberculosis.

It is important to note that all the patients recruited in the study received their nutrition via the enteral route and this may have had an impact on the final results [11].

Albumin, constituting 60% of protein in humans, is a biochemical marker of visceral protein status. Low levels of albumin (<35 g/L or 3.5g/dL) in an acutely ill patient indicate a depletion of body protein. It is also one of the negative acute phase reactants reported to fall as a component of metabolic response to injury or infection, independent of the nutritional status. Other mechanisms proposed include hemodilution, decreased synthesis and also increased protein catabolism. Normal range of human serum albumin in adults is 35 to 50 g/L (3.5-5g/dL). Various studies have suggested serum albumin to be a valuable nutritional assessment tool and prognostic indicator in critically ill patients [26, 27].

In this study, the prevalence of hypoalbuminaemia was noted to be 63.5%, 85.5% & 86.4% at admission, 7 days & 14 days respectively. Gender had no significant association with degree of changes in albumin levels with a p-value of 0.099. Age on the other hand showed a significant association with the degree of changes in albumin levels with a p-value of 0.041. The incidence of low albumin levels was 9.4% at 7 days followed by an incidence of 14.4% at 14 days. Gender specific incidence was noted to be at 7.3% at day 7 and 11.4% at day 14 for males while it was lower in the females at 2.1% at 7 days and 2.9% at 14 days.

High albumin levels of above 5g/dL were noted in 4.2% and 2.4% of the patients at 7 days and 14 days respectively. Hyperalbuminaemia is almost always caused by dehydration or in some cases of Vitamin A deficiency.

Assessment of muscle mass can provide an index of protein reserves of the body. MUAC correlates with measures of total muscle mass and therefore can be used to predict changes in protein nutritional status [25]. In this study, at admission mean MUAC values were within normal at >28cm. This can be explained by the fact that majority of our CCU admissions are as a result of acute events and not chronic illnesses, which are associated with loss of muscle bulk. Hence the patients with acute illnesses exhibited normal muscle bulk at admission.

On reassessment at 7 and 14 days the MUAC values remained within the normal range though with a slight decrease in the mean values regardless of age or gender.
Critically ill patients on mechanical ventilation are prone to loss of muscle tissue as a result of decreased nutritional intake or inadequate nutritional supplementation or even the hypercatabolic state of critical illness [5, 19].

This would explain the slight drop in the mean MUAC over the follow up period. In as far as gender is concerned, female patients exhibited higher mean MUAC values (29.9cm) at admission than males (27.5) which was statistically significant at a p-value of 0.04. This reflects the fact that females tend to have a higher body fat percentage than males and may offer an explanation for the difference in MUAC between the genders.

Fat is the main storage form of energy in the body and is sensitive to acute malnutrition. Thus alterations in body fat content provide indirect estimates of changes in energy balance.

At admission, 27.1% (26) of the patients had TSFT values within normal, 26% (25) had low values indicating depletion of fat stores and therefore some level of undernutrition. Interestingly, 46.9% (45) of the patients were noted to have above normal skin thickness values indicative of an excess of stored fat and this is highly correlated with many health indices e.g. morbidity/mortality, hypertension and Type 2 diabetes.

The mean TSFT values neither showed significant increase nor decrease over the follow-up period. Our patients neither lost nor gained fat reserves during their stay in CCU; however, a longer follow up period would probably be more informative in this respect.

The incidence of low TSFT values was 1% at 7 days & 4.8% at 14 days showing a slight increase. Female patients were noted to have higher mean TSFT values than males throughout the follow-up period. This finding probably reflects the fact that males tend to have a lesser proportion of body fat percentage compared to females. Studies have shown that the fat content of women is higher than that of men representing 26.9% of their total body weight compared with 14.7% for men.

Whereas the conclusion that patients' outcome is adversely affected by a poor nutritional status is not new or startling, malnutrition continues to be a persistent problem in hospitalized patients, which can be readily identified using simple and easily available indices and, furthermore, readily treated.
7.0 CONCLUSION

• Some deterioration in the nutritional status of patients during their stay in CCU was apparent, with a decline in mean MUAC, mean TSFT and albumin levels over the follow up period.

• Low albumin levels at admission suggested that the nutritional status for most patients was poor prior to admission to the unit and declined further during their stay in the ICU.

• This audit however cannot be used to recommend treatment for the low albumin levels noted in these patients. The objective of the study was just to determine the prevalence and incidence of hypoalbuminemia in this group of patients. Furthermore, studies have not shown that the therapeutic "normalisation" of albumin levels in critically ill patients is beneficial. Indeed the Cochrane group's recent "meta" analysis suggests a higher mortality rate in critically ill patients treated with albumin.
8.0 RECOMMENDATIONS

- Encourage the practice of nutrition evaluation in intensive care particularly amongst the physicians as this role has solely been left to the nutritionists.

