THE EFFECT OF THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN CHILDREN, SOUTH AFRICA

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College of Agriculture, Engineering and Science

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DECLARATION OF ORIGINAL WORK

I Magda (MM) Botha, declare that:

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Magda (MM) Botha (Candidate)

PREFACE

The work within this thesis was conducted in the School of Agricultural, Earth and Environmental Sciences, College of Agriculture, Engineering and Science at the University of KwaZulu-Natal under the supervision of Prof Susanna Maria Kassier and Prof Frederick Johannes Veldman.

The research represents the original work by the author and has not otherwise been submitted in any form for any degree or diploma at any other university. Where applicable, the work of others is acknowledged in text.

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Date 29 March 2021

Prof Susanna Maria Kassier (Co-Supervisor)

Signed 

Date 29 March 2021

Prof Frederick Johannes Veldman (Supervisor)

Signed 

Date 29 March 2021

DEDICATION

This thesis is dedicated to my family. To my father, that always encouraged me and told me that nothing was impossible. To my loving and supportive mother, Marie, sister Rachel, family Thinus, Jacques, Chinèlle and Annelize; thank you for all the love, care, support and encouragement and for believing in me. To Alex, Chris, extended family, friends and colleagues: "Thank you so much for your prayers, support and encouragement during my studies. I really appreciate each and every one of you for being a valuable part of my life!". And lastly, but most importantly: "Lord God, thank you for the opportunity that You have brought into my life to embark on this study. I dedicate all of these results to You and pray that it may be used to the benefit of Your Kingdom to save the lives of Your precious infants and young children."

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- A number of key individuals have contributed to the development of this thesis from the development of the topic to completion. I wish to recognize my supervisors Prof S. Kassier and Prof F. Veldman. A special word of thanks to Prof Kassier for her tireless support and for vigorously and willingly reviewed my work throughout the various stages of completion. Without their guidance and encouragement, I would not have reached the submission stage.

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- Thank you to Ms. Andiswa Ngqaka who assisted me with obtaining gatekeeper permissions.

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- Lastly, I want to acknowledge the passion, hard work and commitment of every fieldworker. Thank you so much for traveling daily for 3-4 consecutive months to the hospitals to collect data. The preciseness of the data collected by you contributed profusely to the success of this study!

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ABBREVIATIONS

ATNF	Access to Nutrition Index
BREC	Biomedical Research Ethics Committee
CDC	Centres for Disease Control and Prevention
CEO(‘s)	Chief Executive Officer(s)
CFR	Case Fatality Rate
CI	Confidence Interval
CM	Centimetre
DHIS	District Health Information Systems
DHS	Demographic and Health Survey
DOH	Department of Health
EFB	Exclusive Breastfeeding
FAO	Food and Agriculture Organization of the United Nations
G	Gram
GAP	Global Action Plan
GOBI-FFF	Growth Monitoring, Oral Rehydration Therapy, Promotion of Breastfeeding, Immunisation, Female Education, Family Planning and Food Supplementation
HFIAP	Household Food Insecurity Access Prevalence
HHFIA	Household Food Insecurity Access
HFIAS	Household Food Insecurity Access Scale
HHFIS	Household Food Insecurity
HIV	Human Immunodeficiency Virus
IAP	Indian Association of Paediatricians
INP	Integrated Nutrition Program
IV	Intravenous
IYC	Infants and Young Children
KCAL	Kilocalorie
KG	Kilogram
LARI(‘s)	Lower Acute Respiratory Infection(s)
LBW	Low Birth Weight

MAM	Moderate Acute Malnutrition
MDG	Millennium Development Goals
MG	Milligram
MUAC	Mid-upper Arm Circumference
NCHS	National Centre for Health Statistics
NDOH	National Department of Health
OPD	Out-patient Treatment Department
ORS	Oral Rehydration Salts Solution
PACSA	Pietermaritzburg Agency for Community Social Action
PEM	Protein Energy Malnutrition
PEMP	Protein Energy Malnutrition Program
PHC	Primary Health Care
Q	Question
RA	Research Assistant
RTHC	Road to Health Chart
RUTF(‘s)	Ready-to-be-use Therapeutic Feed(s)
SA	South Africa
SADHS	South Africa Demographic and Health Survey
SAM	Severe Acute Malnutrition
SASSA	South African Social Security Agency
SD	Standard Deviation
SDG	Sustainable Development Goals
SMHSU	Sefako Makgatho Health Science University
SPSS	Statistical Package for Social Sciences
STATS SA	Department of Statistics in South Africa
TB	Tuberculosis
TFR	Total Fertility Rate
TTO	To Take Out
UKZN	University of KwaZulu-Natal
UN	United Nations
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children’s Fund

UN IGM	United Nations Inter-Agency Group for Child Mortality Estimation
USAID	United States Agency for International Development
WASH	Water, Hygiene and Sanitation
WFP	World Food Program
WHO	World Health Organization
WHZ	Weight-for-Height z-score

CONTRIBUTIONS TO THESIS

All research data was collected by provincial study coordinators and local fieldworkers. Data was coded and entered by Magda Botha and verify by research assistant, Ms. Marie Botha. Technical advice regarding data entry and statistical analysis was given by Professor Fredrick Veldman and Dr. Suna Kassier.

A photo of the provincial study coordinators and fieldworkers who assisted with data collection:

EASTERN CAPE:

- Welfare Diko — Provincial study coordinator
- Liatile Tshona — Provincial study coordinator
- Rejoice Chili — Fieldworker: Mthatha Regional Hospital
- Princess Mpakati — Fieldworker: St. Barnabas Hospital
- Nolufefe Lwandle — Fieldworker: St. Patrick's Hospital
- Nombulelo Mofokeng — Fieldworker: St. Elizabeth's Hospital
- Cynthia Sibidla — Fieldworker: Holy Cross Hospital

GAUTENG:

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- Theresa Mandlate — Dr. George Mukhari Academic Hospital
- Dinte Matjiane — Jubilee Hospital
- Mmaphuti Livhuwani — ODI Hospital

MPUMALANGA:

- Lizette Janse van Rensburg — Provincial study coordinator
- Nedsingashe Vhushavhelo — Fieldworker: Middelburg Hospital
- Mirriam Qwaba — Fieldworker: Standerton Hospital
- Fortunate Mkhatshwa — Fieldworker: Shongwe Hospital
- Andizolele Moyeni — Fieldworker: Kwa-Mhlanga Hospital

FREE STATE:

Absent from the photo:

- Dineo Mopeli, — Provincial study coordinator & Fieldworker: Elizabeth Ross Hospital
- Ntsoaki Moloi — Fieldworker: Mofumahadi Manapo Mopeli Regional Hospital
- Maggy Mhkonza — Fieldworker: Thebe Hospital

ABSTRACT

Globally, 14.3 million infants and young children (IYC) suffer from severe acute malnutrition (SAM), with 75% living in low and low-middle income countries like South Africa (SA). Inpatient management of SAM forms an essential component of SAM treatment among IYC. In SA, the SAM treatment protocol is based on the World Health Organization (WHO) Ten Steps to the successful management of SAM. As a result of SA efforts, the SAM mortality rate decreased from 12,7% in 2012 to 8% in 2017, being below the global and national target of 9%. The study aim was to determine if compliance with the national SAM treatment protocol improves SAM treatment outcomes. A multi-centre prospective, descriptive and comparative observational study was employed. IYC hospitalized for SAM treatment (N=245) were conveniently sampled. The study sample comprised of 150 males (61.2%) and 95 females (38.8%) with a mean age of 14.6 ± 8.2 months. Mean admission and discharge weight, height-for-age and MUAC was 6.63 ± 1.89kg and 7.03 ± 2.02kg; 66.16 ±16.06 cm and 71.29 ± 11.47 cm, and 11.38 ±2.35cm and 11.51±2.35cm. There was a significant difference between mean admission and discharge weight (p= 0.0278) and height-for-age (p= 0.0005), with no significant difference between admission and discharge MUAC (p= 0.6533). Prevalence of mild, moderate and severe oedema was 21.7%, 11.1% and 8.2% respectively. The study sample had a mortality rate of 6.1%. SAM treatment was complicated by LARIs, sepsis, HIV, TB, anaemia, herbal intoxication, vomiting, hypoglyceamia and cerebral palsy. Using the designed scoring tool, overall compliance with the SAM treatment protocol was 63.1%, with 98.6% compliance with admission and 4.4% compliance with discharge standards. Nearly three out of ten (27.2% of households) were food insecure, of which 14.6% were moderately and 10.7% severely food insecure. Food insecurity was associated with delayed recovery from oedema (X^2= -0.235; 0.035) and diarrhoea (X^2= -0.199; 0.037), inadequate daily weight gain of less than 10g/kg/day (X^2= -0.190; 0.003) and IYC mortality (X^2= -0.131; 0.522). These associations define HHFIS as a predictable risk factor for poor SAM treatment outcomes, recovery and possible mortality. Compliance with the SAM treatment protocol was average (61.3%), with premature discharge, increasing the risk for relapse, readmission and mortality. A cyclic link between HHFIS and the outcome of inpatient management of SAM should be considered when revising and updating national SAM treatment protocols.

CHAPTER 1

PROBLEM STATEMENT

1.1.INTRODUCTION & IMPORTANCE OF THE STUDY

Historically, the prevention and treatment of severe acute malnutrition (SAM) was unclear and not well described (Briend, Prudhon, Weise Prinzo, Daelmans & Mason, 2005). Although the World Health Organization (WHO) designed and published an inpatient protocol for the management and treatment of SAM, this protocol was not well implemented because of poor hospital capacity and the unavailability of effective, suitable products (WHO, 1999; Ashworth, 2005; Briend *et al.*, 2005, Mambulu-Chikankheni, Eyles, Eboreime & Ditlopo, 2017). The first step in the transformation of the treatment of SAM came with the development, affordability and availability of new therapeutic foods. These therapeutic foods included a high energy milk product and energy-dense pastes (Ashworth, 2005; Lenters, Wazny, Webb, Ahmed & Bhutta., 2013; Versloot, Voskuijl, van Vliet, van den Heuvel, Carter, Phiri, Kerac, Heikens, van Rheenen & Bandsma, 2017).

The outcomes of this study can be used by global and national policy makers and program designers to strengthen SAM treatment protocols to contribute to the reduction of infant and young child (IYC) mortality. These research findings can also guide implementers of the guidelines to improve the quality of health services provided to malnourished IYC and strengthen multidisciplinary team collaboration in achieving the same goal when treating an IYC hospitalised for the management of SAM. In addition, the association between household food insecurity status (HHFIS) and inadequate inpatient SAM recovery highlights the importance of liaising with other government departments and non-government organisations to improve the living conditions of malnourished IYC and their mothers/caregivers. Furthermore, political support is needed to facilitate decision making and legislate programme and policy changes.

1.2.PROBLEM STATEMENT

Although the global mortality rate for IYC under five years of age has reduced by almost 60% since 1990, under-five mortality remains the highest in Sub-Saharan Africa at 53%

(United Nations Inter-agency Group for Child Mortality Estimation (UN IGME), 2020; Ghazawy, Bebars & Eshak, 2020; Obasohan, Walters, Jacques & Khatab, 2020). Unfortunately, SAM accounts for 50% to 60% of deaths amongst hospitalised IYC, with about one-fourth of inpatient SAM IYC mortality during hospitalisation (Mambulu-Chikankheni *et al.*, 2017; Ghazawy *et al.*, 2020). Globally, as within South Africa (SA), the approach to managing SAM is standardized. Initially, health facilities implemented the WHO SAM inpatient management Ten Step protocol, which recommends resuscitation, stabilization and rehabilitation phases (WHO, 1999, Mambulu-Chikankheni *et al.*, 2017; Ghazawy *et al.*, 2020). However, various countries designed in-country and institutional protocols for the management of SAM, based on these WHO SAM protocol, within the local context (Mambulu-Chikankheni *et al.*, 2017). In SA, the SA protocol for the management and treatment of SAM, which was based on the WHO Severe Malnutrition inpatient management Ten Step protocol, was published and available for implementation in 2015 (NDOH, 2016).

Despite adopting and implementing these protocols for the management and treatment of SAM since 2006 in SA, case fatality rates (CFR) for SAM remained by 2015 higher than the global and national target of 9% at 11.6% (NDOH, 2015; Bamford, McKerrow, Barron & Aung, 2018). However, in 2018, Bamford *et al.* reported that the CFR for SAM reduced from 11.6% in 2015 to 8% in 2017. The SAM CFR in Eastern Cape and Free State was in 2017 higher than the national target of 9%, at 10.2% and 9.6% respectively. However, the CFR for SAM in both Mpumalanga and Gauteng was below the national target at 8,4% and 6,5% respectively (NDOH, 2016; Bamford *et al.*, 2018).

Both the WHO and SA SAM treatment protocols described that IYC hospitalized for the management of SAM, must receive a starter therapeutic feed (also known as F-75) within 24 hours of resuscitation and stabilization. The purpose of this starter therapeutic feed is to promote recovery of the metabolic function and nutrition-related electrolyte imbalance. Following successful rehabilitation, IYC are fed a follow-up therapeutic feed (commonly known as F-100), which is a follow up formula used to accelerate weight gain (WHO, 1999; Lenters *et al., 2013;* NDOH, 2015).

Both these formulae are mostly milk-based with added vitamins and minerals with the aim to supply a specific nutrient content to the severely acute malnourished child as suggested by the WHO protocol (WHO, 1999; Lenters *et al.*, 2013; NDOH, 2015; Mambulu-Chikankheni *et al.*, 2017). F-75 and F-100 are either commercially available as ready-to-use products or prepared on-site in hospitals, using local ingredients. The macronutrient content of the hospital-based prepared formulae is similar to that of the commercially available F-75 or F-100 products. However, the micronutrient content of the hospital-based prepared formulae depends on whether or not the commercially available micronutrient pre-mix have been added to the milk-based formulae or not (NDOH, 2015, UNICEF, 2020).

Prepared or opened F-75 and F-100, although extremely effective in managing cases of SAM, is very susceptible to microbial contamination and, as a result, should not be stored for more than a few hours (Marino, Goddard, Whitelaw & Workman, 2007; Crawley, Westland & Sibson, 2020, UNICEF, 2020). F-75 (75 kcal or 315 kJ/100 ml), is used during the initial phase of treatment, while F-100 (100 kcal or 420 kJ/100 ml) is used during the transition and rehabilitation phases, after the appetite has returned (WHO, 1999; Lenters *et al.*, 2013; NDOH, 2015). Where sufficient resources are available, the inpatient treatment model for the management and treatment of SAM can achieve low CFR. However, exclusive inpatient treatment strategies are resource-intensive and require many skilled staff (Trehand & Manary, 2020). In addition, resource poor health facilities do not always offer a safe environment where these products can be prepared. Because the prevalence of SAM is the highest in resource-poor environments, there is usually a substantial mismatch between the many patients requiring treatment and few skilled staff and scarce resources available to treat them (WHO, World Food Programme, United Nations System Standing Committee and United Nations Children's Fund (UNICEF), 2007; Trehand & Manary, 2020).

The WHO has granted approval to companies to formulate products with similar nutrient profiles to F-75 and F-100, but ready-to-be-used (WHO, 2013; UNICEF, 2020). These ready-to-be-use therapeutic feeds (RUTFs) have greatly eased the difficulties associated with providing a suitable high energy, nutrient-dense food that is safe to use. In addition,

they solve a considerable number of problems related to the original F-75 and F-100, such as storage, shelf life, preparation time, incorrect preparation, contamination and availability (Lenters *et al.*,2013, UNICEF, 2020).

In SA, several local companies developed RUTF's similar in nutritional composition to the WHO-recommended F-75 / F-100 formulae used for the treatment of moderate acute malnutrition (MAM) and the testing of appetite to determine whether a child with SAM needs to be hospitalized for treatment or not (NDOH, 2015). These formulas are available on government tender and already used by hospitals throughout the country. An appropriate study to substantiate the use of these RUTFs in the treating SAM is required, as in many cases their use is based on anecdotal evidence and practicality. This study sought to determine and compare the effectiveness of therapeutic feeds, specifically focussing on F-75 and F-100 formulae, currently used in the management of SAM among IYC aged 6 months to 60 months.

1.3.STUDY SETTING

This study was conducted in SA. Based on accessibility to hospitals and approval from provincial health research departments, four provinces and sixteen hospitals were selected to collect data. The provinces selected for data collection were Eastern Cape, Free State, Gauteng and Mpumalanga. Stakeholders from the Department of Health (DOH) has used information and data from the district health information system (DHIS) to select districts and hospitals within the various provinces where the incidence of SAM is the most prevalent.

1.3.1. Operational definitions for the study

For the purpose of this study, the following definitions will be used to define the following terms:

- *Malnutrition:*

  Although the term malnutrition includes the concepts of wasting, stunting, underweight, overweight and micronutrient deficiencies (Bhutta, Das, Rizvi, Gaffey, Walker & Horton, 2013; NDOH, 2015; Akombi, Agho, Hall, Wali, Renzaho & Merom, 2017; WHO, 2020), for the purpose of this study, malnutrition was used to

describe acute underweight amongst IYC between the ages of 6 months and 5 years. Key concepts that will contribute to the definition of malnutrition include anthropometric indicators and clinical features of SAM (Mehta, Corkins, Lyman, Malone, Goday, Carney, Monczka, Plogsted, Schwenk & American Society for Parenteral and Enteral Nutrition (ASPEN) Board of Directors, 2013).

- *Undernutrition:*

  Undernutrition develops as a result of a nutrition deficiency that develops due to an inadequate consumption of food providing energy (carbohydrates and fats), protein or micronutrients or a poor absorption thereof (NDOH, 2015, WHO, 2020).

- *Severe acute malnutrition / SAM:*

  Acute malnutrition is also known as wasting and is classified according to levels of severity into moderate or severe acute malnutrition (NDOH, 2015). For the purpose of this study, SAM will be referred to as the weight-for- length / height of an IYC between the ages of 6 months and 5 years, which was below -3 SDs from the WHO Growth Standards mean for the same age and gender (Metha *et al.*, 2013; Akombi *et al.*, 2017). In addition to weight-for-length / height, a mid-upper arm circumference (MUAC) of less than 11.5cm in IYC aged 6–60months (circumference of child's left upper arm) or the presence of bilateral pitting pedal oedema are also used to describe SAM (NDOH, 2015; Ghosh-Jerath, Singh, Jerath, Gupta & Racine, 2017).

- *Wasting:*

  Wasting was defined as IYC 6 months to 5 years with a weight-for-length / height below -2 SDs from the WHO Child Growth Standards median for the same age and gender (Metha *et al.*, 2013; Akombi *et al.*, 2017).

- *Stunting:*

  Stunting was defined as IYC 6 months to 5 years with a length / height-for-age below -2 SDs from the WHO Child Growth Standards median for the same age and gender. In addition to this, IYC between 6 months and 5 years, with a length / height-for-age below -3 SDs from the WHO Growth Standards median for the same age and gender,

was identified as severely stunted (Metha *et al.*, 2013; De Onis & Branca, 2016; Akombi *et al.*, 2017).

- *Anthropometric measurements:*

  For the purpose of this study, anthropometric measurements refer to weight, length/height, mid-upper arm circumference (MUAC), growth (weight gain) (Metha *et al.*, 2013).

- *Clinical features of SAM:*

  For the purpose of this study, clinical features that will be included in diagnosis and monitoring of SAM, includes diarrhoea, oedema and lack of appetite (NDOH, 2015; Ghosh-Jerath *et al., 2017*).

- *SAM treatment protocol:*

  For the purpose of this study, SAM treatment protocol refer to the treatment guidelines for the in-hospital management and treatment of IYC with SAM, as described in the Operational guidelines for the integrated management of IYC with acute malnutrition in South Africa as published in 2015 and based on the 1999 and 2013 WHO guidelines for the ten steps to the management of SAM. This SAM treatment protocol consists out of three phases: stabilization, transition and rehabilitation phases (NDOH, 2015).

- *Cure rate:*

  For the purpose of this study, "cure rate" is defined as the percentage of IYC discharged from hospitals after receiving inpatient management of SAM. The following formula was used to calculate the SAM cure rate:

$$\text{SAM cure rate} = \frac{\text{Number of IYC admitted for inpatient management of SAM that has been discharged}}{} \times 100$$

Interpretation of the SAM cure rate was described as child mortality (percentage of IYC that passed away), defaulters (percentage of IYC that was transferred to other facilities and for which data was incomplete) and percentage recovery. Outcomes were interpreted according to the following standards as defined in Sphere standard 2.2. for the

management of SAM: Died <10%; Recovered >75%; Defaulted <15% (Sphere Association, 2018).

- *Compliance with the SAM treatment protocol:*

  For the purpose of this study, the following indicators were used to measure compliance to the SAM treatment protocol as a contributing factor to improved nutritional and clinical status as well as improved hospital recovery rate among IYC diagnosed with SAM:

  - A SAM treatment protocol must be available;
  - All health professionals involved in multidisciplinary team, caring and treating the severely malnourished child, must be trained on the SAM treatment protocol;
  - A RUTF appetite tested must be conducted to determine whether the child should be admitted for treatment or referred to the outpatient department (OPD);
  - Both F-75 and F-100 formulas must be available;
  - As strategy must be in place to replace F-75 and F-100 when these nutrition supplements are out of stock;
  - If therapeutic feeds are self-mixed at the hospital, the recipes as prescribed in the SAM treatment protocol must be followed to prepare F-75 and F-100 formulas;
  - A commercial vitamin and mineral mix are added to the self-mixed feeds;
  - The child must receive a therapeutic feed at casualty or immediately after arrival in the ward;
  - F-75 formula must be administered to the infant or child before admission or upon arrival at the ward;
  - The feeding regime must transition from F-75 formula to F-100 formula within a week (7 days) after admission;
  - Nutrition supplements must be prescribed and issued as treatment to take out (TTO) at discharge;
  - TOT nutrition supplements must last a month after discharge;

- The infant must be referred for follow-up to either come back to the hospital where discharged or to the local clinic.

Neither the amount of each feed nor prescribed medication prescribed to the patient as part of SAM treatment was evaluated as a part to measure compliance to the SAM protocol.

- *Therapeutic feeds:*

  In this document the term therapeutic feeds were used as a collective name to refer to nutritional supplements (F-75 formula, F-100 formula and RUTF), prescribed and administered to patients as part of the stabilization, transition and rehabilitation of a severely malnourished child, hospitalized for treatment.

- *F-75 formula:*

  F-75 formula or also known as stabilizing feed refers to either a self-mixed or commercially available nutrition supplement, which provide approximately 75 kcal energy and 0,9 grams of protein per 100 ml formula. The nutrient content of the F-75 formula is described in table 1.1.

- *F-100 formula:*

  F-100 formula / rehabilitation / rebuilding / catch-up feed is a therapeutic feed prescribed and administered to the severely malnourished child after return of the child's appetite or when oedema is reduced or resolved. This formula provides 100 kcal energy and 2.5-3.0 gram of protein per 100 ml formula. The nutrient content of the F-75 formula is described in table 1.1.

- *Recipe for mixing of F-75 and F-100:*

  In the absence of commercially available F-75 formula or F-100 formula, a stabilizing and / or catch-up feed can be mixed at the hospital, using local ingredients such as full cream cow's milk, sugar, oil and water as demonstrated in table 1.2. A commercially available vitamin and mineral mix must be added to these ingredients to ensure that the micronutrient content of the self-mixed stabilizing / catch-up feeds are equal or similar to the standard F-75 and F-100 formulas described in table 1.1.

Table 1.1: Nutritional content of F-75 and F-100 formulas used for the treatment of SAM

F-75 FORMULA / STABILIZING FEED (containing per 100ml reconstituted feed)	**F-100 FORMULA / CATCH-UP FEED (containing per 100ml reconstituted feed)**
Energy 75 kcal	Energy 100 kcal
Protein 0.9 g	Protein 2.5–3.0 g
Fat 2.0 g	Fat 5.5–6.0 g
Carbohydrate 13 g	Carbohydrate 8–10 g
Vitamin A 150 mcg	Vitamin A 171 mcg
Vitamin D 3.0 mcg	Vitamin D 3.0 mcg
Vitamin B_1 0.07 mg	Vitamin C 10 mg
Vitamin B_2 0.2 mg	Vitamin B_1 0.1 mg
Vitamin B_6 0.07 mg	Vitamin B_2 0.3 mg
Vitamin B_{12} 0.1 mcg	Vitamin B_6 0.1 mg
Vitamin C 10 mg	Vitamin B_{12} 0.3 mcg
Folic acid 35 mcg	Vitamin K 4.0 mcg
Niacin 1.0 mg	Folic acid 40 mcg
Vitamin K 4 mcg	Niacin 1.0 mg
Calcium 32 mg	Calcium 91 mg
Phosphorus 24 mg	Phosphorus 76 mg
Magnesium 10.5 mg	Magnesium 15 mg
Potassium 157 mg	Potassium 209 mg
Zinc 2.0 mg	Zinc 2.2 mg
Selenium 4.7 mcg	Selenium 4.7 mcg
Copper 0.28 mg	Copper 0.26 mg
Iron < 0.03 mg	Iron < 0.06 mg
Sodium < 13 mg	Sodium < 46 mg
Osmolarity 280 mOsm / litre	Osmolarity 320 mOsm / litre

Source: NDOH, 2015

Table 1.2: Recipe for the mixing of a stabilizing or catch-up feed for the management of SAM

INGREDIENTS	Stabilizing feed / F-75	Catch-up feed / F-100
Full cream Cow's Milk	300 ml	880 ml
Sugar	100 g	75 g
Oil	20 ml	20 ml
Vitamin & Mineral Mix	1 scoop	1 scoop
Water: make up to	1000 ml	1000 ml

Source: NDOH, 2015

- *Ready-to-use therapeutic food (RUTF):*

  The reference to RUTF in the current study was used to define specialized ready-to-eat, shelf-stable products, available as pastes that are administered to IYC as part of the SAM treatment protocol to treat IYC with SAM. This RUTF is used for the appetite test. The nutrient content of the RUTF is similar to that of the F-100 formula as described in table 1.1 (NDOH, 2015).

- *RUTF appetite test:*

  Because a poor appetite is the only indication of severe metabolic malnutrition, a RUTF appetite test is performed to determine the child's appetite. A child with a poor appetite has a major infection or metabolic abnormality such as liver dysfunction, electrolyte imbalance and cell membrane / biochemical pathway damage, which increase the child's risk for death. The amount of RUTF that the child consume must be evaluated in the context of the child's weight. The outcome of this RUTF appetite test must be used to determine whether the child should be admitted to hospital or referred to the outpatient division for the management of SAM. All cases who fail the appetite test should be admitted for inpatient care (NDOH, 2015).

- *Participant / child / infant & young children (IYC):*

  For the purpose of the current study the terms “participant” or child was used to refer to an infant or child between the ages of 6 months and 5 years, hospitalized for the management and treatment of SAM.

- *Study conceptual framework:*

  This term is used to describe the framework in which the concept for the study was designed. This conceptual framework has been used to design the aim, objectives and hypothesis of this study. With this in mind, findings of the study were discussed referring to:

  - Causes and risk factors contributing to the manifestation of malnutrition applicable to this conceptual framework; and
  - Compliance to the SAM treatment protocol as a contributing factor to improved nutritional and clinical status as well as improved hospital recovery rate among IYC diagnosed with SAM.

- *Treatment outcomes:*

For the purpose of this study, the term treatment outcome will be used to describe the result or consequences (recovery status, relapse and re-admission of mortality) of IYC after SAM treatment protocols and guidelines have been implemented for inpatient management of SAM.

- *Household Food Insecurity:*

Household food insecurity (HHFIS) is defined as a situation where household members have limited access to food and nutrients, which support their daily individual requirements to meet nutritional requirements and attain optimum health (Coates, Swindale & Bilinsky, 2007). For this study, HHFS was measured using the household food insecurity access scale (HFIAS), which aims to measure various indicators associated with household food insecurity (HHFIS), including household food insecurity access related conditions and domains and HFIAS score and prevalence (Coates *et al.*, 2007).

1.3.2. Study conceptual framework

Various factors contributing to the development of SAM as seen in the UNICEF conceptual framework (UNICEF, 2013; Black, Lutter & Trude, 2020). As seen in figure 1.1. the management of SAM can be divided into preventative and curative measures. Various other sectors such as Department of Agriculture, Social Development, Water and Sanitation, Education and Land Affairs, together with DOH have projects that focus on addressing the various factors contributing to the manifestation of SAM. The health sector is responsible for the treatment of IYC with SAM. The purpose of this study was more focused on the in-hospital treatment of SAM to determine whether the implementation of a SAM treatment protocol and compliance thereto, can assist in the prevention and reduction of child mortality.

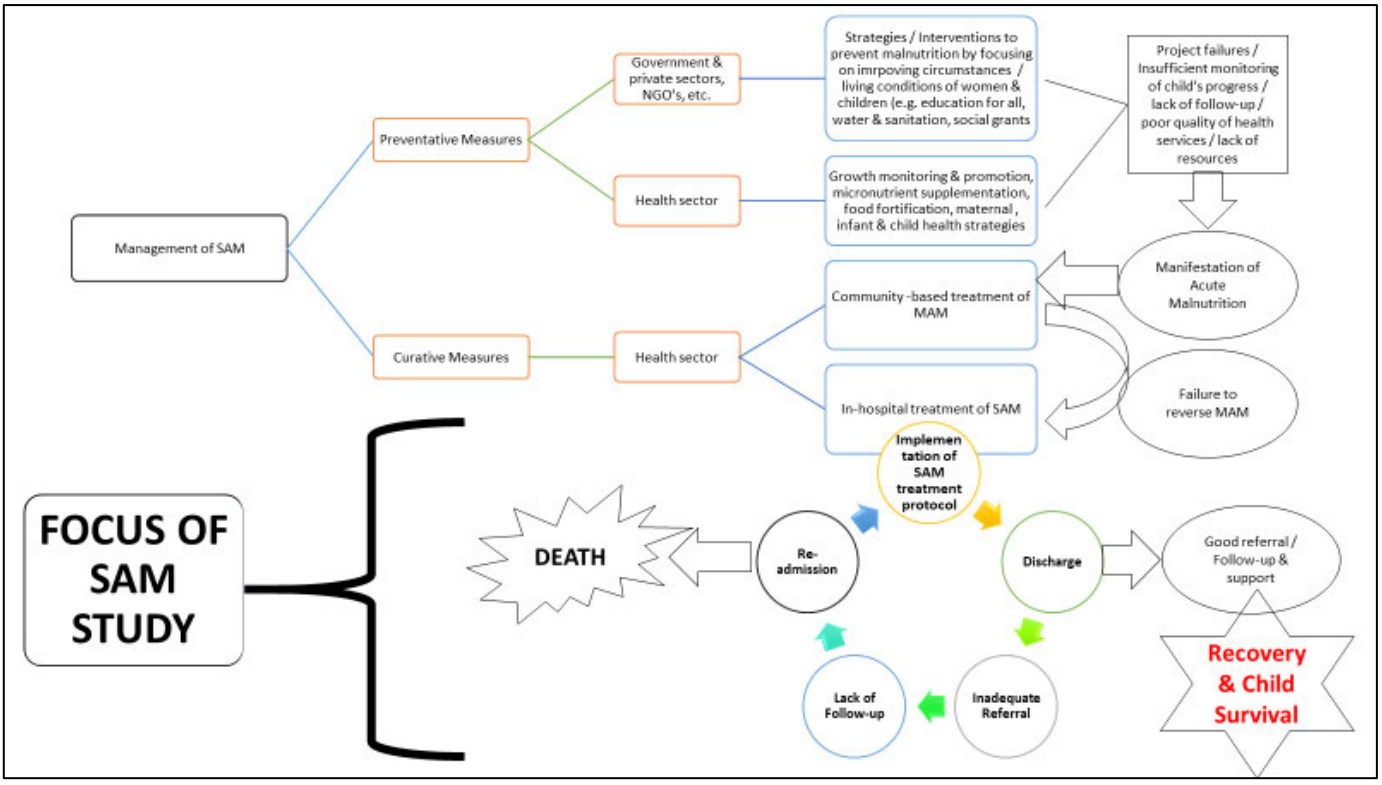

Figure 1.1: Study conceptual framework

1.4.AIM

The overall aim of this study was to determine and compare the effect of therapeutic feeds, specifically focussing on F-75 and F-100 formulae, currently used in the management of SAM among IYC aged 6 months to 60 months. With this in mind, the

main aim of the study was to establish if compliance with the feeding regimes as described in current international and national SAM treatment protocol would result in improved nutritional and clinical status and recovery rates among IYC diagnosed with SAM. The secondary aim was to determine and compare the treatment outcomes of hospitalized severely acute malnourished IYC receiving ready-to-use F-75 and F-100 in the management and treatment of their condition versus those receiving alternative therapeutic feeds or self-mixed therapeutic milk feeds.

1.5.OBJECTIVES

The objectives of this study were to:

- Determine the nutritional status of IYC admitted to hospital for inpatient management of SAM;
- Determine the clinical status of IYC admitted to hospital for management of SAM;
- Determine which therapeutics feeds was used as part of the SAM protocol at the selected facilities;
- Determine compliance to SAM treatment protocols and compare the rate of recovery by assessing length of hospital stay, subsided oedema and diarrhoea, return of good appetite and adequate weight gain of IYC admitted for inpatient management of SAM;
- Determine SAM recovery rate and follow-up practices and readmission of IYC after hospitalization;
- Determine the association between household food insecurity and SAM recovery.

1.6.HYPOTHESIS

For the purpose of the study, the following hypotheses were formulated:

H_0: Non-compliance with the feeding regimes as contained within the current SAM treatment protocol will not result in improved nutritional and clinical status as well as improved hospital recovery rate among IYC diagnosed with SAM.

H_1: Compliance with the feeding regimes as contained within the current SAM treatment protocol will result in improved nutritional and clinical status as well as improved hospital recovery rate among IYC diagnosed with SAM.

1.7.OUTLINE OF THE THESIS

The background to this study and research findings will be outlined in this thesis as follow:

Chapter 1:	Problem Statement
Chapter 2:	Literature Review
Chapter 3:	Research Methodology
Chapter 4:	The evolution of nutrition strategies for the management and treatment of severe acute malnutrition amongst young children
Chapter 5:	Nutritional Status of Infants and Young Children Admitted for Inpatient Management of Severe Acute Malnutrition
Chapter 6:	Compliance with Treatment Protocols for Inpatient Management of Severe Acute Malnutrition
Chapter 7:	Treatment outcomes for the inpatient management of severe acute malnutrition
Chapter 8:	Household Food Security Status of inpatient children with severe acute malnutrition
Chapter 9:	Synthesis, Conclusions & Recommendations

It should be noted that chapters 4, 5, 6, 7 and 8, will be presented as manuscripts for publishing purposes in peer-reviewed journals.

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CHAPTER 2

LITERATURE REVIEW

2.1. INTRODUCTION

According to the United Nations (UN) convention on the rights of the child, IYC have the right to life, irrespective of their race, colour, gender, or the political, cultural or religious orientation of their parents. In addition, all IYC have the right to enjoy the highest achievable standard of health care and access to health facilities to prevent or treat illnesses with accompanying rehabilitation care. In order to ensure that these human rights of IYC are respected and met, governments globally have the responsibility to provide healthcare and facilities which support IYC survival and to combat illness and malnutrition (UNICEF, 1998; SA Parliament, 2019).

As early as 2005, Briend *et al.* (2005) tabled the treatment of SAM as the "neglected disease" at the joint WHO/SCN/UNICEF meeting on community-based management of SAM in IYC. The absence of clear, effective, research-based prevention and treatment strategies was hypothesised as a possible reason for neglecting the treatment of SAM. However, the 1999 WHO recommendations for the in-patient treatment of SAM (WHO 1999), followed by the 2003 guidelines (Ashworth *et al.,* 2003), paved the way for improving and strengthening prevention.

In support of this, 191 UN member states, including South Africa (SA), in September 2000 committed to combat poverty, hunger, disease, illiteracy, environment degradation, and discrimination against women (UN 2000). Eight millennium development goals (MDG) were developed, for which targets had to be reached by 2015. MDG 1 and MDG 3 specifically focused on eradication of extreme hunger and poverty and to reduce IYC mortality. Although worldwide significant progress was made between 1990 and 2013 to reduce IYC mortality, the goal of reducing the under-five mortality rate by two-thirds has not been attained (WHO, 2018). Globally, under five mortality decreased by 59% from an estimated 93 deaths per 1000 live births in 1990 to 46 in 2013 and 38 in 2019 (Nannan, Dorrington, Laubscher, Zinyakatira, Prinsloo, Darikwa & Bradshaw, 2010; UN IGME,

2020). The SA under five mortality was an estimated 37 to 40 deaths per 1,000 live births in 2015, compared to 18 to 62 in 1997 (Bamford *et al.*, 2018).

In further support to reduce IYC mortality, on 25 September 2015, the UN General Assembly adopted the new development agenda "Transforming our world: the 2030 agenda for sustainable development" (UN 2015). Since 2016, the global focus was to transition from the MDG to the sustainable development goals (SDG) to ensure that the MDG targets which were not met in 2015, can be reached beyond 2015 to 2030 (WHO, 2015). The MDG were superseded by the SDG (Sachs, 2012). These seventeen goals are interconnected and provide a blueprint to succeed in providing a better, sustainable future for all (Sachs, 2012). The target set for SDG 3.2 is to globally reduce the under-five mortality rates to at least or less than 25 deaths per 1 000 live births by 2030. In support of this, SDG 1 aims to eradicate global poverty by 2030, while the purpose of SDG 2 is to reduce the number of individuals suffering from hunger, as measured by the prevalence of underweight, especially that of children under the age of five years (WHO, 2015).

Despite the universal right of IYC to be protected against malnutrition, IYC malnutrition remains a global challenge, threatening child survival, with 75% of the world's wasted children living in lower-to-middle income countries, including SA. In addition, these IYC are at a greater risk of developing malnutrition (Bamford *et al.*, 2018; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). Worldwide, 47 million IYC under the age of five years suffer from acute malnutrition, of which 14.3 million are severely malnourished. In Africa, 12.7 million IYC, suffer from acute malnutrition; with 3.5 million suffering from SAM (UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

Data released by the Department of Statistics in SA (STATS SA), indicated that more than 145 000 IYC suffered from acute malnutrition (STATS SA, 2019). Furthermore, acute malnutrition was identified as one of the major causes of death amongst IYC, since wasted IYC were 11 times more likely to die than a well-nourished child (Bamford *et al.*, 2018; WHO, 2020). Globally, the child mortality rate for children under the age of five years, was reported as 21.8% in 2017 (Global Hunger Index, 2019). In SA, the reported

national mortality rate for children under the age of five was 28.5% for the same year (STATS SA, 2019). Nationally and internationally, much was done to prevent the manifestation of malnutrition amongst IYC (Bamford *et al.,* 2018). As a result of SA efforts, the local SAM case fatality rate (CFR), reduced from 12.7% in 2012 to 8% in 2017, being below the global and national target of 9% (NDOH, 2016; Bamford *et al.*, 2018).

2.2. DEFINING MALNUTRITION

The term *malnutrition* is used as a collective term to refer to underweight, overweight and micronutrient deficiencies (WHO, 2016).

Underweight includes wasting, stunting and micronutrient deficiencies (Black, Allen, Bhutta, Caulfield, De Onis, Ezzati, Mathers & Rivera, 2008). Historically, underweight or malnutrition was commonly known as protein-energy-malnutrition (PEM) and categorised as marasmus (energy deficiency), kwashiorkor (protein deficiency) or marasmic-kwashiorkor (energy and protein deficiency) (Adamu, Omar, Namadi, Muhammad & Mashi, 2016; Ghosh-Jerath *et al.*, 2017). Today, "acute severe underweight" is incorporated into the blanket term "severe acute malnutrition", differentiating between SAM with or without complications (Cloete, 2015; Adamu *et al.*, 2016; Ghosh-Jerath *et al.*, 2017).

Stunting develops as a result of chronic malnutrition due to inadequate nutrition from as early as in-utero and in early childhood, especially the first two years postnatally (Briend, 2019). Stunting is recognised by a low length / height-for-age and stunted IYC may never have the ability to catch-up to their intended height in later years. Consequences of stunting include cognitive incapability due to restricted brain development in early childhood, and in later years learning disabilities, unproductivity, unemployment and poverty. Stunting is also associated with increased morbidity and mortality from infections such as pneumonia and diarrhoea, sepsis, meningitis, hepatitis and tuberculosis (Black *et al.*, 2008; De Onis & Branca, 2016; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

Wasting, also referred to as acute malnutrition, is a life-threatening condition and needs immediate health and nutritional intervention to improve child survival. Wasting is a direct cause of inadequate food and nutrient intake or may be disease-acquired. Wasted IYC are immuno-compromised and if emergency treatment is not provided, these IYC are at a greater risk of mortality, especially when they are severely malnourished (NDOH, 2015; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

In the context of household food insecurity due to unavailability of or inability to access food, the term hunger can also be used to refer to malnutrition. However, hunger is defined as a feeling of discomfort caused by a lack of consuming food. Malnutrition is of vital importance when assessing the nutritional and health status of an IYC (Black *et al.*, 2008).

2.3. PATHOPHYSIOLOGY OF SAM

SAM is aggravated by a deficiency of essential nutrients, which increase the risk of morbidity and mortality in IYC (Saurabh, Ranjan & Narayan, 2017). Each of these nutrient deficiencies determine the physiological response of the IYC to these deprivations (Kulkarni & Mamidi, 2019). The essential nutrients are categorised as either functional- or growth nutrients. Functional nutrients include iron, iodine, vitamin C and vitamin A and a deficiency of these micronutrients, result in tissue depletion, metabolic dysfunction and consequent ill health after the body's reserves have been depleted. Shortages of these micronutrients cannot be detected through anthropometric measurements, but present as clinical signs and symptoms. Growth nutrients such as potassium, magnesium, zinc, selenium and amino acids have the ability to interrupt growth and tissue repair in an attempt to conserve it (Picot, Hartwell, Harris, Mendes, Clegg & Takeda, 2012; Bhutta *et al.*, 2017). The body will break down its own tissue to ensure nutrient availability. Anthropometric measurements can be used to identify these deficiencies that manifest as wasting and stunting. Usually, a deficiency in growth nutrients is accompanied by a deficiency in one or more functional nutrients. SAM, in the presence of infectious diseases, initiates a downward cycle of tissue depletion and lowered resistance to disease. The pathophysiological responses to nutrient deficiencies

increase the risk of IYS suffering from SAM to life-threatening complications that ultimately result in death (NDOH, 2015; UNICEF$_a$, 2015).

2.4. CLASSIFICATION OF THE SEVERITY OF MALNUTRITION

In 1986, the WHO established the global surveillance system based on data compiled from child growth and malnutrition data of global nutrition studies conducted since the 1960's. The aim of establishing this surveillance system, was to collect, standardize and circulate child anthropometric data using a standardized format, with the surveillance system being globally used to monitor patterns and trends in IYC growth and malnutrition. In the past, scientists have been using these growth and malnutrition patterns and growth to define not only the health and nutritional status of IYC, but also to measure of socio-economic status indirectly. In 1990 the WHO Global Database on Child Growth and Malnutrition was established as a global standard for child growth data (De Onis & Blössner, 2003).

Globally it is recognised that weight, height and other anthropometric measurements should be used to determine malnutrition at a population level. In IYC, the most commonly used anthropometric indicators are weight-for-height, height-for-age and weight-for-age. These indices are expressed in terms of z-scores, percentiles or percentage of median, which enable comparison of a child or group of children to a reference population. The occurrence of wasting, stunting, underweight and overweight amongst preschool children are presented using z-scores based on the National Centre for Health Statistics (NCHS) / WHO international reference population (De Onis & Blössner, 2003).

2.4.1. Historic classification systems of malnutrition

Based on the standards set out in the WHO Global Database on Child Growth and Malnutrition, various classification systems have been established in developing countries over the past centuries to quantify the extent and severity of undernutrition (Naidoo, Padayachee & Verburgh, 1993). In this section, a few of these classification systems will be discussed.

The classification of malnutrition according to the WHO global database on child growth and malnutrition

As described in table 2.1, the WHO Global Database on Child Growth and Malnutrition uses a z-score cut-off point of less than -2 standard deviations (SD) to classify low weight-for-age (underweight), low height-for-age (stunting) and low weight-for-height (wasting) as moderate undernutrition and less than -3 SD to define severe undernutrition. The cut-off point of more than +2 SD classifies high weigh-for-age as overweight in IYC (Pelletier, 1995, De Onis & Blössner, 2003).

Classification of malnutrition according to weight-for-height, height-for-age and oedema

The nutritional status of IYC has also been classified according to weight-for-height, height-for-age and oedema as moderate malnutrition or severe malnutrition (table 2.2.). When an IYCs weight-for-age was below -3 SD or less than 70% of the median NHCS (termed "severely wasted"), or when the IYC has symmetrical oedema involving at least the feet (termed "oedematous malnutrition"), the IYC was classified as severely malnourished and was admitted to hospital for treatment (WHO, 1999).

Table 2.1: Classification of malnutrition based on the WHO Global Database on Child Growth and Malnutrition

Term	Description of classification
Underweight	Weight-for-age < -2 SD of NCHS*/WHO reference values, or < 80% of median weight-for-age.
Stunting	Height-for-age < -2 SD of NCHS*/WHO reference values, or < 90% of median height-for-age.
Wasting	Weight-for-height < -2 SD of NCHS*/WHO reference values, or < 80% of median weight-for-height.
Severe malnutrition	Severe wasting < -3 SD of reference (< 70% weight-for-height), or Severe stunting < -3 SD of reference (< 85% height-for -age), or The presence of oedema of both feet, or clinically visible severe wasting.
Overweight	Weight-for-height > +2 SD of NCHS*/WHO reference values.