- Establish guidelines for feeding critically ill patients at KNH CCU.

- A follow-up study to document a causal relation between malnutrition and its impact on morbidity and mortality in CCU patients can be conducted.

- Further research with a larger sample of patients and for a longer follow-up period should be conducted to expand our understanding of nutritional status for critically ill patients in our setting.

- Research needs to be carried out to come up with local age, gender and even ethnic specific anthropometric values that can be utilised in local nutritional studies.
9.0 LIMITATIONS

- The group of patients recruited in this study was heterogenous; it might have been preferable to study patients with a single pathology in detail.
- The relatively small sample size used may have limited the power of the study or hindered the ability to detect differences between the groups.
- Time constraint.
- Anthropometric measurements are affected by factors such as age, gender and ethnicity. The lack or limited availability of local data of normal anthropometric values was a huge drawback in the conduction of this study.
List of References

1. The impact of malnutrition on morbidity & mortality, length of hospital stay and costs evaluated through a multivariate model analysis; Clinical Nutrition, Vol 22, issue 5, Pg 235.


9. The route of nutrition support in critically ill; Physiologic and economic Considerations; Nutrition, Vol 13, issue 9, Pg 58-63.

10. Bruce bristian, David Driscoll; Enteral and parenteral therapy; Harrisons principles of internal medicine, chapter 13, Pg 456.


22. Quirk J. 2000, Malnutrition in critically ill patients in ICU’s, British journal of nursing, Vol 9, Pg 537-541.


Appendix 1: Harris Benedict Equation

Women = 66.5 + (9.6 X weight in kg) + (1.85 X height in cm) - (4.7 X age in years)

Men = 66.5 + (13.7 X weight in kg) + (5.0 X height in cm) - (6.8 X age in years)

Calorie requirements/day = 1.25 X BMR (for each 1°C above 37 add 10% extra allowance)

Appendix 2: Budget

<table>
<thead>
<tr>
<th>DESCRIPTION OF EXPENSES</th>
<th>APPROXIMATE COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Fold Calipers</td>
<td>10,000</td>
</tr>
<tr>
<td>Statistician</td>
<td>10,000</td>
</tr>
<tr>
<td>Stationery</td>
<td>5,000</td>
</tr>
<tr>
<td>MUAC Tapes</td>
<td>2,500</td>
</tr>
<tr>
<td>Photocopy/Printing</td>
<td>2,500</td>
</tr>
<tr>
<td>TOTAL</td>
<td>30,000</td>
</tr>
</tbody>
</table>

NB: The expenses incurred in this study will be met by the researcher. No external source of funding has been solicited.

APPENDIX 3: WORK PLAN.

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>2009 July</th>
<th>2009 Sept</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal Writing</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Presentation to Ethical Review Committee</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Data Collection</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Data Processing</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Report Writing</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Study Presentation</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4A: Specific Reference Values for MUAC.

MUAC values for severe acute malnutrition (SAM) for adults <16 centimetres irrespective of clinical signs or between 16-18.5 centimeters plus one of either oedema, inability to stand or apparent dehydration.
MUAC values for moderate acute malnutrition (MAM) for adults -16 -18.5 centimetres.
MUAC values for mild acute malnutrition- 22-22 centimetres.

Source: IMAM guideline, June 2009

Appendix 4B: Specific Reference Values for TSFT.

Males 7.3- 12.5 millimeters

Females 9.9-16.5 millimeters

Source: Assessment of the nutritional status of the community, WHO Issue No. 53.
Appendix 5: Research Instruments

Part 1:- Data Collecting Tool

A) SOCIO-DEMOGRAPHIC HISTORY

Patient ID Number.................................

1) Age in years

2) Gender
   1= Female 2= Male

3) Marital status
   1=Single 2=Married 3=Divorced 4=Widowed

B) MEDICAL HISTORY

1) Primary Diagnosis
   1=Head Injury 2=CVA 3=DKA 4=Hypertension
   5=Renal Failure 6=Sepsis 7=Post-operative 8=Others (specify)

2) Comorbid Disease
   1=Infection 2=Diabetes 3=Hypertension 4=Renal Failure
   5= Others (Specify)
PART 2: Anthropometric Assessment/Serum Albumin Results Table

<table>
<thead>
<tr>
<th>ID Number</th>
<th>Average MUAC</th>
<th>Average TSFT</th>
<th>Serum Albumin g/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
Appendix 6: Informed Consent Form

Part 1: Information Sheet

Introduction
You are invited to participate in a study conducted by Dr. James C. Mumba, a third year resident in the Masters in Medicine anaesthesia program. I am conducting a review on the nutritional status of critically ill patients admitted in the Kenyatta National Hospital Critical Care Unit. I will strive to answer any queries that may arise before and during the course of the study.