** NCHS: National Centre for Health Statistics*

Source: Pelletier (1995)

Table 2.2: Classification of malnutrition according to weight-for-height, height-for-age and oedema

	Classification of Malnutrition	
	Moderate Malnutrition	**Severe Malnutrition**
Symmetrical oedema	No	**Yes** (termed "oedematous malnutrition")
Weight-for-height	-3 ≤ SD score < -2 (70-79%)	SD score < -3 (< 70%) (termed "severe wasting")
Height-for-age	-3 ≤ SD score < -2 (85-89%)	SD score < -3 (<85%) (termed "severe stunting")

Source: WHO (1999)

(i) WHO protein energy malnutrition (PEM) classification of 1971

In 1971, protein energy malnutrition (PEM) was classified as kwashiorkor, marasmic-kwashiorkor, marasmus, nutritional dwarfing or underweight by making use of clinical signs such as body weight, oedema and height (Passmore & Eastwood, 1986, p.281). Refer to table 2.3. for a description for this classification of malnutrition.

Table 2.3: WHO PEM classification of 1971

PEM Classification	**Body Weight As % Of Standard (50^{th} Percentile)**	**Oedema**	**Inadequate Weight-For-Height**
Kwashiorkor	60-80%	+	+
Marasmic-Kwashiorkor	< 60%	+	++
Marasmus	< 60%	0	++
Nutritional Dwarfing	< 60%	0	Minimal
Underweight IYC	60-80%	0	+

Source: Passmore & Eastwood (1986, p.281, Table 29.1)

(ii) Wellcome classification

The Wellcome classification for distinguishing between the various PEM syndromes referred to marasmus (loss of weight and severe underweight) when the weight of the IYC was less than 60% of the 50^{th} percentile (the standard or NCHS median). The clinical diagnosis of kwashiorkor focused on the presence of oedema with or without flaky paint dermatosis and ulcerations as seen in table 2.4. (Hansen, 1993).

Table 2.4: The Wellcome classification of PEM

Weight-For-Age (% Of Expected Weight-for-Age According to NCHS)	Oedema Present	Oedema Absent
60-80%	Kwashiorkor	Undernutrition
< 60%	Marasmic-Kwashiorkor	Marasmus

Source: Hansen (1993)

(iii) The GOMEZ classification of protein energy malnutrition

Another classification system that was commonly used to identify PEM was the GOMEZ classification, as described in table 2.5. According to the GOMEZ classification, IYC weight-for-age was categorised according to the deviation thereof from the expected weight-for-age. The percentage of reference weight-for-age was calculated using the following formula (Garrow & James, 1993, p. 441):

$$\frac{\text{Patient weight}}{\text{Expected weight-for-age}} \times 100$$

Table 2.5: The GOMEZ classification of PEM

% of Weight-for-Age	Classification of PEM
90-109%	Normal
75-89%	First grade or mild malnutrition
60-74%	Second grade or moderate malnutrition
≤ 60%	Third grade or severe malnutrition

Source: Garrow & James (1993, p. 441, Table 30.1)

(iv) Waterlow classification

The Waterlow classification system was based on classifying PEM according to the level of wasting (the percentage of expected weight-for-height) and the degree of stunting (the percentage of height-for-age) as seen in table 2.6. The percentage of reference weight-for-age or height-for-age were calculated using the following formulas (Bender, 2014; World Heritage Encyclopaedia, 2018):

$$\textbf{Percentage weight-for-age} = \frac{\text{Weight of patient}}{\text{Normal weight-for-age}} \times 100$$

$$\textbf{Percentage height-for-age} = \frac{\text{Height of patient}}{\text{Normal height-for-age}} \times 100$$

Table 2.6: The WATERLOW classification of PEM

PEM Classification	% Weight-for-Age (Wasting)	% Height-for-Age (Stunting)
Normal	> 90%	> 95%
Mild	80-90%	90-95%
Moderate	70-80%	85-90%
Severe	< 70%	< 85%

Source: Bender (2014); World Heritage Encyclopaedia (2018)

Classification of protein energy malnutrition according to the severity of the disease

Another way of classifying PEM was based on the severity of the disease, the duration thereof and the predominant nutrition deficiency as is depicted in table 2.7. This classification was predominantly used for the diagnosis and treatment of PEM in the public health sector. Hence, the duration of the disease was classified as acute (underweight), chronic (stunting) or acute with a chronic background (wasting). Severe PEM was confirmed by clinical characteristics and biochemical data (Torun & Chew, 1999, p. 971-972).

Table 2.7: Classification of PEM according to the severity of the disease, it's duration and predominant nutrient deficiency

Severity of PEM	Duration	Main Deficit
Mild PEM	Acute	Energy
Moderate PEM	Chronic	Protein
Severe PEM	Both	Both

Source: Torun & Chew (1999, p. 971)

Indian association of paediatricians (IAP) classification of PEM

In addition to the WHO classification of PEM, a separate PEM classification system was developed for use in India. Where the WHO classification considers < -2 and ≤ -3 SD or Z-scores for classifying the severity of PEM, the IAP refers to 0 SD or the 50^{th} percentile as 100% the expected weight-for-age with a downgrading system from grade I to grade IV PEM as seen in table 2.8 (Patel & Ghandi, 2016).

Table 2.8: IAP classification of PEM

Stage of Malnutrition	% Weight-for-Age	PEM Classification
Normal	> 80%	Normal
Grade I	70-80%	Mild
Grade II	60-70%	Moderate
Grade III	50-60%	Severe
Grade IV	< 50%	

Source: Patel & Ghandi (2016)

2.4.2. Current classification systems of acute malnutrition

Currently, malnutrition is referred to as "acute malnutrition" with only two forms being referred to, namely SAM and moderate acute malnutrition (MAM) (NDOH, 2015; Adamu *et al*., 2016).

Moderate acute malnutrition

MAM makes a larger contribution to the burden of malnutrition than SAM. Although the risk for mortality is lower among those with MAM as opposed to SAM, more IYC is affected by it (Briend *et al.*, 2005). Acute malnutrition is defined as MAM when the IYCs weight-for-height is between -3 to -2 SD below the median of the WHO child growth standards / z-score, or when the mid-upper arm circumference (MUAC) measurement is between 11.5 – 12.5 cm (NDOH, 2015; Adamu *et al.*, 2016).

Severe acute malnutrition

SAM is defined by using weight-for-height, MUAC and / or oedema. Where an IYC presents with any one of the following indicators, the IYC is classified as suffering from SAM (NDOH, 2015; Adamu *et al.*, 2016):

- Weight-for-length / height < 3 SD or Z-score < -3; or / and
- MUAC of < 11.5 cm in children aged 6-60 months; or / and
- The presence of bilateral pitting pedal oedema (nutritional).

2.5. FACTORS THAT CONTRIBUTE TO AND CAUSE MALNUTRITION

Various factors contribute to the development of SAM. To enable the successful management of SAM, the factors that contribute to the development of malnutrition must be identified, understood and managed to reduce IYC mortality (Black *et al.*, 2008). SAM is the result of both medical and social instabilities, including household and social problems and challenges. Malnourished IYC grow up in a milieu where they are deprived from a loving and caring environment due to a lack of understanding, poverty and family problems. The recovery and eradication of SAM should therefore be a combined effort from various sectors to address and improve both the medical and social causes, preventing IYC from relapsing following treatment (WHO, 1999; Akombi *et al.*, 2017).

Over a quarter of a century ago, UNICEF developed a conceptual framework that demonstrates factors contributing to the development of SAM (UNICEF$_b$, 2015; Black *et al.*, 2020). These factors were divided into basic, underlying and immediate causes. As seen in figure 2.1, social, economic and political contextual factors are basic causes of SAM, resulting in unemployment, poverty and a loss or lack of income and financial assets. In the long run, these financial losses will contribute to household food insecurity, inadequate care for women and IYC and an unhealthy environment and substandard healthcare services. Due to these underlying causes, women and IYC will encounter inadequate food intake and diseases, which ultimately results in malnutrition (Black *et al.*, 2008; Adamu *et al.*, 2016; Black *et al.*, 2020). Apart from an increase in IYC mortality, morbidity and disability, malnutrition has a long-term impact on intellectual ability and contributes to health challenges which will negatively influence the ability of the individual to contribute productively to the economic wellbeing and growth of the household and country (Black *et al.*, 2008, Black *et al.*, 2020).

Gender inequality in literacy, employment and political rights, remains an international challenge, with detrimental consequences to the upliftment of financial, social and household conditions of women and IYC. Ecological conservation is of utmost importance in order to preserve natural resources for the provision of water, sanitation, energy and agricultural sustainability. Hence, these determinants of malnutrition remain a global priority in the fight to preserve lives of IYC (WHO, 2015).

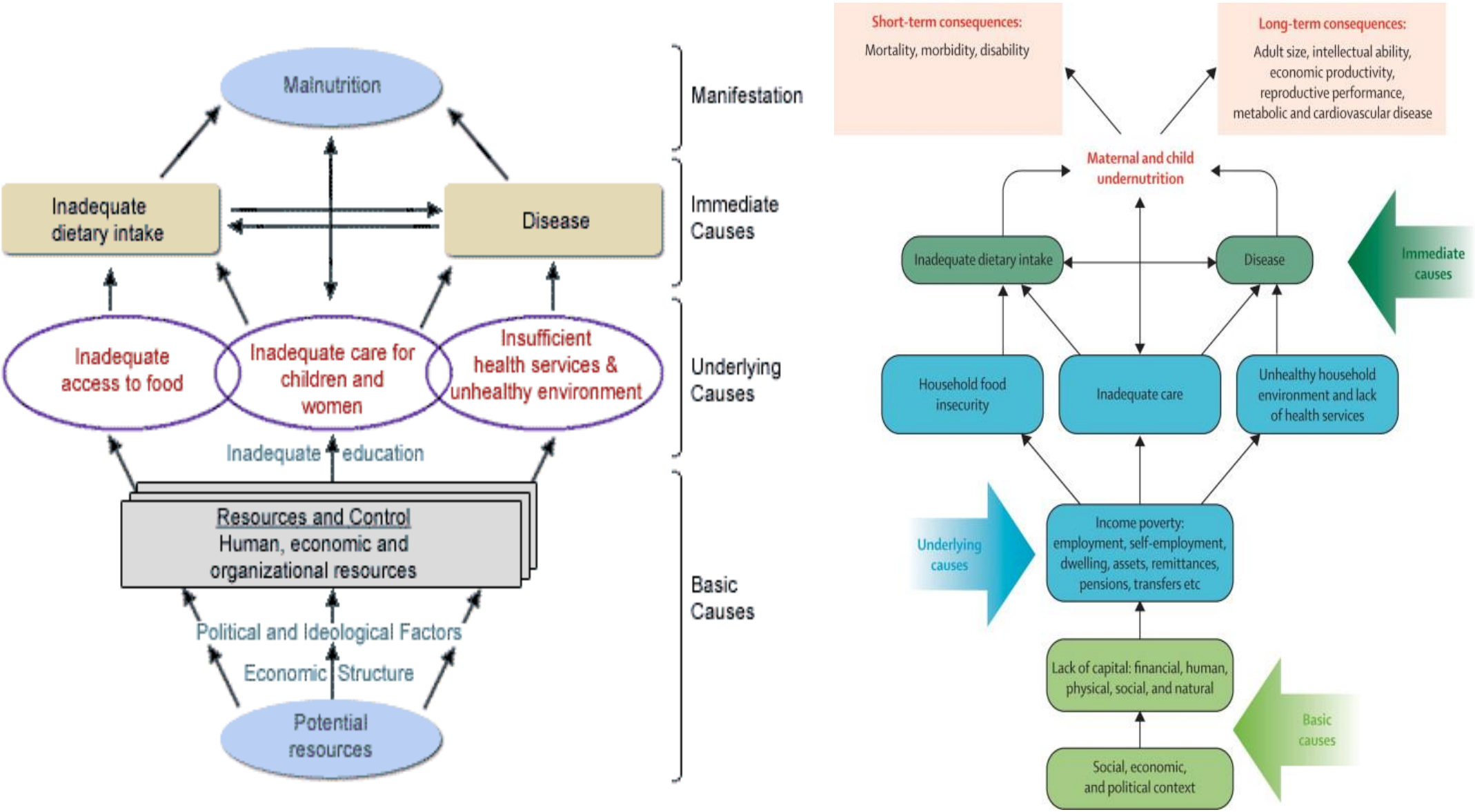


Figure 2.1: UNICEF Conceptual framework for malnutrition
Source: Black et al., (2008); Adamu et al., (2016); Black et al., 2020

In March 2020, five UN Agencies (UNICEF, World Food Program (WFP), WHO, United Nations High Commissioner for Refugees (UNHCR) & Food and Agriculture Organization of the United Nations (FAO) developed and published a collective framework and road map to fast-track the progress in the global reduction of IYC acute malnutrition. This framework, known as the "Global Action Plan (GAP) on Child Wasting: A Framework", aims to reduce and manage global IYC acute malnutrition in order to achieve the 2025 and 2030 targets of the SDG, namely, to reduce IYC mortality by 5% and 3% respectively. The GAP Framework presents the concept that the SDG targets can be separately achieved by 2025 and 2030 by addressing four concepts, namely: reducing the incidence of low birth weight, improving child health, improving IYC feeding and improving treatment of IYC with SAM (UNICEF, WFP, WHO, UNHCR & FAO, 2020).

To improve nutrition practices for IYC, the focus needs to be placed on strengthening and sustaining multi-sectoral nutrition programming over the long-term (UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). The above implies that there is a need to radically and rapidly scale up interventions to address the immediate fundamental causes of malnutrition, namely frequent common childhood illnesses and inadequate food intake. Since the underlying causes of SAM is complex and multisectoral, collaboration is needed to improve access to and availability of clean, safe water, hygiene and sanitation facilities. In addition, actions are needed to address household food insecurity. A sustainable and constructive impact on alleviating these immediate and underlying causes that contribute to the manifestation of malnutrition, can only be achieved through a combination of sustainable and robust nutrition intervention strategies to increase access to and availability of healthy food and adequate healthcare services of a good quality. Currently, this much needed intersectoral collaboration between various stakeholders is non-existing and nutrition intervention strategies aimed at the management of SAM is dysfunctional, unaligned and fragmented (UNICEF, WFP, WHO, UNHCR & FAO, 2020). One of the consequences of this fragmented service delivery in the approach to manage and decrease the manifestation of SAM, is the delivery of inadequate health services (WHO, 2015).

2.5.1. Inadequate health services

Section 28 of the Constitution of the Republic of South Africa (1996) stipulates that IYC have the right to basic nutrition, shelter, basic health care services, and social services (SA

Constitution, 1996; Mutshaeni, 2009). The right to healthcare services include assurance that IYC have access to promotional, preventative, curative, rehabilitation and palliative health services of a satisfactory quality. However, major health system limitations remain due to inadequate health budgets required for the provision of health services of sufficient quality and quantities, a reduced health workforce and infrastructure (especially in remote areas), substandard and unavailability of medical products and medicines and lack of accountability. Ineffective health systems result in enormous interruptions in the proper management of illnesses such as SAM (WHO, 2015; UNICEF, WFP, WHO, UNHCR & FAO, 2020). Inadequate access to health services and the mediocre quality thereof, increases IYC mortality (UNICEF, WFP, WHO, UNHCR & FAO, 2020; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

The approach of the GAP Framework as illustrated in figure 2.2 is to focus on starting with access to adequate, functional and good quality health services during pregnancy. Proper antenatal care support and a healthy, well-nourished mother will result in IYC that have a chance of surviving for least the first five years of their lives. This is especially critical during the first thousand days of an IYC life, starting at conception to the child's second birthday, as healthy children grow up to be healthy, well-nourished adolescents, adults and parents (UNICEF, WFP, WHO, UNHCR & FAO, 2020).

As previously mentioned, one of the goals of the GAP Framework, is to strengthen in-patient management of SAM. Over the past two decades, global effort has focused on the treatment of IYC with SAM, especially those admitted for in-patient hospital treatment. However, regardless of progress that has been made to improve the availability of and access to these SAM treatment protocols, one in three severely malnourished IYC do not have access to in-patient treatment of SAM. To improve child survival outcomes by 2025 and 2030 respectively, drastic policy changes are needed to enhance efforts to eradicate malnutrition in all its forms. Improved access to healthcare services and implementation of national policies and protocols on the management of SAM at all levels of health services, including those in rural and resource-limited areas, the number of IYC suffering from SAM can be reduced (UNICEF, WFP, WHO, UNHCR & FAO, 2020; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

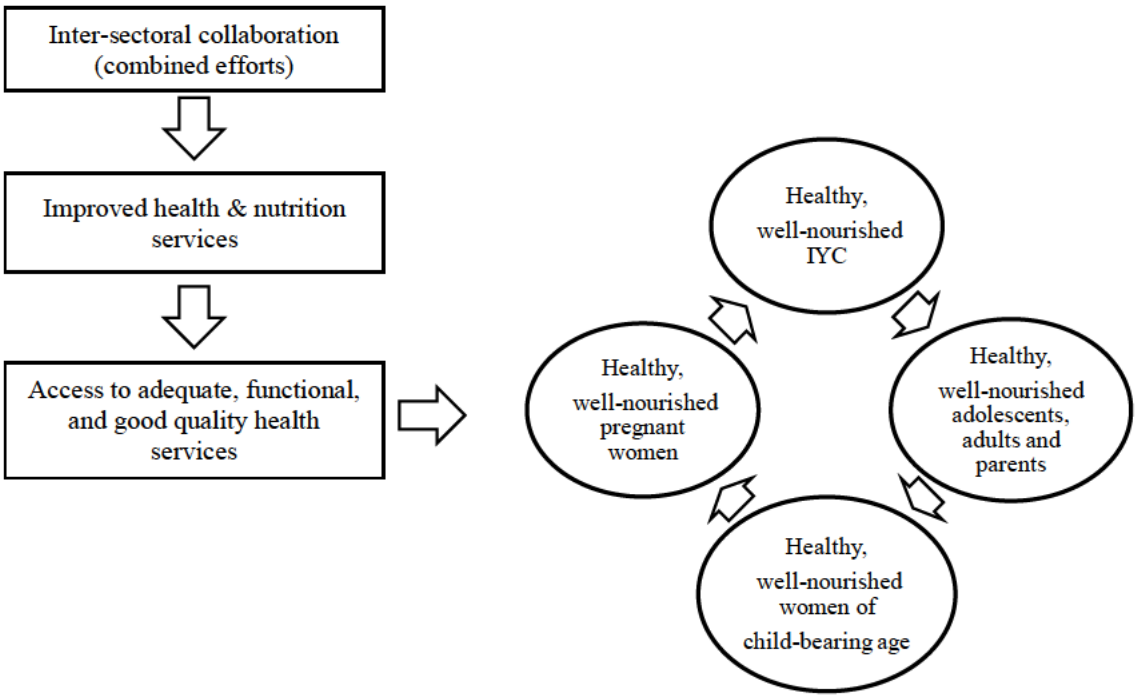


Figure 2.2: Approach of the GAP Framework to improve outcomes of treating SAM

Source: UNICEF, WFP, WHO, UNHCR & FAO (2020)

As illustrated in figure 2.3, various pillars are needed to ensure the successful implementation of health and nutrition intervention strategies to improve IYC survival. The success of these strategies lies in the implementation and monitoring of these strategies by committed, trained and passionate health professionals, supported by the availability of resources. Health services need to be modified to ensure that malnourished IYC are timeously diagnosed and referred to appropriate levels of care for the management of SAM. In addition, health services need to provide further support to IYC and their mothers / caregivers until they achieve full recovery from the condition, preventing relapse and re-admission to the health system. Health services need to build strong relationships with industry to ensure that nutrition supplements such as F-75, F-100 and RUTF is commercially available and affordable, making them available and ensuring that they provided at all levels of healthcare to IYC who are recovering from SAM. Health professionals are also required to support mothers and caregivers with health and nutrition education to empower them to care for the IYC recovering from SAM and preventing the IYC from becoming wasted again, as it may result in mortality (Akombi *et al.*, 2017; UNICEF, WFP, WHO, UNHCR & FAO, 2020).

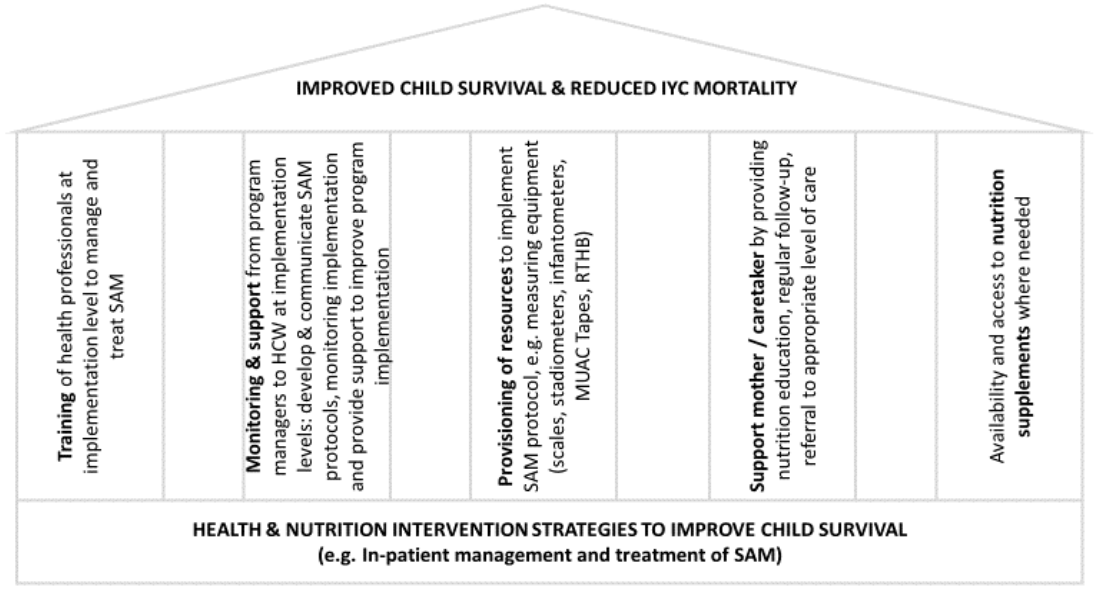


Figure 2.3: Pillars to strengthen the implementation of health and nutrition strategies to improve IYC survival
Source: UNICEF, WFP, WHO, UNHCR & FAO (2020)

2.5.2. Childhood diseases contributing to SAM and increased IYC mortality

Universally, millions of IYC live in unhealthy environments that lack access to clean, safe water and hygiene and sanitation facilities (WASH) (UNICEF, 2016). These unhealthy environments IYC are born into and must grow up in, increase the risk for contracting diarrhoea, malaria, acute respiratory infections and other infectious and parasitic diseases (UNICEF, WFP, WHO, UNHCR & FAO,2020; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). The interaction between malnutrition and the development of infections are commonly known (Darmon & Drewnowski, 2015). in figure 2.4, a vicious cycle exists between malnutrition, SAM and the development of infectious diseases, as IYC suffering from these diseases have an increased risk of developing SAM, requiring hospitalization for the treatment thereof. In addition, SAM increase the risk of mortality when developed in combination with childhood illnesses such as pneumonia and diarrhoea (Adamu *et al.*, 2016; Akombi *et al.*, 2017). To improve the chance of survival amongst IYC that suffer from SAM, access to WASH is of the utmost importance (UNICEF, WFP, WHO, UNHCR & FAO,2020).

Human immunodeficiency virus (HIV) and Tuberculosis (TB) can cause malnutrition directly or indirectly amongst IYC (Sashindran & Thakur, 2020). The combination of SAM and HIV is detrimental to child survival (Akombi *et al.*, 2017; Sashindran & Thakur, 2020), as the vicious

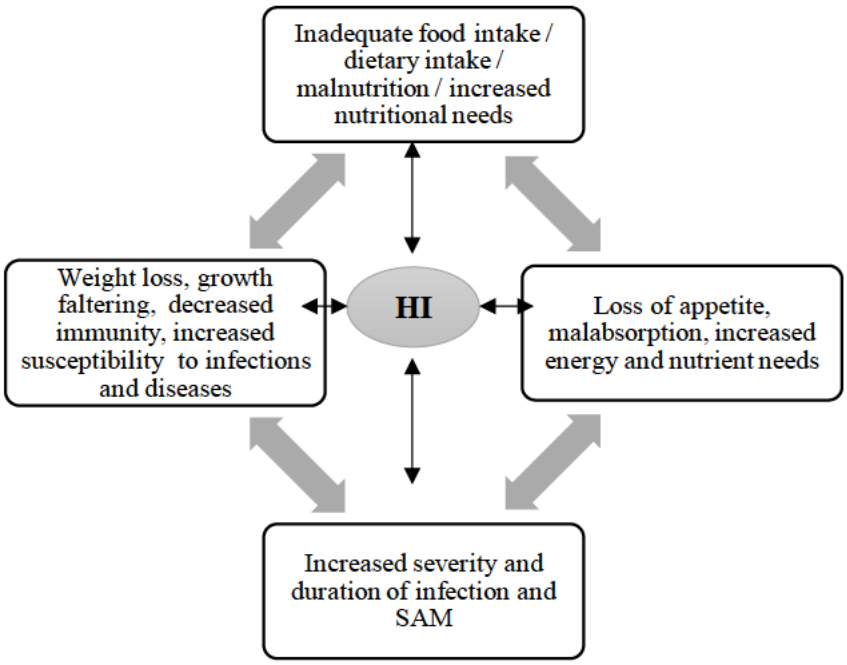


Figure 2.4: Vicious cycle between infection, SAM and HIV
Adapted from: Adamu et al., (2016); Akombi et al., (2017)

cycle between infection and SAM is aggravated by HIV due to immune suppression, increasing IYC susceptibility to infectious diseases. Since oral thrush, a lack of appetite, nausea, vomiting and diarrhoea are all known symptoms of HIV infection, inadequate food intake and micronutrient deficiencies increase the IYC risk for the development or worsening of SAM, hampering recovery from SAM during treatment (Katona & Katona-Apte, 2008; Sashindran & Thakur, 2020). SAM and stunting are common amongst IYC, with cerebral palsy (CP). Feeding is associated with CP as reduced motor skills and mental capacity contribute to a lack of food intake (Polack, Adams, O'banion, Baltussen, Asante, Kerac, Gladstone & Zuurmond, 2018).

2.5.3. Household food insecurity

Although globally extensive progress was made to reduce household poverty, millions of families are still subjected to unemployment and hunger. Therefore, poverty eradication remains a global priority (WHO, 2015). Even though the Global Hunger Index rates the prevalence of hunger in SA as low, 28% of the population were risk for experiencing hunger, whilst 26% experienced hunger, due to unemployment and household food insecurity (HHFIS) (Shisana, Labadarios, Rehle, Simbayi, Zuma, Dhansay, Reddy, Parker, Hoosain, Naidoo, Hongoro, Mchiza, Steyn, Dwane, Makoae, Maluleke, Ramlagan, Zungu, Evans, Jacobs, Faber & SANHANES-1 Team, 2013; Global Hunger Index, 2019). The 2020 SA unemployment rate

was 30.1% (STATS SA, 2020). In addition, more than half (54%) of the SA population was classified as being food insecure at a household level (Shisana *et al.*, 2013).

Most often, IYC malnutrition and morbidity is associated with poverty, unemployment and HHFIS (Shisana *et al.*, 2013; Faber & Drimie, 2016; Von Grebmer, Bernstein, Hossain, Brown, Prasai, Yohannes, Patterson, Sonntag, Zimmerman, Towey, Olive & Foley, 2017). Inadequate food intake as a result of HHFIS, is associated with SAM and is exacerbated by the vicious cycle of poverty (Akombi *et al.*, 2017). As illustrated in figure 2.5, food shortages and an inadequate food intake by pregnant women at the commencements of the first thousand days, followed by IYC developing SAM during this critical period, has a negative impact on cognitive development, with detrimental consequences in the long run, resulting in economic unproductivity and an inability to earn a suitable income as an adult. The latter creates a poor environment, leading to household food insecurity and inadequate food intake amongst the next generation, repeating the cycle of SAM and poverty from its inception. This results in generations of poverty, unemployment, household food insecurity and SAM (UN, 2015; Akombi *et al.*, 2017).

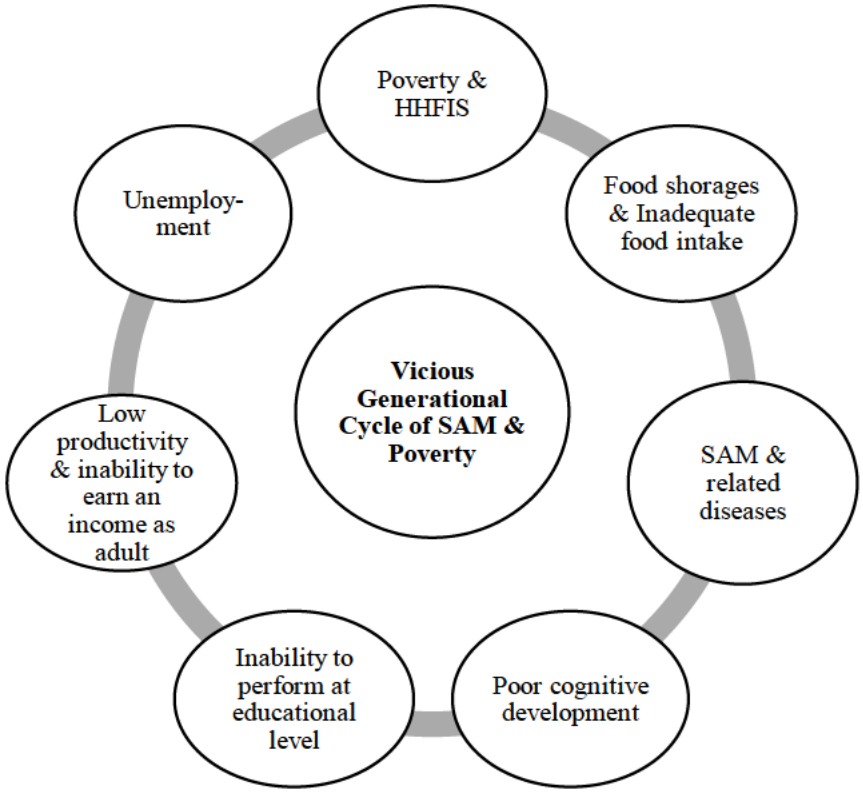


Figure 2.5: Vicious cycle between SAM and poverty
Source: UN, (2015); Akombi et al., (2017)

Since the protection of IYC is of paramount importance in every aspect concerning IYC and the environments in which they grow up, the "Child Support Grant" was formulated to provide financial assistance to unemployed parents to improve household food security (SA Constitution, 1996; Mutshaeni, 2009) as well as being a poverty alleviation strategy (Khosa & Keseke, 2017). Almost half (45%) of the SA population are dependent on social grants, including the child support grant. Of those receiving social grants, 20% exclusively rely on it as their main source of income (Stats SA, 2020). In 2020, the child support grant paid to eligible households amounted to R440 per month for each child under the age of 18 years, on condition that the child is a SA citizen that permanently resides with the primary caregiver (SASSA, 2020). The majority of beneficiaries that received a child support grant, indicated that the bulk of the grant was used for purchasing food. However, although the child support grant was intended to be solely used to the benefit of the child, this money was also used to meet the needs of other household members. This included payment of electricity bills, house rental and contributions to burial societies. For school going children, the grant was used to pay school fees, transport and procurement of school uniforms and stationery. Contrary to the above, the child support grant was also misused by the parents or caregivers, being used for gambling or to purchase alcohol and clothes for themselves. In addition to this, young mothers often had no decision-making power in their households and were forced to hand over the child support grant to their parents, husbands or partners. In addition, the SASSA grant card was handed over to loan sharks as security to loan money and settle accumulated debt (Khosa & Keseke, 2017).

Rising food prices could increase the prevalence of hunger amongst South Africans as the household's ability to access food is closely related to household food insecurity. Although SA nationally had an adequate food supply, it was not guaranteed that individual households would have access to food, since most local households were net buyers of food (Altman, Hart & Jacobs, 2009; Mkhawani, Motadi, Mabapa, Mbhenyane & Blaauw, 2016; Van Wyk & Dlamini, 2018). The inability to access food is not only a direct cause of poverty and unemployment, but is correspondingly related to the affordability of food. As food prices increased, the quality and quantity of food consumed by food insecure households decreased (Faber & Drimie, 2016; Mkhawani *et al.*, 2016). Households who were in financial distress were critically exposed to upward trends in food prices (Mkhawani *et al.*, 2016). Urban households spend 15% of the household income on food, whilst urban households spend 23% of their income on food (Van Wyk & Dlamini, 2018). Increased prices of basic foods such as cereal, maize meal, bread, sugar, tea, oil, salt, flour and other staples, resulted in poor households minimising the quality and

quantity of food intake (Mkhawani *et al.*, 2016). Data published in 2017 by the Pietermaritzburg Agency for Community Social Action (PACSA), indicated that households struggled to keep up with increased food prices. It was estimated that a food basket of basics foods costed more than R2000 per month for a household of five. This estimated cost of a basic food basket annually increased by an estimated 6% since 2017 (PACSA, 2017). In addition, this food basket is nutritionally incomplete and would, over time, result in malnutrition amongst IYC from poor households (Mkhawani *et al.*, 2016). The cost of a nutritionally complete food basket for a household of five costed twice as much than that of a basic food basket (PACSA, 2017).

Climate change, droughts and loss of land for agricultural activities and food production, is another factor increasing the unavailability of food, resulting in an increase in household food insecurity and the concomitant global increase in the prevalence of SAM (Akombi *et al.*, 2017).

2.5.4. Inadequate food intake

Section 28 of the of the Constitution of the Republic of South Africa (1996) stipulates that all IYC have the right to basic nutrition and health care services. This is in support of ensuring the daily consumption a diverse diet, as it can contribute to general health and wellbeing of IYC. It has been accepted in the nutrition community that adequate dietary diversity reflects nutrient adequacy, necessary for optimal health and general wellbeing (Kennedy, Ballard & Dop, 2013; Akombi *et al*., 2017).

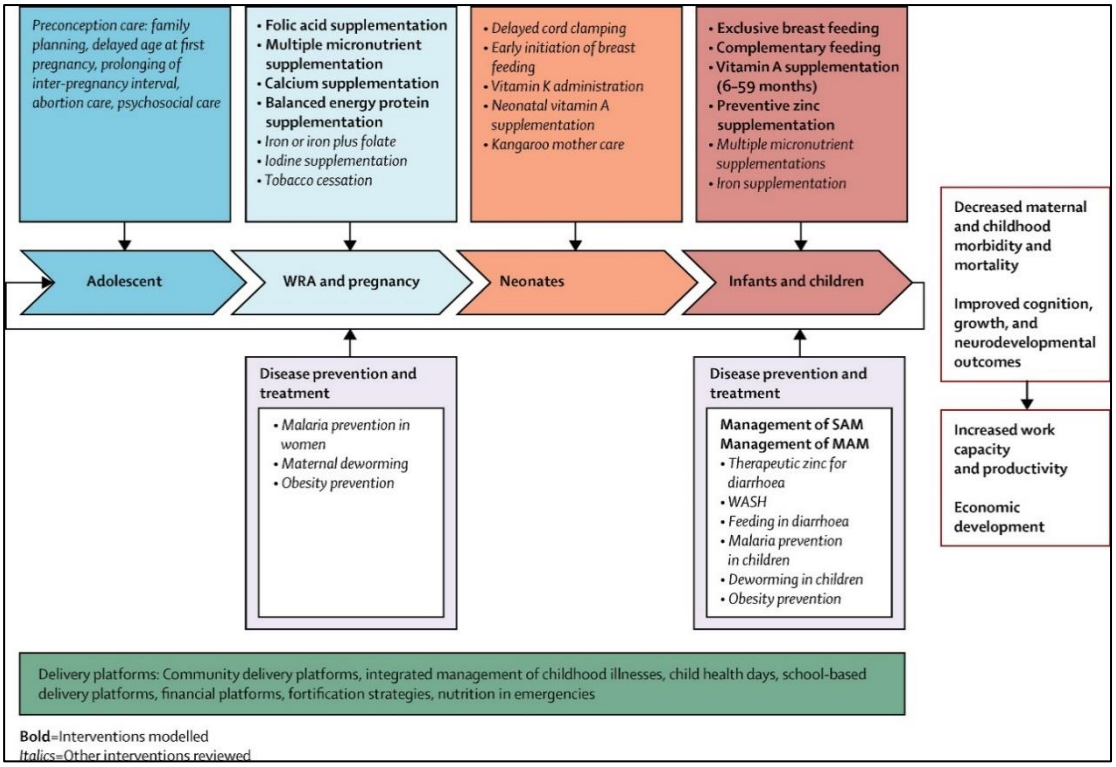
Adequate food intake needs to start during gestation, therefore maternal nutrition during pregnancy and lactation plays a vital role in reducing IYC risk for developing SAM (Akombi *et al.*, 2017; UNICEF, WFP, WHO, UNHCR & FAO, 2020*).* Together with maternal undernutrition, inadequate and early cessation of exclusive breastfeeding (EBF) is also associated with SAM. EBF during the first six months of an IYCs life, provides optimal nutrition (WHO, 2019). However, after six months, breastfeeding should be accompanied by a variety of nutritious food from the family pot. The introduction of complementary feeding for IYC must be well-timed, of a good quality and given at regular intervals (Akombi *et al.*, 2017*),* as appropriate feeding practices enhance child survival (Akhtar, 2016).

Older research findings from the SANHANES-1 study (Shisana *et al.*, 2013) indicated that food intake from various food categories amongst IYC and their mothers/caregivers were

documented as satisfactory in SA, meaning that families consume food from at least four groups out of nine food groups as part of their daily diet. Foods most often consumed by households in this category include food products from the cereals, green leafy vegetables, vitamin A-rich fruits and oil food groups (Kennedy *et al.*, 2013). More recent SA data presented by Steyn, Nel, Malczyk, Drummond & Senekal (2020) indicated that food intake amongst IYC did not include a variety of food and IYC between one and under three years consumed mostly maize porridge with soups / sauces, fish and vegetables. Dietary patterns of IYC between three and under six years old included the intake of bread, salty spreads and condiments, chicken, white rice / maize meal porridge, vegetables, and legumes. For both age groups potato and sweet potato was consumed, as well as granulated sugar, sweets and cold drinks (Steyn *et al.*, 2020).

However, due to nutrition transition, associated with urbanisation and the affordability of energy-rich foods high in refined grains, added fats and sugar, impoverished families buy foods of inferior nutrient quality and quantities. This results in the consumption of diets that lack diversity (Shisana *et al.*, 2013; Mkhawani *et al.*, 2016). Diets that lack diversity do not adequately meet nutrient requirements, since the consumption of food from three or less food groups are regarded as an inadequate food intake, as measured by the dietary diversity score (Kennedy *et al.*, 2013). In addition to consuming monotonous diets, due to the scarcity of food quantities, certain members of the family are required to reduce their number of daily meals and portion sizes to ensure adequate quantities of food for all household members. Consuming a diet that lacks variety in addition to inadequate quantities to meet nutrient requirements, result in nutrient deficiencies and disorders. (Mkhawani *et al.*, 2016). The most common micronutrient deficiencies amongst IYC include deficiencies in Vitamin A, iron, iodine and zinc (Shisana *et al.*, 2013; UNICEF, 2018), and are often referred to as hidden hunger (UNICEF, 2018). Dietary diversification is the first strategy to address hidden hunger (UNICEF, 2018).

However, since the consumption of a variety of food is not viable in poor households, programme-based nutrition interventions can assist with the reduction of malnutrition as a result of nutrient deficiencies (Black *et al.*, 2008; Van Wyk & Dlamini, 2018). Various health and nutrition interventions are globally implemented to prevent maternal and IYC malnutrition. These interventions are presented in figure 2.6, with the focus on prevention of malnutrition as early as adolescence due to the high prevalence of teenage pregnancies, resulting in small-for-gestational age births (Buttha *et al.*, 2013; Akombi *et al.*, 2017). In SA the total fertility rate



* WRA= women of reproductive age; WASH= water, sanitation & hygiene

Figure 2.6: Conceptual framework for health and nutrition interventions supporting the prevention and management of malnutrition

Source: Bhutta et al. (2013); Keats et al. (2021)

(TFR) from 2013-2016 was 2.6 children per women. The fertility rate for teenagers was 71 births per 1000 women aged 15-19 (STATS SA, 2017).

Outcomes of an equity analysis performed by Bhutta *et al.* (2013) indicates that in cases where the focus is placed on key nutrition interventions, which aim at preventing small-for-gestational age births and stunting, the overall burden of IYC mortality will be reduced noticeably. These interventions include multiple micronutrient supplementation during pregnancy, promotion of breastfeeding, appropriate complementary feeding practices, management of SAM, vitamin A supplementation, preventative zinc supplementation, the treatment of diarrhoea with zinc and iodised salt (Bhutta *et al.*, 2013; Keats, Das, Salam, Lassi, Imdad, Black, & Bhutta, 2021).

Since 2003, a national food fortification programme was implemented in SA, in alignment with global nutrition interventions. The national food fortification programme mandates that all maize meal and wheat flour be fortified with vitamin A, thiamine, riboflavin, niacin, pyridoxine, vitamin B12, folic acid, iron and zinc to levels as dictated by the SA government ($NDOH_a$,

2003). To address iodine deficiency in SA, the NDOH passed a regulation in 1995, that promulgated that all salt be iodized (NDOH, 2007).

To address SAM in SA, a treatment protocol was published in 2015 for the in-patient treatment of SAM. This SAM treatment protocol is based on the 1999 WHO SAM treatment protocol, with additional updates and amendments made in 2013 (NDOH, 2015).

2.6. MANAGEMENT OF SAM

As illustrated in figure 2.7, the purpose of both international and local SAM treatment protocols is to break the cycle of IYC becoming malnourished, receive in-hospital treatment, recover, preventing relapse and become malnourished again, thereby decreasing IYC mortality. By breaking this cycle, IYC survival will be improved (UNICEF, WFP, WHO, UNHCR & FAO, 2020).

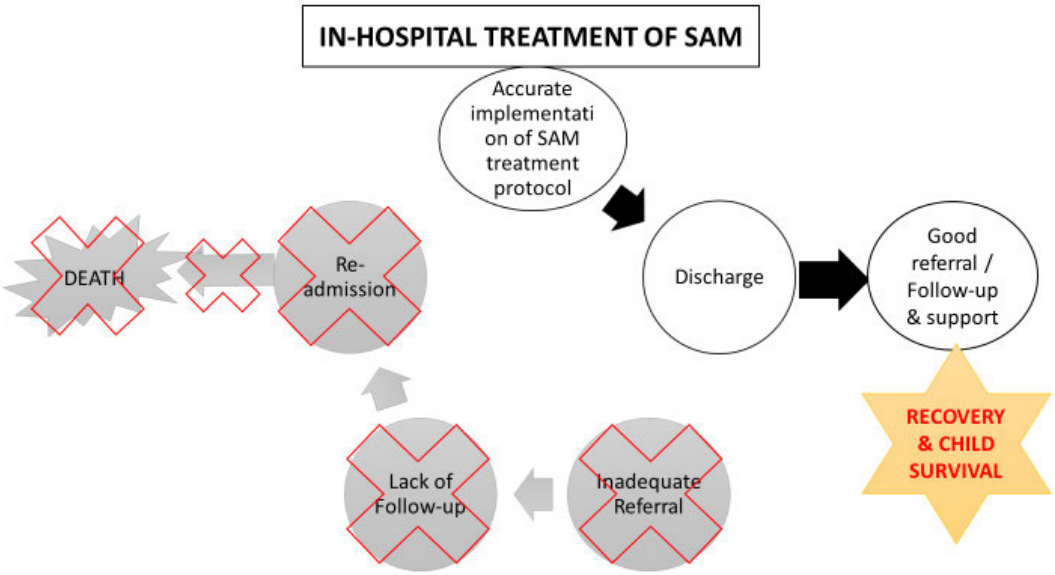


Figure 2.7: Breaking the cycle of IYC SAM to improve child recovery and survival

Source: UNICEF, WFP, WHO, UNHCR & FAO, (2020)

2.6.1. Historic nutrition interventions for the management of SAM

Historically, the UNICEF "GOBI-FFF approach" was used as to decrease the prevalence of malnutrition (Chen & Singh, 1997).

The GOBI-FFF approach focused on growth monitoring, oral rehydration therapy, promotion of breastfeeding, immunisation, female education, family planning and food supplementation and was implemented through primary healthcare (PHC) principles (Waterlow, 1992).

In 1972, the Protein Energy Malnutrition Program (PEMP) was implemented in SA for the nutritional management of malnourished children. The PEMP was based on the UNICEF GOBI-FFF approach and aimed to strengthen activities around the prevention and treatment of malnutrition among children younger than five years of age by means of what was coined as the Integrated Nutrition Program (INP) (DOH 2003). The purpose of the INP was to facilitate a co-ordinated, intersectoral approach to solve nutrition challenges in SA. Primary interventions of the INP included nutrition education, the protection, promotion and support of EBF for six months, appropriate complimentary feeding practices, growth monitoring and the prevention of growth faltering. In addition, the PEMP formed part of secondary interventions that included the provision of supplementary food to malnourished IYC and referral of mothers to community-based nutrition interventions and projects of the INP. Food supplements issued to malnourished IYC included enriched maize meal, an enriched protein drink, acidified / soya based infant formula and a multivitamin syrup. Individual needs were predominantly based on age, with food supplements being provided for a period of three to six months. Household food insecure families were referred to Social Welfare for registration and enrolment in the social grant program. Vegetable seeds were also distributed to establish vegetable gardens at household level. In-patient care of IYC with SAM was based on recommendations and opinions of experts in the field ($NDOH_b$, 2003; NDOH, 2004). However, the implementation of the PEMP was hampered by staff shortages and a lack of training at PHC facilities, heavy workloads of the health care team, unavailability of food supplements, and a lack of monitoring and evaluation of the implementation of the PEMP (Botha, 2008; USAIDS, 2007; Melito, 2007).