Purpose of the study
The objective of this study is to determine the nutritional status of critically ill patients admitted in the Kenyatta National Hospital Critical Care Unit.

Type of Research Intervention
During the study, your nutritional status will be determined at admission and after 7 and 14 days post admission respectively. This will be done by taking measurements of your upper arm, using a special tape measure to determine its circumference and a special caliper to determine the thickness of the skin fold behind your arm. Further, blood will be drawn as part of the routine investigations done in the CCU and the levels of a protein called Albumin assessed.

Participant Selection
You were selected to participate in the study using the stratified random selection.

Voluntary Participation
Your participation is voluntary. Refusal to participate or withdrawal of your consent or discontinued participation in the study will not result in any penalty or loss of benefits or rights to which you might otherwise be entitled. The principal investigator may at his discretion remove you from the study for any of a number of reasons. In such an event, you will not suffer any penalty or loss of benefits or rights which you might otherwise be entitled.
Duration

The research takes place over a period of four months in total but each participant will be followed up from admission and at 7 days and 14 days where applicable.

Risks

You will neither be exposed to any risk nor any added cost to you by participating in this research.

Benefits

There may be no personal benefit from your participation but the knowledge received may be of value to humanity.

Confidentiality

Your anonymity will be maintained during data analysis and publication/presentation of results by any or all of the following means: (1) You will be assigned a number as names will not be recorded. (2) The researchers will save the data file by your number, not by name.

Whom to contact

If you have any questions about this study, you should feel free to ask them now or anytime during the study by contacting:

Dr James C. Mumba, (Researcher)-0722733239 or email chitibzy@yahoo.com.

Prof. Zipporah Ngumi, (Supervisor)-0722218921
PART 2: Certificate of Consent

I understand the nature of this study and agree to participate. I received a copy of this form. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I give the principal investigator permission to present this work in written and/or oral form for presentation to advance the knowledge of science and/or academic without further permission from me provided that my name or identity is not disclosed.

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

Statement by the researcher/person taking consent

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

Name of Researcher ____________________________

Signature of Researcher ____________________________

Date ____________________________

Day/month/year
Kibali Cha Mgonjwa

Unaalikwa kushiriki katika utafiti utakaotekelezwa na Dr. James .C. Mumba.Lengo la utafiti huu ni kuchunguza hali ya kiafya ya wagonjwa mahututi waliolazwa katika chumb cha wagonjwa mahututi cha hospitali kuu ya Kenyatta.Hali hii itabainishwa wakati wa mgonjwa kulazwa na baada ya siku saba na kumi na nne mtawaliya.Hii itafanywa kwa kuchukua vipimo vya mkono (upana na uzito wa mkunjo wa ngozi) kutumia utepe na kifaa maalum.Damu pia itachukuliwa kwa vipimo vya kawaida vya hospitali na kiwango cha madini spesheli (Albumin) kubainishwa.

Hakutakuwa na malipo yoyote zaidi kw kushiriki katika utafiti huu.Huenda kusiwe na faida kw kushiriki binafsi kwa kushiriki bali elimu itakayopatikana itakuwa ya manufa kwa binadamu wote kwa jumla.

Utashiriki kwa hiari yako mwenyewe na hata ukikataa au kujiondoa, hutaadhibiwa wala kunyimwa haki zako zozote.Mchunguzi naye pia ana uhuru wa kukuondoa katika utafiti kwa sababu moja au nyingine.

Matokeo ya utafiti huu hayatafichuliwa hadharani na majina ya washiriki hayatatumika bali nambari tu ndizo zitakazotumika.

Ukiwa na maswali yoyote kuhusu utafiti huu,wasiliana na Dr James .C. Mumba kupitia nambari ya simu 072273339 au barua pepe chitibzy@yahoo.com.


Tarehe............................... Sahihi..............................
KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd.
P.O Box 20723, Nairobi.
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP*, Nairobi.
Email: KNHolan@Ken.Healthnet.org
9th April 2010

Dear Dr. Chitibwi

RESEARCH PROPOSAL: "ANTHROPOMETRIC AND BIOCHEMICAL ASSESSMENT OF THE NUTRITIONAL STATUS OF CRITICALLY ILL MECHANICALLY VENTILATED PATIENTS AT THE KENYATTA N. HOSPITAL CRITICAL CARE UNIT" [P14/01/2010]

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and approved your above revised research proposal for the period 9th April 2010-8th April 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 studies so as to minimize chances of study duplication.

Yours sincerely

PROF N GUANTAI
SECRETARY, KNH/UON-ERC

CC: Prof. K. M. Bhatt, Chairperson, KNH/UON-ERC
The Deputy Director CS, KNH
The Dean, School of Medicine, UON
The Chairman, Dept. of Surgery/Apaeesthesia, UON
The HOD, Records, KNH
Supervisor: Prof. Zipporah Ngumi, Dept. of Surgery/Apaeesthesia, UON