Treatment practices for the in-hospital management of SAM were, at many hospitals, based on discretional practices and staff that were unfamiliar with the WHO guidelines for in-patient care of children with SAM (Schofield & Ashworth, 1997; Puoane, Sanders, Chopra, Ashworth, Strasser, McCoy, Zulu, Matinise & Mdingazwe, 2001). The overuse of intravenous (IV) fluids for rehydration, inadequate nutrition practices resulting in hypoglycaemia and hypothermia, untreated infections, and an inability to restore electrolyte and micronutrient deficiencies increased IYC deaths. IYC experienced delayed recovery due to a lack of foods and supplements which could assist with rapid catch-up growth (Puonae *et al*., 2001).

2.6.2. Current nutrition interventions for the management of SAM

Following the global trend, the SA focus in treating acute malnutrition is divided into community-based interventions and hospital-based treatment protocols. MAM is treated at community level, whilst SAM is treated ambulatory or in hospital (NDOH, 2015; Adamu *et al.*, 2016).

2.6.2.1. Community-based treatment

Since the development of acute malnutrition is complex and multisectoral, all-inclusive and intersectoral strategies at community level is needed to reduce factors associated with acute malnutrition (Akombi *et al.*, 2017). MAM and uncomplicated SAM can be treated successfully at community level. The treatment regime for the management of MAM includes early detection and prevention of SAM. IYC with MAM is treated with RUTF until they have adequately gained weight. Mothers / caregivers are educated on the best possible meals to feed their IYC, based on the variety and amount of food available at household level. Food and supplement intake may be supplemented with micronutrients. Follow-up and re-issuing of food supplements should be conducted weekly or bi-weekly by skilled, trained healthcare workers (WHO, WFP & UNICEF, 2007; Annan, Webb & Brown, 2015).

2.6.2.2. In-hospital treatment of SAM

Although the main priority in the management of malnutrition remains the prevention thereof, prevention strategies and programmes are flawed and malnourished IYC still require in-patient treatment. Therefore, treatment policies, protocols and guidelines for the in-patient management of SAM should be implemented as "safety nets", parallel to community-based prevention strategies (Briend *et al.*, 2005; WHO, 2013).

In 2015, the SA government published a policy for the "integrated management of children with acute malnutrition" (NDOH, 2015). This SAM treatment protocol was based on the WHO guidelines for in-patient care of children with SAM, which comprises of ten steps (WHO, 1999; WHO, 2013, NDOH, 2015). The ten steps for the in-patient management of SAM are depicted in figure 2.8.

In figure 2.9, the three stages of treating SAM are presented. The first priority is to stabilise the IYC immediately upon admission to hospital, with the goal of restoring cellular function,

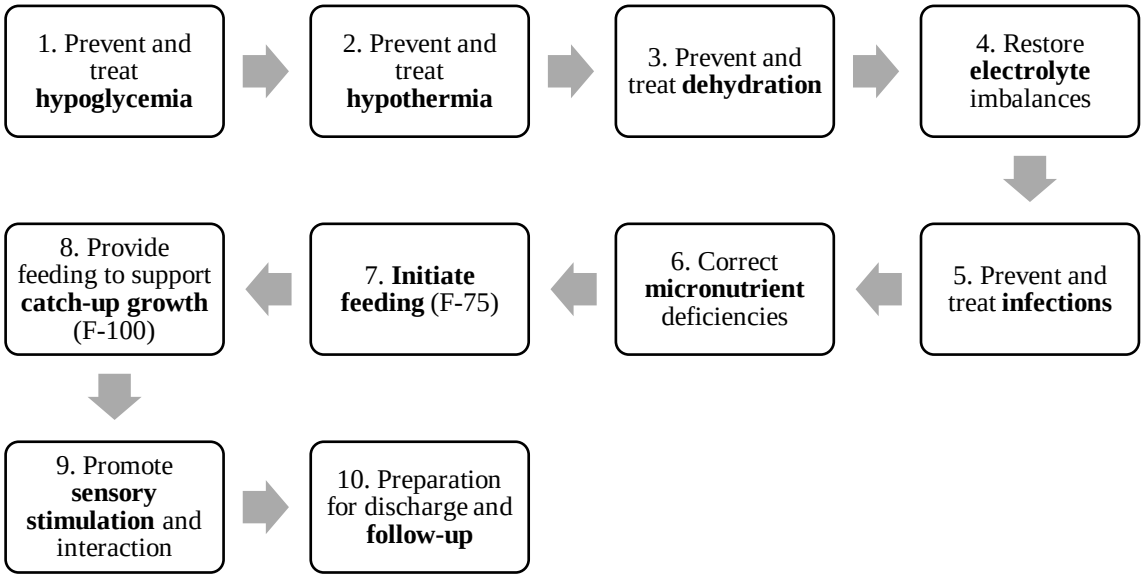


Figure 2.8: Ten steps for the in-patient management of SAM

Source: WHO (1999); WHO (2013); NDOH (2015)

controlling infection, managing and treating hypothermia and hypoglycaemia and to detect/respond to inadequate feeding and diarrhoea. During this phase, F-75 is administered at a volume of 100-130ml/kg/day, based on the IYC condition and ability to tolerate the volume of feed. Once the IYC is able to tolerate the required amount of feed needed for recovery, diarrhoea has resolved and the IYC has a good appetite, transition to rehabilitative feeding can commence. Transitioning from phase one to phase three should be monitored closely and implemented over a period of two days. On day one, replace the F-75 with equal amounts of F-100 and evaluate the tolerance thereof. From day three of transition, gradually increase the feed volume by 10ml per feed until the required amount of feed to support catch-up growth is reached. After successful transitioning from F-75 to F-100, feed the IYC a volume of 220 ml/kg/day. In all stages, continue breastfeeding and support catch-up growth with F-100 and a balanced, soft, mixed high energy diet. In preparation for discharge, replace the F-100 with RUTF and encourage the IYC to drink lots of clean, safe water. Once the IYC appetite has returned, diarrhoea and oedema has resolved and weight gain is consistent and more than 10g/kg/day, the IYC can be discharged to a local clinic or outpatient department for recovery and rehabilitation support. RUTF must be issued to supplement food intake (WHO, 1999; NDOH, 2015).

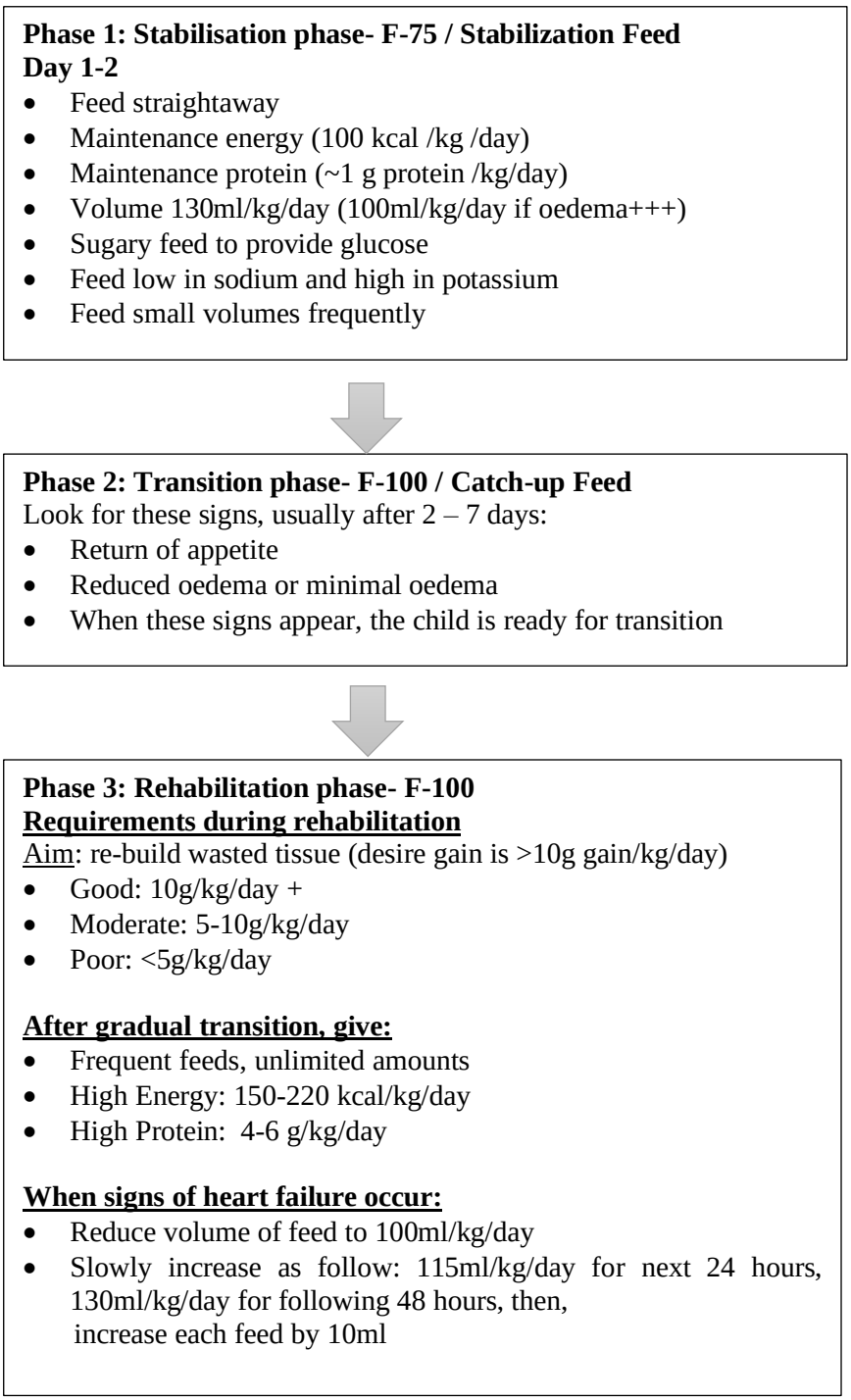


Figure 2.9: Phases of in-patient management for severely malnourished IYC

Source: NDOH (2015)

It is of the utmost importance that continuous breastfeeding and appropriate complementary feeding form part of the SAM treatment of malnourished IYC admitted for inpatient management of SAM. Other interventions which form part of the SA SAM treatment protocol include the use of oral rehydration solution (ORS) and medication such as anti-diuretics, antiemetics and pre/probiotics to address shock and dehydration amongst IYC suffering from SAM complicated by diarrhoea and vomiting. Severe anaemic IYC will also receive packed red blood cells at 5–10ml/kg over four hours. Antibiotics and other medication such as deworming

agents and TB / HIV specific medicines will be used to address sepsis, bacterial infections and underlying causes and symptoms of malnutrition. Measles vaccinations will be updated according to the individual IYC immunization schedule as part of SAM treatment. Electrolyte imbalances and micronutrient deficiencies will be addressed through the implementation of specific supplementation strategies to administer potassium, magnesium, copper, zinc, vitamin A and folic acid. Iron deficiencies will only be corrected after the stabilization phase is completed (NDOH, 2015).

2.7. SUMMARY

Despite continuous developments within the recommended feeding regimes for the management of SAM, there is limited independent evidence-based findings and adjustments to existing protocols to substantiate recommendations based on the WHO ten steps in the management of SAM. The absence of relevant published data has negated dependence on expert opinion. Over the past few years, major research gaps have been identified regarding the implementation of feeding regimes in the context of managing and treating SAM, complicated by HIV infection. It should also be noted that current treatment guidelines exclude or provide limited and vague information on the management of malnourished infants younger than six months of age. In addition, more robust post-discharge treatment guidelines are needed to prevent and decrease the incidence of SAM readmissions.

In conclusion, although the feeding regimes for the management of malnourished IYC evolved significantly from the 1950's, very few changes have been introduced since 1999. The current feeding recommendations are predominantly focussed on the in-patient management of SAM and on IYC older than six months of age. It should be noted that the purpose of presenting the information in this review, is not to criticize the WHO or the authors of these guidelines or any other subject experts but merely a call for action to researchers and policy makers to update, improve and strengthen current nutrition intervention strategies, in accordance with recent research outcomes, for the management of SAM, thereby curbing increasing levels of IYC mortality.

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CHAPTER 3

RESEARCH METHODOLOGY

3.1. INTRODUCTION

The development of the research proposal and research instruments, obtaining ethics approval, fieldworker recruitment and training, piloting, data collection, data coding and statistical analysis of the study was conducted in five phases. These phases are reported in figure 3.1.

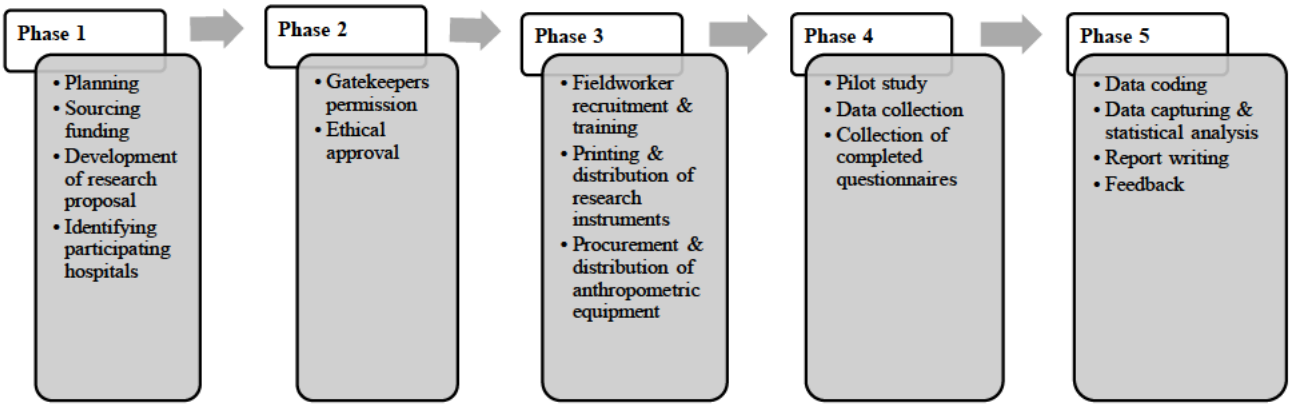

Figure 3.1. Phases of the study process

3.2. STUDY DESIGN

A multi-centre prospective, descriptive and comparative observational study was employed.

3.2.1 Descriptive design

In order to attain the study objectives, the study employed a descriptive design. Descriptive research is used to obtain information regarding the characteristics of an observed phenomenon or exploring the possible relationship between two or more phenomena (Leedy & Ormrod, 2016; Kumar, 2011). Descriptive research methods can be cost effective, easy to administer and can sample a wide range of people (Leedy & Ormrod 2016). Polit and Beck (2018) reported that the usefulness of descriptive research is that it enables the ability to analyse the relationship between the phenomena under investigation.

3.2.2 Quantitative research

According to Leedy and Ormrod (2016), quantitative research involves looking at an amount or quantities of one or more variables of interest. The approach often follows the scientific method

of data collection, using designs that allow various levels of confidence in making causal interpretation. As a result, it is used to answer questions about relationships among measured variables with the purpose of explaining, predicting and controlling phenomena. Quantitative findings are likely to be generalised to a whole population or a sub-population, as it involves the larger sample which is randomly selected (Shidur, 2017). However, regardless of its strength, quantitative research is unable to determine deeper underlying meanings and explanations, being referred to as the positivism that cannot account for how the social reality is shaped and maintained, or how people interpret their actions and others (Blaikie, 2007).

In the current study, socio-demographic variables of study participants, anthropometric measurements and compliance with the SAM Treatment Protocol were collected as quantitative data. In addition, the absence/presence of diarrhoea, appetite and oedema was observed (and confirmed through reviewing participant records) to determine treatment outcomes.

3.3. STUDY SITES

The study was conducted at 16 hospitals in four SA provinces (Table 3.1). In the Eastern Cape, all six hospitals from the Alfred Nzo Health District were included as study sites, while in the Free State, three hospitals from Thabo Mofutsanyana Health District located in the Maluti-a-Phofung municipal area was identified. In addition, three hospitals in the most rural areas of the city of Tshwane municipal area were identified as study sites, while in Gauteng and in Mpumalanga, four hospitals from each health district were selected. Hospitals included as study sites were identified by the Provincial Health Management, based on SAM statistics from the district health information system (DHIS), approval from hospital Chief Executive Officer's (CEOs), accessibility to data at institutional level and approval from Provincial Ethical Committees/Research Departments.

3.4. STUDY POPULATION

The study population were IYC aged between six months and five years, diagnosed with SAM and hospitalized at the study sites for the management of SAM.

3.5. INCLUSION CRITERIA AND EXCLUSION CRITERIA

For the purpose of this study, the following inclusion and exclusion criteria were used to select study participants.

3.5.1 Inclusion criteria

- Newly hospitalized IYC aged six months to five years diagnosed with SAM;
- First time diagnosis and hospitalisation for SAM; and
- IYC hospitalized for stabilisation of SAM.

3.5.2 Exclusion criteria

- IYC in the transition or recovery phase.

3.6. SAMPLING AND SAMPLE SIZE

Hospitals with active programmes for the management and treatment of SAM, were selected for inclusion in the current study. As previously discussed, and presented in table 3.1, 16 hospitals spanning across four provinces, namely Eastern Cape, Free State, Gauteng and Mpumalanga were selected as study sites for data collection. Convenience sampling was followed at institutional level to select study participants. All IYC between the ages of six months and five years, admitted at the selected hospitals between 7 February and 30 April 2019 diagnosed with SAM, were included in the study sample. A maximum of 30 children per hospital were identified as an adequate number of participants for inclusion in the study sample.

A power calculation was done to provide 80% power, at a 0.05 level of significance. Interrogation of data from similar studies investigating weight change, and an expected medium effect size (d=0.5), rendered the calculation of a sample size of 120 IYC to be adequate. This sample size allowed for drop-out and other losses (i.e. mortality) without having a significant impact on the power of the study.

3.7. PILOTING

The two questionnaires were piloted before data collection commenced. Pilot testing of the questionnaires took place at Jubilee hospital. Approval for testing the questionnaires at this hospital was obtained from provincial and institutional management. The questionnaires were tested by the researcher and two independent individuals (a registered dietitian and post-graduate student) with a total of ten questionnaires being completed. Sections A, B and D of

Table 3.1. Hospitals included as study sites

Province	Health District	Municipality Area	Nearest Town / City	Name of hospital	Number of beds
Eastern Cape	Alfred Nzo	Mbizana	Bizana	St. Patrick's	290
	Alfred Nzo	OR Thambo	Flagstaff	Holy Cross	242
	Alfred Nzo	OR Thambo	Mthatha	Nelson Mandela Academic Hospital	512
	Alfred Nzo	Matatiele	Mount Flethcer	Tayler Bequest	146
	Alfred Nzo	Nyandeni	Libode	St. Barnabas Mission Hospital	268
	Alfred Nzo	OR Thambo	Lusikisiki	St. Elizabeth's Mission Hospital	260
Free State	Thabo Mofutsanyana	Maluti-a-Phofung	Harrismith	Thebe District Hospital	71
	Thabo Mofutsanyana	Maluti-a-Phofung	Witsieshoek	Elizabeth Ross District Hospital	100
	Thabo Mofutsanyana	Maluti-a-Phofung	Phuthaditjhaba	Mofumahadi Manapo Mopeli Regional Hospital	270
Gauteng	City of Tshwane Metropolitan	TSH-NE	Hammanskraal	Jubilee	414
	City of Tshwane Metropolitan	Tshwane-Odi	Mabopane	Odi	198
	City of Tshwane Metropolitan	City of Tshwane	Ga-Rankuwa	Dr. George Mukhari Academic Hospital	1650
Mpumalanga	Ehlanzeni	Nkomazi	Malelane	Shongwe	183
	Nkangala	Steven Tshwete	Middelburg	Middelburg	218
	Gert Sibande	Lekwa	Standerton	Standerton	171
	Nkangala	Thembisile	Kwamhlanga	Kwamhlanga	148

questionnaire one was tested amongst nine IYC admitted to the paediatric ward for in-patient management of SAM and one copy of questionnaire two was completed by one of the dietitians of the institution. IYC and the dietitian who participated in piloting, was not included in the study sample. The purpose of the pilot was to determine whether questions were appliable and understandable. Following piloting, the following changes were made to the questionnaires:

(i) Questionnaire 1

Demographic data of study participants were collected with section A. The word "caretaker" was replaced with the word "caregiver". In section B, used for the collection of data regarding HFIAS, the words "you and your household members" were replaced with the words "your child" for each of the occurrence questions.

In section D, used for monitoring in-patient data, the option "not anymore" was added to questions 14 and 15, where data on the continuation of breastfeeding after admission was collected. For question 16, "The child is getting breastmilk" was added as a response option to accommodate IYC who had not received any milk feed, despite still being breastfed by the mother.

(ii) Questionnaire 2

As the majority questions in questionnaire two was open-ended, no changes following piloting were necessary.

3.8. FIELDWORKER TRAINING

Before commencement of data collection, all provincial study coordinators and fieldworkers attended a three-day in-service training session conducted by the researcher. Training was conducted in line with a training manual to ensure the following:

- Fieldworkers were familiarised with the study aim and objectives;
- Fieldworkers were familiarised with the contents and definitions of concepts forming part of the questionnaires; and
- Fieldworkers used the same measuring techniques when collecting anthropometric data.

The content covered during the training session included:

- Introduction and background of the current study;
- Background regarding the prevalence of SAM, the classification of malnutrition and the treatment protocols for the inpatient management of SAM amongst IYC;
- An overview of all study sites included in the study sample;
- The roles and responsibilities of the researcher, provincial study coordinators and fieldworkers;
- Study population;
- Data collection process;
- Standard techniques on how to perform anthropometric measurements (i.e. weight, length/ height, MUAC);
- Techniques regarding the observation, assessment and classification of clinical features such as diarrhoea, appetite and oedema;
- Follow-up actions required for monitoring IYC following discharge and upon re-admission;
- Completion and interpretation of all questions included in the respective data collection instruments;
- Obtaining and recording informed consent from mothers/caregivers; and
- Maintaining anonymity and ensuring confidentiality during data collection.

3.9. DATA COLLECTION

Questionnaire-based data was obtained through trained fieldworker administered interviews and reviewing the hospital records of study participants, in addition to conducting anthropometric measurements that included weight, length/height and MUAC and documenting health indicators obtained through clinical examination.

3.9.1. Data collection instruments

Structured questionnaires were used to collect data. The following questionnaires, developed for the purpose of the study, were developed and used for data collection amongst all participants recruited from the 16 hospitals included in the study sample:

3.9.1.1.Admission resuscitation questionnaire

Questionnaire 1 (refer to Addendum A) was used to collect data upon admission following resuscitation. It included the following four sections:

- **SECTION A**: Socio-demographic information such as the age of the IYC, diagnosis, age of the mother/caregiver and relationship of caregiver to the study participant;
- **SECTION B**: Household Food Security (HHFIS) using the Household Food Insecurity Access Scale (HFIAS) and feeding practices during hospitalisation and following discharge;
- **SECTION C**: Anthropometric measurements including participant birth weight, baseline and discharge weight, length/height and MUAC;
- **SECTION D**: Daily monitoring of clinical data, including the evaluation of appetite, presence or absence of oedema and diarrhoea, daily weight and hydration status.

3.9.1.2.Feeding regimes questionnaire

Questionnaire 2 (refer to Addendum B) was used to collect data on feeding regimes and SAM protocols.

3.9.1.3.Weekly post-discharge monitoring

Questionnaire 3 (refer to Addendum C) was used to record weekly post-discharge data for a period of three months.

3.9.1.4.Re-admission data

Re-admission data was collected using **Questionnaire 4** (refer to Addendum D).

3.9.2. Data collection stakeholders

The research team consisted out of 24 individuals. The composition of the research team is illustrated in figure 3.2.

3.9.2.1. Role of the researcher

The researcher was responsible for planning, organising and monitoring the implementation of the study as described in the study process. Other responsibilities included data analysis and report writing (phases 1-5 of the study process). These aspects can be outlined as follows:

- Planning, organising and monitoring of the current study;
- Presentation of the research protocol to the funder;

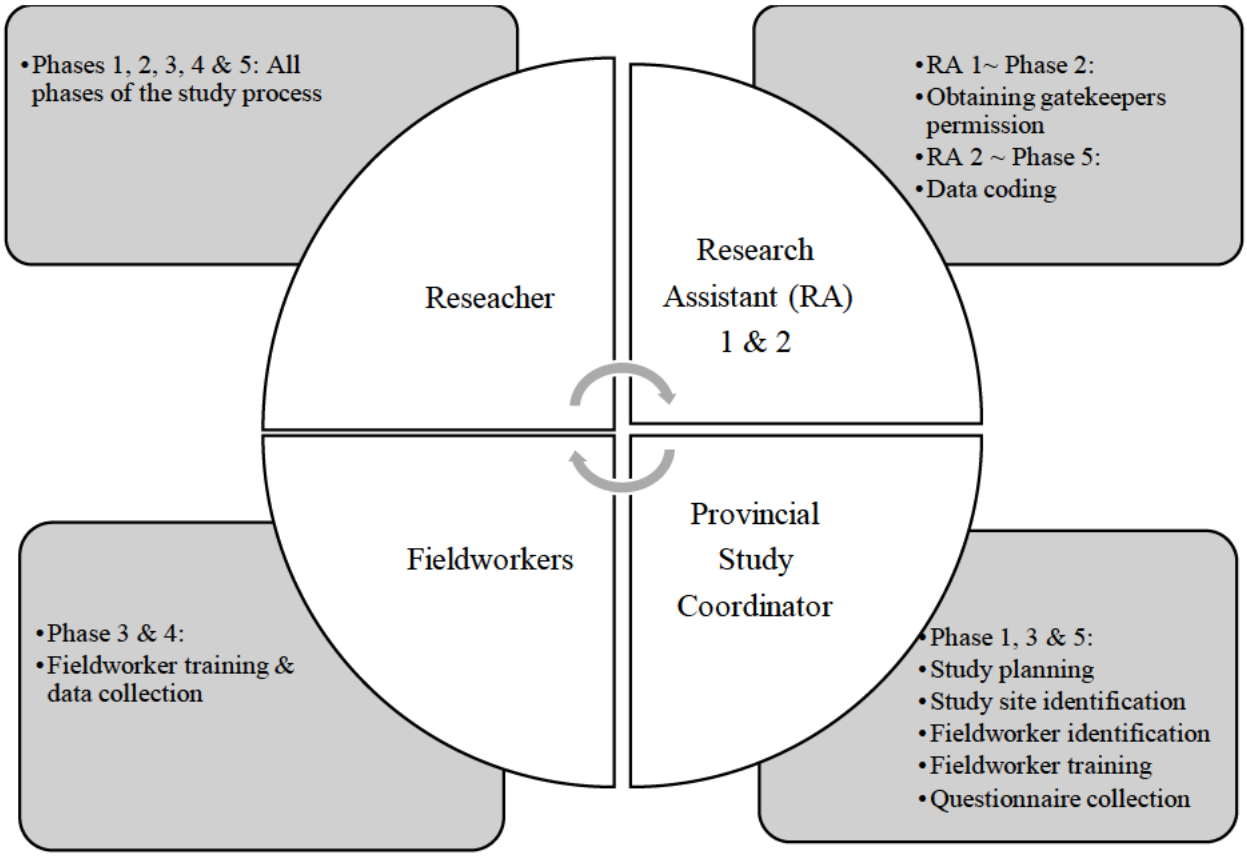

Figure 3.2: A summary of the research team and involvement during the study process

- Identification of provincial study coordinators (two in the Eastern Cape, one in the Free State, one in Gauteng, and one in Mpumalanga);
- Convening SAM roundtable discussions to identify hospitals, finalise data collection instruments, and making logistical arrangements for implementation of study;
- Compilation of the research protocol, data collection instruments and informed consent form;
- Preparing and submitting all documentation and information necessary to obtain ethical approval and gatekeepers' permission at institutional, provincial and national level within the Department of Health (DOH) of SA;
- Designing training materials and conducting a three-day training session for the research team;
- Facilitating the registration of research assistant one and fieldworkers on the payroll of Sefako Makgatho Health Science University (SMHSU) for payment of stipends;
- Liaison with human resource and financial departments from SMHSU to ensure payment of stipends to research assistant one and fieldworkers;

- Collection of completed data collection instruments from the provincial study coordinators in the Free State, Gauteng and Mpumalanga;
- Collection of completed data collection instruments from seven fieldworkers stationed at the six hospitals in the Eastern Cape and one hospital in Mpumalanga;
- Data collation;
- Assisting the statistician with data analysis;
- Data interpretation and formulation of conclusions and recommendations;
- Report writing for DOH and the Funder;
- Compilation of journal papers for publication in peer-reviewed scientific journals; and
- Provision of feedback to stakeholders at DOH regarding the outcomes of the study.

3.9.2.2. Role of research assistants

Two research assistants were used in the course of the study. The first research assistant was responsible for:

- Submission of the research protocol to the National Health Research Database;
- Liaison with the provincial health managers and hospital CEOs and managers to obtain support for the implementation of the SAM study;
- Collecting signed requests for approval from 16 hospitals for inclusion in the study; and
- Obtaining gatekeepers permission letters from provincial health research departments.

The second research assistant assisted with data coding and capture, in addition to being responsible for evaluation and validating the accuracy of coded data captured on Microsoft Excel Spreadsheets before data was imported into the Statistical Package for Social Sciences (SPSS) version 25.

3.9.2.3. Role of provincial study coordinators

Four provincial study coordinators supported the study. Their responsibilities included the following:

- Supporting the first research assistant to secure meetings with hospital Chief Executive Officers (CEOs) and managers to obtain gatekeepers permission;
- Identifying on-site fieldworkers;

- Daily liaison with fieldworkers during the first week of data collection to provide assistance and support and ensuring the validity and reliability of data collection techniques used by fieldworkers;
- Provision of ongoing fieldworker support during the data collection period; and
- Collection of completed questionnaires from fieldworkers.

3.9.2.4. Role of on-site trained fieldworkers

On-site trained fieldworkers were appointed for each of the study sites to assist with daily data collection over a period of three months; followed by weekly follow-up monitoring of participants for a further three months. The 16 fieldworkers were responsible for:

- Data collection throughout the data collection period;
- Daily screening of all IYC between the ages of six months and five years regarding the management of SAM during the data collection period for inclusion in the study sample;
- Informing the mother/caregiver regarding the study aim and objectives and obtaining informed consent for identified IYC for inclusion in the study sample;
- Collecting demographic and baseline anthropometric data of participants following admission and resuscitation;
- Daily data collection regarding the presence/absence of oedema, appetite and diarrhoea from admission to discharge;
- Daily weighing and measuring of MUAC from admission to discharge;
- Recording mother/caregiver contact details upon discharge, in addition to other relevant data used to monitor the participant for a period of three months post-discharge;
- Marking the patient's file with an identification sticker upon discharge for identification in event of re-admission;
- Reviewing participant records for the management of SAM for three months post-discharge to determine how many IYC included in the original study sample were re-admitted for the treatment of SAM. Fieldworker identification of re-admissions were possible as the files of all study participants could be identified with a sticker on the patient file indicating "SAM Study", in addition to the participant's study number and date of discharge. These identification stickers were removed by the fieldworker after the three-month period post-discharge had lapsed.

3.9.3. Data collection process

Data collection took place as per figure 3.3. Fieldworkers were responsible for identifying IYC with SAM between the ages of six months and five years for inclusion in the study sample. Daily screening was conducted to ensure that all newly hospitalized IYC with SAM were included in the study if the met the study's inclusion criteria and the mother/caregiver gave informed consent for participation. Study participants were examined daily to collect data regarding clinical signs such as the presence/absence of diarrhoea, oedema and the presence/absence of appetite. MUAC was also measured daily. Upon discharge, the fieldworker obtained the mother/caregiver's contact details and marked the participant's file with a sticker for identification purposes, in event of re-admission. IYC were followed-up on a weekly basis for a three-month period post-discharge to determine treatment outcomes/progress following discharge and whether re-admission for the treatment of SAM occurred.

3.9.4. Data collection methods and procedures

When determining nutritional status of IYC, anthropometry, biochemistry, clinical and dietary assessments are the core elements. For the purpose of this study, anthropometric, clinical and diet-related assessments were conducted to generate data regarding the nutritional status of the study sample and to determine whether the treatment to manage SAM complied with the feeding regimen and national DOH SAM treatment protocol. As standardised measuring techniques and calibrated scales were used for collecting anthropometric data, it was ensured that weight, length/height and mid-upper arm circumference (MUAC) measurements were reliable and valid (CDC, 2007; Cashin & Oot, 2018). The presence/absence of oedema and diarrhoea was documented to serve as clinical indicators associated with SAM (Cashin & Oot, 2018). Diet-related data was collected to determine compliance with the recommended feeding regimen and SAM treatment protocol.

Data collection for the abovementioned study variables were conducted according to the methods and procedures described below.

3.9.4.1. Weight

Body weight was determined upon admission and every day at the same time one hour before or after a feed. Infants were weighed without clothes (only dry nappies were allowed), whereas children were weighed wearing only a dry nappy. Weight was measured using an electronic

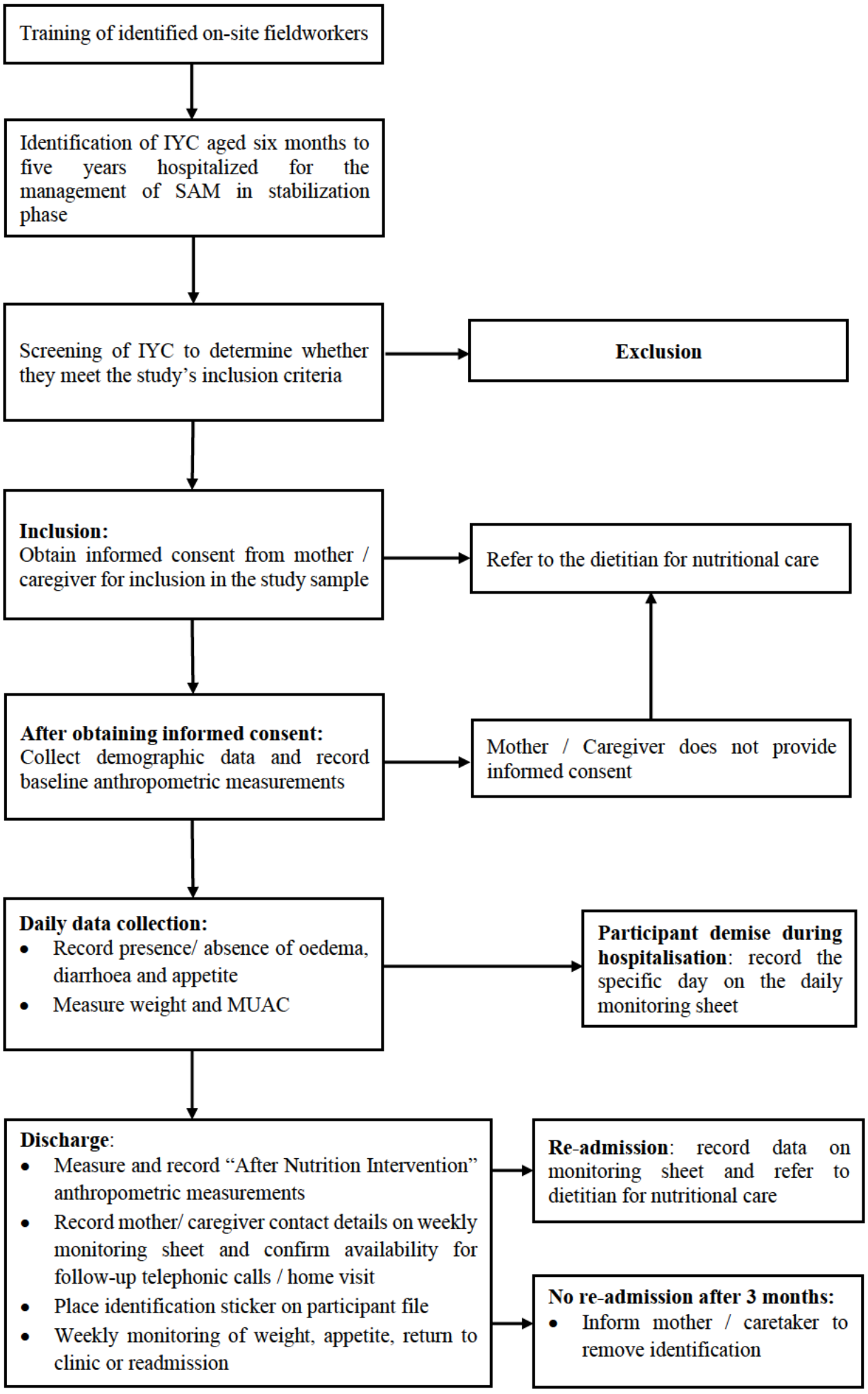

Figure 3.3: Data collection process

baby scale that was calibrated before each IYC were measured. To measure the weight of IYC younger than 24 months, a SECA® 354 digital baby scale (see figure 3.4) was used.

Figure 3.4: SECA® 354 digital baby scale used for measuring the weight of IYC younger than 24 months.

The weight of children between the ages of two and five years was measured using the SECA® 750 mechanical floor scale (see figure 3.5).

Figure 3.5: SECA® 750 mechanical floor scale used for measuring the weight of children two to five years.

IYC were weighed according to the following international procedures (WHO, 2008):

IYC younger than 24 months

1. Ensure the scale is positioned on an even, flat surface;
2. Remove the IYC clothes (dry nappies for infants allowed);
3. Put a cloth in the pan of the baby scale;
4. Adjust the scale to zero with a cloth in the pan;
5. Place the IYC on the pan (lying down or sitting upright);
6. Wait for the weight to stabilize;
7. Measure weight to nearest 0.01kg/10g;
8. Clothe the IYC immediately.

Children aged two to five years

1. Ensure the scale is positioned on an even, uncarpeted floor;
2. Remove the child's clothes and shoes (underwear allowed);
3. Request the child to step onto the scale, standing still and upright in the middle of the platform, facing the fieldworker, looking straight ahead with the feet flat and slightly apart until the reading is taken.
4. Wait for the weight to stabilize;
5. Measure weight to nearest 0.01kg/10g;
6. Mother/caregiver is requested to clothe the child immediately after stepping off the scale.

Historic information regarding birth weight and growth monitoring was collected, using the Road-to-Health-Chart.

3.9.4.2. Length and height

A SECA® 416 infantometer (figure 3.6) was used to measure the length of IYC between six and 24 months, with length being measured in a supine position as depicted in figure 3.7.

Figure 3.6: SECA® 416 infantometer used for measuring height of IYC younger than 24 months

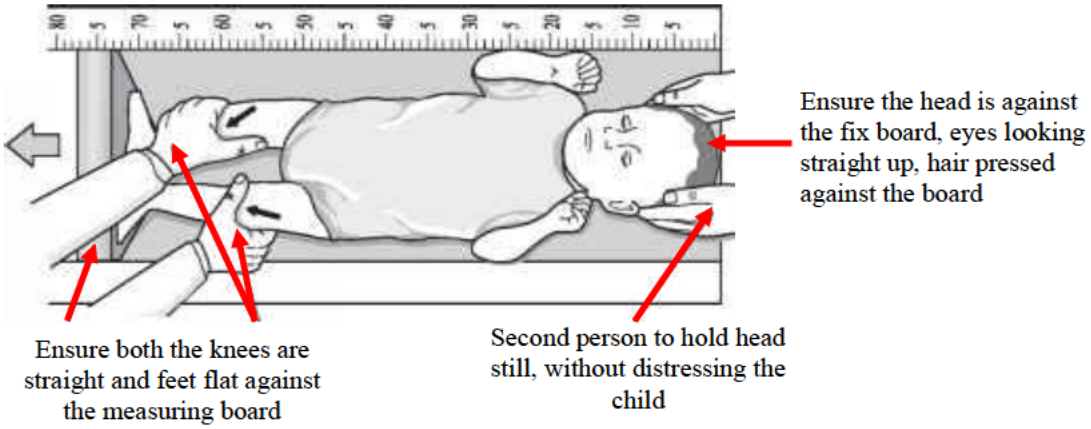

Figure 3.7: Measuring the length of IYC, aged 6 to 23 months
Source: WHO (2008)

The height of children aged between two and five years was measured using the SECA® 217 stadiometer (see figure 3.8). In addition, the height of children taller than 85cm that was also measured in a standing position.

Figure 3.8: SECA® 217 stadiometer to measure height of IYC two to five years

Infants and young children 6 to 23 months

When using a measuring board with a headboard and sliding foot piece (infantometer), the following guidelines were followed (WHO, 2008):

1. Position the board flat on a table;
2. Cover with a thin cloth or paper;
3. Undress the child;
4. Position the child lying on his/her back, support the head and position against the headboard;
5. Hold the head with two hands and tilt upwards with eyes facing upwards;
6. Support the child's trunk as the head is positioned;
7. Press shins or knees gently and firmly downwards;
8. Straighten knees;
9. Place foot piece firmly against feet so that soles are flat on the board and pointing upwards;
10. Measure length to last completed 0.1cm;
11. Dress the child immediately;

Two people are required to measure length, with one person holding the head and ensuring that the legs are straight, while the other person documents the height (WHO, 2008).

Children two to five years

For children, whose height was measured using a stadiometer, the following steps were followed (Stewart, Marfell-Jones, Olds & De Ridder, 2011):

1. The child stood upright with the heels together and heels, buttocks and upper part of the back touching the scale;

2. The head was placed in the Frankfort plane, i.e. the lower socket of the eye (the orbitale) being in the same horizontal plane as the notch superior to the tagus of the ear (the tragion), and did not touch the scale;
3. Once the child's head was positioned in the Frankfort plane, the child was instructed to take and hold a deep breath;
4. The recorder placed the headboard firmly down on the highest point of the skull (the vertex), compressing the hair as much as possible;
5. The measurement was taken before the child exhaled.

3.9.4.3. MUAC

The MUAC of the left upper arm, measured at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromium), was determined using a colour coded tape or non-stretch measuring tape that measures in cm (WHO, 2011), with the following steps being followed:

1. The mid-point between the elbow and the shoulder (acromion and olecranon) was determined;
2. The tape measure was placed around the left arm, while the arm was relaxed and hanging down the side of the body (see figure 3.9);
3. MUAC was measured while ensuring that the tape neither pinched the arm, nor was left loose;

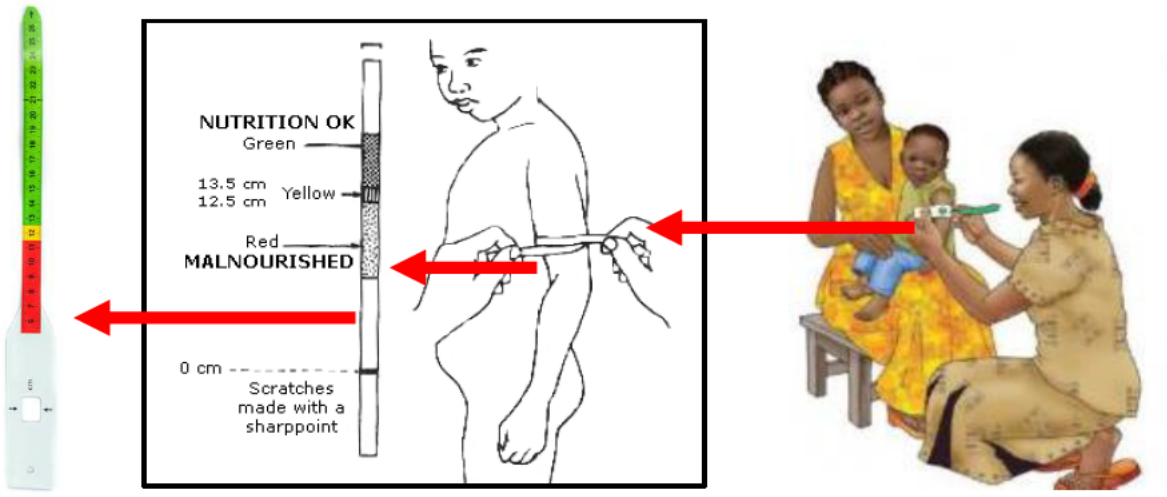

Figure 3.9: Measuring MUAC using a MUAC tape
Source: WHO (2008)

4. The measurement was read from the window of the tape;
5. MUAC was recorded to the nearest 0.1 cm/ 1mm.

3.9.4.4. Oedema

Oedema, characterised by the swelling caused by the accumulation of fluid in body tissues, was classified as absent, mild, moderate or severe (see table 3.2) (Cashin & Oot, 2018; WHO, 2019). It was measured by pressing a thumb gently on the top of the participant's feet as illustrated in figure 3.10., and classified as present when dents remained in the participant's feet after the fieldworker's fingers were removed (NDOH, 2015; WHO, 2019). In addition, the various grades of oedema as described in table 3.2 was used to classify the daily presence / absence of oedema.

Table 3.2: Grades of Bilateral Pitting Oedema

Grade	Description	Nutritional Status
Absent or 0	No bilateral pitting oedema	Non oedematous malnutrition
Grade + (Mild)	Mild: Both feet/ankles	SAM
Grade ++ (Moderate)	Moderate: Both feet, plus lower legs, hands or lower arms	SAM
Grade +++ (Severe)	Severe: Generalised bilateral pitting oedema, including both feet, legs, arms and face	SAM

Adapted from: *NDOH (2015); Cashin & Oot (2018); WHO (2019)*

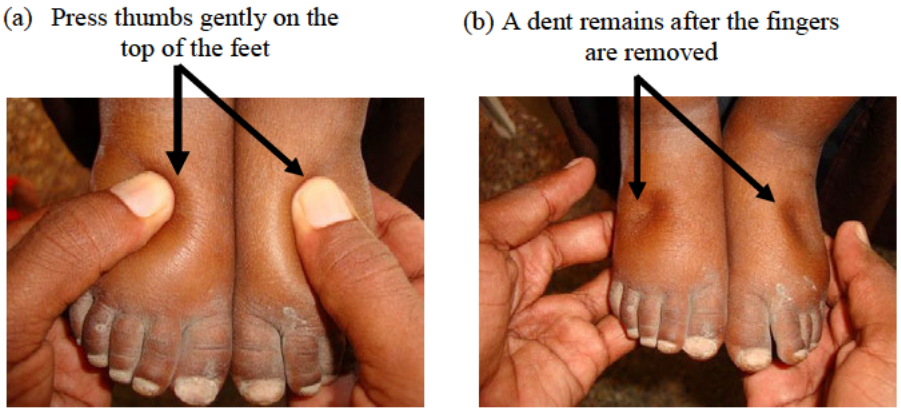

Figure 3.10: Determining the presence of bilateral oedema
Source: WHO (2019)

3.9.4.5. Diarrhoea

Diarrhoea is defined as an increase in the frequency, size or loosening of the bowel movement and volume of stool consistency from normal (Irena, Mwambazi & Mulenga, 2011; NDOH,

2015). Diarrhoea was recorded on admission, followed by daily recordings based on reviewing inpatient notes of the IYC and fieldworker observations.

3.9.4.6. Household Food Security

Household food security (HHFS) is defined as a situation where all household members can access food daily according to individual requirements to meet nutritional requirements and attain optimum health. The access to food can be hindered by an inability to be productive or because of the unavailability of funds to access food at a household level (Coates, Swindale & Bilinsky, 2007).

Internationally, various measuring tools are available to determine HHFS. The most common methods used to determine HHFS include dietary diversity (DD) and food frequency scores (FF), Coping Strategies Index (CSI), The Household Economy Approach (HEA), "Food poverty" (purchasing power) approach and household income/expenditure surveys based on probability sampling (FAO, 2013; Cashin & Oot, 2018).

For this study, HHFS was measured using the household food insecurity access scale (HFIAS), which is a dietary diversity and food frequency scoring method.

Using the guidelines of the HFIAS, ten questions were included in the data collection instrument to measure the IYCs access to food. The intention of these questions was to measure an occurrence of an experience related to HHFIS, followed by a response (rarely, sometimes or often) to determine the frequency of the specific occurrence. The reflection of experiencing HHFIS was focused on the 30 days prior to interviewing the mother/caregiver. The questions regarding HHFIS included in the data collection instruments for this study is outlined in table 3.3.

Table 3.3: HFIAS Questions included in the SAM study

Occurrence questions & response options to measure household food insecurity experience	Frequency-of-occurrence questions & response options
In the last month, did you worry that you and your household members would not have enough food? 1. Yes 2. No (skip to question 12)	How often did you worry about this? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)
In the last month, did you and your household eat limited types and amounts of food because of a shortage of money? 1. Yes 2. No (skip to question 14)	How often did you worry about this? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)
In the last month did your child have to eat a smaller meal than you felt he / she needed because there was not enough food? 1. Yes 2. No (skip to question 16)	How often did you worry about this? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)
In the last month, did your child have to eat fewer meals because of a lack of food at home? 1. Yes 2. No (skip to question 18)	How often did you worry about this? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)
In the last month, was there ever a situation where there was no food of any kind for your child to eat? 1. Yes 2. No (skip to Section C)	How often did you worry about this? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)

3.9.4.7. Feeding regimen and compliance with the SAM protocol

The compliance monitoring tool that was designed according to SAM treatment standards and scored using a scoring scale of one to five, was used to analyse and assess the following information:

- Availability and use of SAM protocols;
- Availability and use of feeding regimens (product specifications, formulas, recipes, etc.)

3.9.4.8. Post- discharge monitoring and re-admission

Following discharge, the field worker monitored the progress of the IYC for three months. Participants that passed away during hospitalisation or who were transferred to other hospitals were excluded from this phase of data collection that was collected via a telephone call/home visit, using a structured questionnaire to record data that included the following:

- Weekly monitoring to determine IYC progress (according to the criteria described above) and whether the IYC was taken to the clinic/hospital following discharge. Where an IYC passed away following discharge, the fieldworker recorded it on the questionnaire;
- After three months, fieldworkers reviewed patient admissions for the previous three months and determined whether any of the study participants had been re-admitted to hospital.

3.10. DATA ANALYSIS

3.10.1. Daily Weight Gain

Daily weight gain was coded as good (1), moderate (2), and poor (3) as outlined in the SA operational guidelines for the Integrated Management of children with SAM (NDOH, 2015) according to the following criteria:

- Good: 10g/kg/day
- Moderate: 5-10g/kg/day
- Poor: <5g/kg/day (WHO 2003)

3.10.2. MUAC

MUAC measurements were conducted daily. The following criteria was used to classify MUAC (NDOH, 2015, Cashin & Oot, 2018):

- SAM (MUAC < 11.5cm),
- Moderate Acute Malnutrition (MAM) - (MUAC between 11.5-12.4cm)
- Well nourished - (MUAC > 12.5cm).

3.10.3. Clinical signs associated with SAM

Appetite was recorded as good (1) or poor (2), with good being recorded if the participant finished his/her feed and the participant's mother/caregiver reported that the participant ate well (NDOH, 2015).

Diarrhoea was recorded as (Irena *et al.*, 2011; NDOH, 2015):

- Absent
- Acute watery diarrhoea – lasts several hours or days, and includes cholera;
- Acute bloody diarrhoea – also called dysentery; and

- Persistent diarrhoea – lasts 14 days or longer.

Oedema was classified as follows, using the data a described in table 3.2 (NDOH, 2015; Cashin & Oot, 2018; WHO, 2019):

- Absent
- Mild: Both feet/ankles (Grade +)
- Moderate: Both feet, plus lower legs, hands or lower arms (Grade++)
- Severe: Generalised bilateral pitting oedema, including both feet, legs, arms and face (Grade +++)

3.10.4. Weight-for-age, weight-for-height/length and height/length-for-age

The WHO z-scores described in Addendum E were used to classify anthropometric indicators according to the WHO growth standards for weight-for-age, weight-for-height / length and height / length-for-age as described in table 3.4.

3.10.5. Household Food Security

The household food insecurity access scale (HFIAS) aims to measure various indicators associated with household food insecurity (HHFIS), including household food insecurity access related conditions and domains and HFIAS score and prevalence (Coates *et al.*, 2007).

- Formula to calculate the percentage of participants that experienced any of the HHFIS conditions at a given frequency:

$$\frac{\text{Number of households with response = 3 to Q10}}{\text{Total number of households responding to Q9}} \times 100$$

(Response = 3 refers to answering “Often”)

Table 3.4: WHO growth standards classification

Anthropometric Indicator	AGE		WHO Z-SCORES						
	6-23 months	2-5 years	< -3	≥ -3 to ≤ -2	≥ -2 to ≤ -1	≥ -1 to ≤ +1	≥ +1 to ≤ +2	≥ +2 to ≤ +3	≥ +3
Length-for-age	✓		Severe stunting	Moderate Stunting	Normal				Extreme Tallness
Height-for-age		✓	Severe stunting	Moderate Stunting	Normal				Normal
Weight-for-age	✓	✓	Severe underweight	Moderate underweight	Normal		Not used to determine overweight		
Weight-for-length	✓		Severe wasting (SAM)	Moderate wasting (MAM)	Normal		Possible risk for overweight	Overweight	Obesity
Weight-for-height		✓	Severe wasting (SAM)	Moderate wasting (MAM)	Normal		Possible risk for overweight	Overweight	Obesity

Adapted from: *WHO (2008); NDOH (2015); Cashin & Oot (2018)*

(i) HFIAS related domains

The purpose of this calculation was to determine the percentage of participants that had insufficient quality of food (Coates *et al.*, 2007).

$$\frac{\text{Number of households with response = 1 to Q3}}{\text{Total number of households responding to Q3}} \times 100$$

(Response = 1 refers to answering "Yes")

(ii) HFIAS related scales score

Calculation of the sum of frequency of occurrence of HHFIS in the last 30 days before the interview was conducted with the mother/caregiver, associated with the food-insecurity related conditions measure in the current study. Before the calculation was done, it was important to change the coding of all "No" responses from "2" to "0", e.g. Q2=0, Q4=0, Q6=0, Q8=0, Q10=0 (Coates *et al.*, 2007).

- Calculating the HFIAS Score out of a total of **15** (Response 3*5 Questions = 15):

$$\text{HFIAS Score (0-15)} = Q2 + Q4 + Q6 + Q8 + Q10)$$

- Formula to calculate the average HFIAS score (Indicator):

$$\text{Average HFIAS Score} = \frac{\text{Sum of HFIAS Scores in the sample}}{\text{Number of HFIAS Scores (i.e. households) in the sample}}$$

(iii) HFIAS related prevalence

Calculation of the Household Food Insecurity Access Prevalence/Status (HFIAP), as described in table 3.6, was reported according to the calculations for four different household food insecurity levels, namely food secure (level 1), mildly food insecure (level 2), moderately food insecure (level 3) and severely food insecure (level 4) (Coates *et al.*, 2007). For the purpose of this study the HFIAP categories were reported as a total, per province and according to IYC gender.

Table 3.6: Calculations used to determine household food security or -insecurity

Level of food security	Category of food security / food insecurity	Calculations
Category 1	Food secure	Q2 response = rarely (1) / never (0); ***and*** Q3, Q5, Q7, Q9 = 0
Category 2	Mildly food insecure	Q2 response = sometimes (2) / often (3); ***or*** Q4 response = rarely (1) ***and*** Q5, Q7, Q9 = 0
Category 3	Moderately food insecure	Q4 response = sometimes (2) / often (3) ***or*** Q6 response = rarely (1) / sometimes (2) ***or*** Q8 response = rarely (1) / sometimes (2) ***and*** Q9 = 0
Category 4	Severely food insecure	Q6 response = often (3) ***or*** Q8 response = often (3) ***or*** Q10 response = rarely (1) / sometimes (2) / often (3)
Total # households with a food (in)security category		? total

Source: Coates et al. (2007)

(iv) Household food insecurity (HHFIS) prevalence

Calculating the percentage of household food insecurity prevalence for each of the food security / food insecurity levels as described in table 3.6 (Coates *et al.*, 2007).

- Percentage of severely food insecure households:

$$\frac{\text{Number of households with HFIA category = 4}}{\text{Total number of households with a HFIA category}} \times 100$$

- Percentage of moderately food insecure households:

$$\frac{\text{Number of households with HFIA category = 3}}{\text{Total number of households with a HFIA category}} \times 100$$

- Percentage of mild food insecure households:

$$\frac{\text{Number of households with HFIA category = 2}}{\text{Total number of households with a HFIA category}} \times 100$$

- Percentage of food secure households:

$$\frac{\text{Number of households with HFIA category = 1}}{\text{Total number of households with a HFIA category}} \times 100$$

3.11. STATISTICAL ANALYSIS

IBM SPSS (version 24) was used for statistical analysis. Descriptive statistics, namely frequency distributions, percentages, means, medians, and standard deviations were used to present continuous and categorical data. Logistic regression analysis and multivariate analysis were done in order to link outcome measures and their associations. The association between categorical variables were compared using the Chi-square test.

3.12. ETHICAL CONSIDERATIONS

3.12.1. Gatekeepers' permissions

For the purpose of describing the approval process, any manager or health professional employed by the DOH at institutional, provincial or national level, that was responsible for providing permission for inclusion of identified health facilities in the SAM study, was referred to as a gatekeeper. The approval process to obtain permission from gatekeepers and ethical approval for the current study, is summarised in the flow diagram presented in figure 3.11.

Before final ethical approval for the current study could be obtained from the Biomedical Research Ethics Committee (BREC) from the University of KwaZulu-Natal, permission from gatekeepers at DOH at national, provincial and institutional level had to be obtained.

The first step in obtaining approval for the implementation of the current study, was to obtain consent from the Director General: National DOH to accept the research grant from SANULAC Nutritionals South Africa Pty Ltd (previously known the Nutritional Division of Aspen Pharmacare) for the implementation of the study as required by South African Regulation 991 of 6 December 2012, Regulations relating to foodstuffs for IYC. This approval was of utmost importance as paragraph 2(h) of these guidelines stipulates that research grants for conducting research in health establishments may only be accepted upon prior approval from the Director General. This approval was obtained on

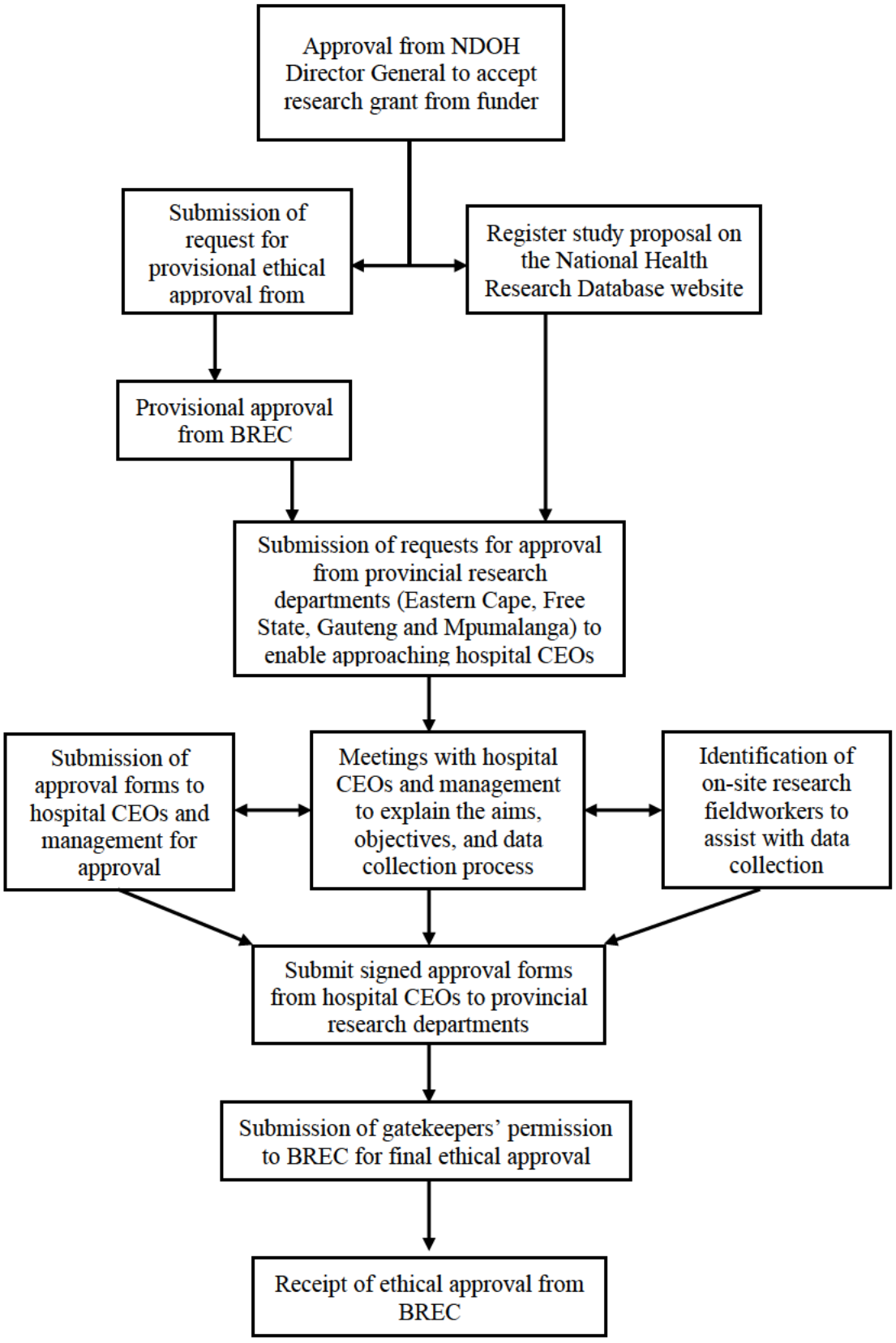

Figure 3.11: Flow diagram to illustrate the process of obtaining gatekeeper permissions and ethical approval

11 September 2017 as seen in the document attached as Addendum F and was attached to the initial application submitted to BREC for provisional ethical approval.

After consent for accepting the research grant from the funder was received, approval from the provincial health research departments were sought. The study protocol was uploaded on the National Health Research Database in order to obtain approval from Eastern Cape, Free State, Gauteng and Mpumalanga health research departments. Following this, research approval requests, together with copies of the research protocol, approval letter from the Director General and provisional approval from BREC was submitted to hospital CEOs at institutional level to obtain permission for the inclusion of the hospital as a study site in the study. The research assistant met with hospital CEOs and hospital management to explain the purpose, aim and objectives of the study, as well as the data collection process. During this meeting, an on-site research fieldworker was identified to assist with data collection at that hospital.

Signed research approval requests were submitted to the provincial health research departments from the four provinces, upon which an approval letter was issued (refer to Addendum F) for copies of these letters received from provincial research committees to be made available. These permissions were submitted to BREC to seek final ethical approval to enable the commencement of data collection.

3.12.2. ETHICAL APPROVAL AND PERMISSION TO CONDUCT THE STUDY

As illustrated in figure 3.11, approval from BREC to conduct the current study was obtained in two phases. The first phase was to apply for provisional approval to conduct the study. The provisional approval was submitted to accompany provincial research approval requests in order to continue with the approval process within DOH. Once permission was obtained from all gatekeepers, the respective permissions were obtained from DOH, followed by a final application to BREC for ethical approval to implement the study. Ethical approval from BREC (Ethical reference number BE603/17) was received on 6 February 2019 (refer to Addendum G for copies of the provisional and final ethical approval obtained from BREC).

3.13. INFORMED CONSENT

Before data collection commenced, written informed consent was obtained from the mothers / caregivers of the IYC (Addendum H). The study objectives and the use of the results were explained to mothers/ caregivers in their home language by the on-site fieldworkers. All mothers / caregivers were informed that participation in the study was voluntary and refusal to participate would not compromise medical treatment of the IYC that was hospitalized for the treatment of SAM. Mothers / caregivers were assured that all information and data collected during the study would be treated as confidential. To ensure participant anonymity, even when results of the study are published in scientific journals or presented at scientific congresses, each participant was allocated a code for identification purposes to ensure that all data collected could be linked to the study participant with the same code.

The mothers / caregivers were requested to sign an informed consent form in duplicate, with an independent witness also signing both copies. The one copy was retained by the participant, while the other was kept by the researcher. Informed consent forms were kept separately from the study questionnaires to ensure participant anonymity.

3.14. CONFIDENTIALITY AND ANONYMITY

Mothers/ caregivers (and hence IYC included in the study sample) were allocated a code for identification purposes, thus ensuring participant anonymity and confidentiality. In addition, the research team had a participant register that was used to allocate numbers to study participants. The consent forms, participant register and completed questionnaires were stored in a filing cabinet that was locked with only members of the research team having access to it. The completed survey questionnaires will be stored in a safe place at the Sefako Makgatho Health Sciences University (Human Nutrition Department) for a period of five years before being destroyed via shredding.

3.15. VALIDITY AND RELIABILITY

In order to evaluate the study outcomes, the rigor of the research process plays a vital role. To ensure that the outcomes of this study are valid and reliable, the study and

methods of data collection was designed to ensure that the study aims, objectives and hypothesis are aligned to the problem statement.

3.15.1 Validity

Validity is defined as the ability of a measuring instrument to measure what it is supposed to measure (Heale & Twycross, 2015; Leedy & Ormrod 2016). Babbie and Mouton (2008) adds that validity refers to the extent to which research conclusions are sound, as well as the level at which documented data adequately reflects the actual meaning of the concept under investigation.

Convenience sampling was used to cover the broad context regarding the treatment of IYC hospitalized for SAM in the identified areas. Input from health and nutrition programme managers from the DOH as a source of expert input was taken into consideration during the design of the data collection instruments and research methods to ensure that all aspects of the management of SAM amongst hospitalized IYC between the ages of six months and five years were included. Provincial study coordinators were nutrition managers from the Eastern Cape, Free State, Mpumalanga and Gauteng. Hence, they had the necessary knowledge and insight regarding the management of SAM in their respective local municipalities. In addition, they were familiar with the respective study areas and health managers (gatekeepers) in the area and supported the research process by identifying the most appropriate hospitals for inclusion in the study sample, based on district health statistics (DHIS). Fieldworkers were members of the local community where the hospital was situated. This enabled fieldworker access to hospitals and can conduct follow-up home visits post-discharge.

In theory, there are three types of validity namely content validity (or also known as face validity), construct validity and criterion validity (Heale & Twycross, 2015). In this study the following steps were taken to ensure validity in the context of these three types of validity:

- **Face validity:** as a source of expert input, roundtable discussions were conducted with nutrition managers from provinces and districts included in the study to discuss the questionnaire content and questions posed to ensure that all the relevant content

was covered to attain the study aims and objectives. Their expert input was also invaluable in planning the logistical aspects of the study by enabling access to facilities and having data collection instruments available during the implementation of the study.

- **Construct validity**: standard internationally recognised methods were used to collect anthropometric data and determine clinical signs of SAM. Standard anthropometric equipment was procured and made available at all health facilities included in study to ensure accurate measurement of weight, length, height and MUAC.

- **Criterion validity:** to demonstrate criterion validity, study variables were defined and measured with reference to international standards. These measurements included the following:

    - Standard anthropometric measuring techniques to measure weight, length/height and MUAC (WHO 2008);
    - Standard criteria and methods to determine clinical signs of SAM such as oedema, diarrhoea and appetite (NDOH 2015; WHO 2019);
    - The WHO z-scores to interpret weight-for-age, length/height-for-age and weight-for-height (WHO 2007);
    - The HFIAS to determine HHFIS (Coates *et al.*, 2007);
    - The SAM treatment protocol compiled by the SA DOH outlining criteria to determine compliance with the protocol for the in-patient treatment of SAM (NDOH, 2015).

Other aspects that enhanced validity included the development of the research instruments and theoretical framework with reference to available research and guidelines on the topic, i.e. both nationally and internationally. In addition, pilot testing of the research instruments also contributed to validity.

3.15.2 Reliability

Reliability refers to the ability of a measuring instrument to accurately deliver consistently the same standards or outcomes when it is repeated by either various researchers or in various research projects (Heale & Twycross, 2015). Polit and Beck (2018) add that reliability relates to the accuracy and consistency of information obtained in a study.

In order to ensure that the data was reliable, all research assistants, provincial study coordinators and fieldworkers received extensive training on all data collection instruments (questionnaires), methods for calibrating anthropometric equipment and conducting anthropometric measurements according to international standards. The training also included the reinforcement of existing skills when conducting clinical examinations. To ensure that the research team was familiar with basic skills and knowledge regarding the measurement of anthropometric indicators and conducting clinical examinations, only dietitians and nurses were included in the research team. In order to curb human error when conducting anthropometric measurements, fieldworkers calibrated the scales before each IYC was weighed, in addition to taking each anthropometric measurement twice to determine the accuracy thereof.

Reliability of the research instruments were ensured by developing it with reference to the most recent available research, international- and national guidelines, in addition to obtaining expert input. To ensure consistency, the same field workers were used for data collection at the respective hospitals that served as study sites for the duration of the study.

Cronbach's alpha is the mostly frequently used test to determine the internal consistency of a data collection tool (Heale & Twycross, 2015). Where appropriate, collected data was analysed on SPSS, using the Cronbach's alpha test as part of the statistical analysis, as it confirms internal reliability of research instruments. However, it does not necessarily confirm validity. Double data entry limited data entry errors.

3.16. STUDY LIMITATIONS

The execution of this study posed minimal limitations. Corrective measures were taken during the planning process to limit potential challenges while awaiting approval from the DOH and the respective ethics committees. Hence, the study only included three hospitals in each of the provinces where the study was conducted, as the inclusion of more hospitals per province, would have complicated the monitoring of the data collection process. However, since the hospitals that were included in the study were identified by managers from DOH, more facilities had to be included in Eastern Cape (six instead of three) and Mpumalanga (four instead of three). Another possible limitation which could affect research findings was the introduction of bias of using a convenience sample as it may misrepresent the target population, i.e. malnourished IYC (Jager, Putnick & Bornstein, 2017).

Limitations encountered during the data collection process are described with reference to: (i) study participants; and (ii) difficulties encountered following discharge and the monitoring of re-admission.

3.16.1. Study participants

- Since current SAM treatment protocols and standards are not different for IYC with a known HIV status, HIV as an underlying causes of malnutrition was not included / determined in this study (Mambulu-Chikankheni, Eyles, Eboreime & Ditlopo, 2017);
- The predominant study limitation was an inability to recruit 30 participants per hospital due to low admission rates;
- Fieldworkers only collected data on weekdays, resulting in clinical data not being collected over weekends;
- The birth weight of all participants could not be documented due to the unavailability of a Road-to-Health Booklet;
- Appetite tests were not conducted during hospitalization;
- Fieldworkers lost contact with participants transferred to other hospitals;

3.16.2. Post-discharge and re-admission monitoring of study participants

The following challenges were encountered during the post-discharge monitoring period. This hampered the collection of post-discharge and re-admission data:

- Fieldworkers were unable to track participants referred to local clinics for follow-up following discharge as mothers/caregivers only brought participants to local clinics a month after discharge;
- Mothers/caregivers provided incorrect telephone numbers and/or home addresses;
- IYC living with siblings or caregivers went to live with grandparents residing in other areas/provinces;
- Employed mothers/caregivers sent study participants to live with grandparent(s);
- Fieldworkers had insufficient airtime to contact mothers/caregivers for monitoring participants post-discharge and hospitals did not allow fieldworkers to use official telephones to contact mothers/caregivers;
- Fieldworkers did not have transport to conduct home visits;
- Fieldworkers were permanently employed, resulting in an inability to continue with participant monitoring following discharge;
- Participants were transferred to other health facilities and fieldworkers were not granted permission access the contact details of mothers/caregivers;
- Fieldworkers were not granted access to patient admission files to determine if any of the study participants were re-admitted, with little or no assistance from hospital personnel to gain access to patient files for data collection purposes. This resulted in the possibility that some IYC were readmitted but excluded from the study due to limited fieldworker access to patient files.

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CHAPTER 4

Title of manuscript:

The evolution of nutrition strategies for the management of severe acute malnutrition amongst young children

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Biomedical Research Ethical Committee (BREC), University of KwaZulu-Natal (Ref.no: BE603/17)

Conflict of interest:

Neither the researcher or the study supervisors accepted any salary, wage, stipend, or any other form of payment from the funder.

Contributor statement:

MB and SK conducted the literature search. MB wrote the first draft of the manuscript. All authors edited the manuscript and approved the final content. MB is primarily responsible for the paper's final content.

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The evolution of nutrition strategies for the management of severe acute malnutrition amongst infants and young children

ABSTRACT

Globally, about 15 000 young children die daily due to diarrhoea, pneumonia and malaria, complicated by malnutrition. Nutrition strategies are worldwide implemented to address SAM, to reduce IYC mortality. The purpose of this scoping review was to evaluate the evolution of SA nutrition strategies for the management of SAM. Key points in this paper were obtained through online literature reviews. Literature included in this review focused mainly on in-patient nutrition strategies recommended by the WHO and those amended for and implemented in the SA context. Various nutrition strategies have been implemented to reduce the incidence of IYC mortality and acute malnutrition. In 1981, the WHO published the *"Ten steps to recovery"* guidelines for the management of malnutrition, which were globally amended by countries according to local milieus. These guidelines were updated in 1999, 2003 and 2013. The term "PEM" has been replaced with "SAM" from 1999. The 2015 SA treatment protocol for the integrated management of SAM was based on the 2013 WHO 10 steps in the of SAM. Before 2015, the PEMP was used for the nutritional care of malnourished IYC. Although nutrition practices for the management of SAM amongst IYC have evolved significantly from the 1950's, little changes have been introduced since 1999. A national and global review of these nutrition strategies is necessary, based on outcomes of recent studies.

KEY WORDS

"severe acute malnutrition", "SAM", "management and treatment of severe acute malnutrition

KEY MESSAGES:

- Preventable and treatable medical conditions such as diarrhoea, pneumonia and malaria are exacerbated by the complexity of malnutrition;
- The SA NDOH SAM treatment protocol of 2015 was based on the 1999 WHO SAM treatment guidelines, as amended in 2013. However, these SAM treatment guidelines are outdated and need to be revised;

- Updated scientific evidence from recent studies conducted globally, should be used to review national and international SAM treatment protocols;
- SAM treatment protocols are essential in reducing IYC mortality through improved inpatient management of SAM.

INTRODUCTION

Today, about 15 000 IYC will die globally. In 2016, 5.6 million IYC died because of preventable conditions such as diarrhoea, pneumonia and malaria, exacerbated by the devastating immensity and complexity of malnutrition (UN IGME, 2020; ATNF, 2018). Approximately half (45%) of these deaths were associated with malnutrition and inadequate nutrition-related practices (ATNF, 2018). In SA, childhood deaths do not only occur because of preventable causes like diarrhoea and pneumonia, but also because of HIV infection (Bamford *et al.*, 2018)

In response to these childhood deaths, countries all over the world committed to allocate resources towards the reduction of IYC mortality rates. SA is one of these countries which are devoted to reach the SDGs pertaining to IYC mortality (UN IGME, 2017; UN IGME, 2020). Implementation guidelines developed by the WHO and UNICEF has been adopted and amended by the SA NDOH to develop policies, protocols, operational guidelines and nutrition intervention programs aimed at the reduction of IYC mortality ($NDOH_a$, 2015). The operational guidelines for the integrated management of IYC with acute malnutrition have been adapted from the 2013 WHO 10 steps in the management of SAM, amending it for the SA milieu. The integrated management of SAM is one of the most important nutrition intervention strategies to reduce IYC mortality ($NDOH_b$, 2015).

The purpose of this review is not only to evaluate the evolution of SA nutrition strategies aimed at managing and treating SAM, but also to highlight research findings which can strengthen these interventions. This is essential for improving and upscaling of current nutrition intervention strategies which contribute to the reduction of IYC mortality.

METHODS

Key points in this paper were obtained in the form of a scoping literature review. An online literature search was used to identify published and unpublished literature. Databases included PubMed, MeSH, PLoS, SA e-Publications (Sabinet) and Google Scholar. Literature searches were also conducted to identify policies, protocols and other relevant publication and study documents produced and published by the Sa doh and other international health organizations such as the WHO, UNICEF and FAO. Key words used to generate results for database searches, included "severe acute malnutrition", "SAM", "management and treatment of severe acute malnutrition", "protein energy malnutrition", "PEM", "kwashiorkor", "marasmus", "child mortality", "protocol for the management and treatment of severe acute malnutrition". Other key words per topic and type of literature sources included in the search are indicated in table 4.1.

Although there is a vast body of written works regarding SAM, including an extensive range of topics, only literature which focused on guidelines for the implementation of nutrition strategies to manage and treat SAM, research findings on the evaluation of the implementation of SAM policies, protocols and guidelines and technical reports, bulletins or reviews which reported on IYC mortality were included in this review. Literature which was excluded from this review were literature written in a language other than English or those written on the pathophysiology of severe acute malnutrition, or which focused on obesity and / or micronutrient deficiency defined as "malnutrition". To include literature on historic practices, literature from as early as 1950 has been included in this review. The focus was mainly on nutrition intervention strategies recommended by the WHO and those amended and adapted for implementation in SA for the management of SAM. For this review, SAM policies and protocols focused on in-patient care. Recommendations, guidelines, policies and protocols for the management of moderate malnutrition and community-based or primary healthcare-based strategies were also excluded. Lastly, although the review focussed on the management of SAM amongst IYC younger than 5 years of age, infants younger than 12 months were also excluded from the literature review.

Table 4.1: Key words and literature sources used during the computerized literature search

Topic	Key words used	Literature sources
Prevalence of severe acute malnutrition	• Child mortality rates • Under-5-mortality rates	• Scientific, peer reviewed articles • WHO/ UNICEF/ FAO reports • NDOH reports/ reviews
Management of severe acute malnutrition: Guidelines/ Protocol/ Policies	• Severe acute malnutrition • "SAM" • South Africa • Guideline/ implementation guideline • Protocol • Policy • Treatment of severe acute malnutrition/ SAM • Management and treatment of severe acute malnutrition/ SAM	• National Department of Health (NDOH): Policies, Protocols, Implementation Guidelines • WHO Guidelines for health workers • UNICEF Programme Guidance Documents/ Technical Papers
Supplementary Foods/ Nutrition Interventions for the management of SAM	• Therapeutic milk • F-75/ F-100 • F75/ F100 • Ready-to-use-Therapeutic Food/ RUTF	• Scientific, peer reviewed articles • Unpublished research & literature • NDOH: Policies, Protocols, Implementation Guidelines • WHO • UNICEF Technical Bulletin • Cochrane Systematic Reviews
History of SAM	• Protein Energy Malnutrition • PEM • Kwashiorkor • Marasmus • Malnutrition • History	• NDOH: Policies, Protocols, Implementation Guidelines • WHO Guidelines for health workers • Cochrane Systematic Reviews

Titles, abstracts and executive summaries of literature were scanned to identify relevant information which were included in this review. The full texts of articles, publications and policies / protocols were obtained and the information to be included in this review was further identified. Citations recommended by literature sources were used for citation and in cases where citations were not recommended, Google Search has been used to confirm the relevant citation.

Because a mixture of scientific articles and publications from health organizations have been used, research methodology or study design was not used as criteria to determine which literature qualifies for inclusion or exclusion. However, conflict of interest was assessed to identify subjectivity in cases where research outcomes focused on the recommendation of specific food supplements, such as therapeutic milks or RUTF as part of the management of SAM.

DISCUSSION

Child survival goals

The SDG target for IYC mortality has called upon a renewed commitment from SA to reduce IYC mortality. The global target of the SDG is to reduce IYC mortality to 25 deaths per 1 000 live births (UN General Assembly, 2015). Globally, the under-5 mortality rate has reduced from 93 deaths per 1000 live births in 1990, to 41 in 2016 (WHO, 2018). Although SA statistics indicate that the under-5 mortality rate has dramatically increased between the late 1990's and early 2000's from 60 deaths per 1000 live births to 78, the under 5-mortality rate have reduced with almost half (37-40.5 deaths per 1000 live births) in 2015 (Bamford *et al.*, 2018).

Recent data published by the UN IGME (2020), indicated that globally, IYC mortality decreased by almost half of what it has been in 1990. In the early 1990's, about 12.5 million IYC died annually, opposed to the reported 5.6 million in 2016, and 5.2 million in 2019 (UN IGME, 2017; UN IGME, 2020). In Sub-Saharan Africa, one in every thirteen IYC will die before their fifth birthday, mainly because of malnutrition (UN IGME, 2020).

Defining malnutrition

The term "malnutrition" is commonly used in literature to refer to the double burden of disease, which include undernutrition and overnutrition. In addition to over- and undernutrition, micronutrient deficiencies are also included under the term "malnutrition" (ATNF, 2018). The WHO define "malnutrition" as a lack, surplus or inequality of energy and / or other nutrients, causing undernutrition and overnutrition. Undernutrition refers to stunting (low height for age), wasting (low weight for height) and underweight (low weight for age) (Ghosh-Jerath *et al.*, 2017).

However, in most cases, malnutrition is used when referring to only underweight, which refers to protein-energy-malnutrition (PEM) (WHO, 1999; World Heritage Encyclopaedia, 2020). PEM, also known as SAM, refers to kwashiorkor (a lack of protein in the diet), marasmus (a deficiency in energy intake) and marasmic-kwashiorkor (a lack of both energy and protein in the diet) (Ghosh-Jerath *et al.*, 2017).

Classification of PEM or acute malnutrition

In 1956 Gomez and Galvan studied various factors which are common contributors amongst Mexican IYC who suffered from severe underweight. These factors were evaluated and used to create a classification system to determine the extent and severity of PEM (World Heritage Encyclopaedia, 2020). According to the GOMEZ classification, the weight-for-age of the child is categorized according to the deviation thereof from the expected weight-for-age or the standard of the National Centre for Health Statistics (NCHS) median. The percentage of reference weight-for-age was calculated by using the following formula: [(Patient weight / Expected weight-for-age) x 100]. The calculated percentage weight-for-age was interpreted as either first grade / mild malnutrition, second grade / moderate malnutrition or third grade / severe malnutrition (Garrow & James, 1993).

Following this classification, various other classification systems have been designed in developing countries to classify the severity and extend of PEM. Other common PEM classification systems used historically included the WHO PEM classification system of 1971, the Wellcome PEM classification system and the Waterlow PEM classification

system. All these classification systems used the percentage of weight-for-age (defined as “wasting”) as an indicator to determine the type of PEM with or without the addition of other anthropometric measuring indicators and clinical signs of undernutrition. As seen in table 4.2, other indicators used to classify the type of PEM included the percentage weight-for-height, the percentage height-for-age (defined as “stunting”) and the presence of oedema. Each of these classification systems had different ranges of percentages which were used to classify the type of PEM. For example, the GOMEZ classification system used less than or equal to 60% weight-for-age to classify malnutrition as severe, whilst the Waterlow classification system used less than 70% of weight-for-age to classify severe malnutrition (Passmore & Eastwood, 1986; Garrow & James, 1993; Bender, 2014, World Heritage Encyclopaedia, 2020).

In today’s world, acute malnutrition is the “term” most commonly used when referring to the prevalence of these conditions defined by the above-mentioned historic classification systems. A clear distinction is drawn between MAM and SAM. SAM is defined by using weight-for-height, MUAC and / or oedema. A child who presents with any one of the following indicators, is classified as a child with SAM: (i) Weight-for-height lower than -3 z-score; and / or (ii) MUAC of less than 11.5 cm in IYC aged six to 60 months; and / or (iii) the presence of bilateral pitting pedal oedema (nutritional). Acute malnutrition is defined as MAM when the child’s weight-for-height is between -3 to -2 z-score; or when the MUAC measurement is between 11.5 – 12.5 cm (NDOH, 2015).

Nutrition interventions for the management of acute malnutrition

Because of a global unavailability of and inaccessibility to adequate and safe food in vulnerable populations, investing in nutrition intervention strategies and programs is vital for achieving child survival goals (USAID, 2018). Various food and nutrition intervention programs have been implemented worldwide over the past 30 years to reduce the incidence of not only IYC mortality, but also acute malnutrition, amongst IYC under the age of 5 years (UN General Assembly, 2015; NDOH, 2003).

Table 4.2: Indicators used for classification of PEM according to the GOMEZ, WELLCOME, WATERLOW and WHO PEM Classification Systems

Classification system	**Types of PEM**	**% weight-for-age (the standard or NCHS median)**	**% weight-for-height (the standard or NCHS median)**	**% height-for-age (the standard or NCHS median)**	**Presence of oedema**
GOMEZ	• 1st grade / mild malnutrition • 2nd grade / moderate malnutrition • 3rd grade / severe malnutrition	Yes	No	No	No
WELLCOME	• Undernutrition • Marasmus • Kwashiorkor • Marasmic-kwashiorkor	Yes	No	No	Yes
WATERLOW	• Mild PEM • Moderate PEM • Severe PEM	Yes	No	Yes	No
WHO	• Underweight • Marasmus • Kwashiorkor • Marasmic-kwashiorkor • Nutritional dwarfing	Yes	Yes	No	Yes

Sources: World Heritage Encyclopaedia, 2020; Garrow & James, 1993; Passmore & Eastwood, 1986; Bender (2014)

Although there is an immense amount of nutrition intervention strategies used globally to manage and treat MAM, the focus for this review will be on nutrition intervention strategies used by the WHO and SA NDOH for the management of SAM.

The WHO has published guidelines for the management of malnutrition as early as 1981. The purpose of these guidelines was to provide clear and easy principles to mid-level healthcare workers for the in-patient treatment and rehabilitation of IYC diagnosed with PEM to speed up recovery and decrease IYC mortality. The 1981 guidelines provided information on the management of (i) moderate or severe dehydration, (ii) manifested or suspected infection, (iii) eye signs of severe vitamin A deficiency, (iv) severe anaemia, (v) hypoglycaemia, (vi) ongoing or recurring diarrhoea, (vii) skin lesions and mucous membrane lesions, (viii) marked anorexia (no desire to eat), and (ix) hypothermia (WHO, 1981). Following the important *Ten steps to recovery* publication, these guidelines were updated in 1999, 2003 and 2013 and the term "PEM" was replaced with "SAM" (Tickell & Denno, 2016). The new guidelines were based on 10 steps, guiding health professionals in the management of SAM, focusing on (i) treating and preventing hypoglycaemia, hypothermia and dehydration, (ii) correcting electrolyte imbalances, (iii) treating infection, (iv) correcting micronutrient deficiencies (without iron), (v) initial and catch-up growth feeding, (vi) stimulating emotional and sensory development, and (vii) preparation for discharge (WHO, 1999).

According to the 1981 guidelines, a child diagnosed with PEM would receive no fluids or food other than Oral Rehydration Salts (ORS) Solution and breastmilk (if breastfed) for the first day of treatment in the presence of dehydration. In the absence of dehydration, a child was fed either half strength milk feeds or breastmilk from day 1. Dehydrated IYC would then receive half strength milk on days 2 and 3. On days 4 and 5, the half strength milk was replaced with full strength milk and from day 6 onwards until discharge a malnourished child would have received high energy milk feeds with accompanying solid foods. Iron was supplemented daily from day 1 as part of the treatment of micronutrient deficiencies (WHO, 1981).

However, these feeding recommendations have been changed from 1999 and therapeutic milks are provided to the malnourished IYC in two phases, namely the initial phase and

the rehabilitation phase. For these phases, therapeutic milk feeds, known as F-75 and F-100, is prescribed for initial and rehabilitation feeding practices. According to the most recent WHO guidelines for the management of SAM, breastfeeding should be continued without interruption during the initial and rehabilitation phases. Unlike the 1981 recommendations, iron is not supplemented during the first 7 days of initial treatment. It is only supplemented from day 8 onwards and continued for 3 months after discharge (WHO, 1981).

A comparison between the feeding guidelines for milk feeds between the 1981 and 1999 guidelines for the management of PEM/SAM is provided in table 4.3. Recipes for the preparation of the recommended milk feeds were included in both the 1981 and 1999 feeding guidelines (WHO, 1983; WHO, 1999). Today, these therapeutic feeds (F-75 and F-100) is commercially available as ready-to-use or ready-to-mix feeds.

From 1972 the Protein Energy Malnutrition Program (PEMP) was used in SA for the nutritional care of a malnourished child. The aim of the PEMP was to strengthen activities around the prevention and treatment of malnutrition amongst IYC younger than 5 years of age by means of what was coined the Integrated Nutrition Program (INP). The purpose of the INP was to facilitate a co-ordinated, intersectoral approach to solve nutrition challenges in SA (NDOH, 2003; NDOH$_a$, 2015). Primary interventions of the INP included nutrition education, the protection, promotion and support of exclusive breastfeeding for 6 months, appropriate complimentary feeding practices, growth monitoring and the prevention of growth faltering. The PEMP was part of secondary interventions which included the provisioning of supplementary food to malnourished IYC and referral of mothers to community-based nutrition interventions and projects of the INP. Food supplements which were issued to malnourished IYC included enriched maize meal, an enriched protein drink, acidified / soya based infant formula and a multivitamin syrup. Individual needs were mainly based on age. These food supplements were provided to IYC for a period of 3–6 months. Household food insecure families were referred to Social Welfare for registration and enrolment in the social grant program. Vegetable seeds were also distributed to establish vegetable gardens at household level

Table 4.3: Comparison of the 1981 and 1999 / 2013 WHO guidelines for the management and treatment of malnutrition (PEM / SAM)

Feeding guideline	**1981 WHO guidelines for the management of PEM**		**1999 / 2013 WHO guidelines for the management of SAM**	
Type of feed used for correcting electrolyte imbalance and treat dehydration	• ORS Solution • *Ingredients:* Sodium Chloride, Sodium Bicarbonate, Potassium Chloride, Glucose • *Dosage:* 50-100 ml/kg in the first 4-6 hours of treatment.		• ReSoMal (provided by UNICEF) • *Ingredients*: Glucose, Sodium, Potassium, Chloride, Citrate, Magnesium, Zinc and Copper • *Dosage*: 70-100 ml/kg within 12 hours (5 ml/kg for the first 2 hours of treatment; children < 2 years 50-100 ml and children ≥ 2 years 100-200 ml after each loose stool)	
Type of supplementary feed	Day 1	ORS (dehydration) or Half strength milk feeds (no dehydration)	Day 1	ReSoMal and F-75** (F-100** no hypothermia, dehydration or septic shock)
	Day 2	Half strength milk feeds	Day 2	ReSoMal and F-75
	Day 3	Half strength milk feeds	Day 3-7	F-75 (start transition to F-100, based on outcome of appetite test)
	Day 4 to 5	Full strength milk feeds	Day 7 onwards	F-100
	Day 6 onwards	High energy milk feeds	Week 2 – 6	Prepare for discharge (transition to RUTF)
Type of milk recommended to prepare milk feeds	• Fresh cow's/goat's/ewe's/buffalo's milk or • Evaporate milk or • Full cream/skimmed milk powder or • Yoghurt (recommended for lactose intolerance) • K-MIX2 (calcium caseinate, skimmed milk powder, sucrose, retinol palmitate)		• Dried skimmed milk powder or • Fresh cow's milk • Yoghurt or commercial lactose free milk (recommended for lactose intolerance)	

Feeding guideline	**1981 WHO guidelines for the management of PEM**				**1999 / 2013 WHO guidelines for the management of SAM**		
Other ingredients added to milk feeds	• Sugar • Water (half strength milk feeds / when milk powder used / K-MIX2) • Vegetable oil (K-MIX2) • Cereal flour (rice/wheat/millet/oatmeal flour)				• Sugar • Water • Cereal flour • Vegetable oil • Vitamin and mineral Mix		
Vitamin/mineral supplementation	• Iron: 60 mg / day (from day 1) • Potassium chloride: 4 mmol/kg/day • Folic Acid: 100 µg / day • Vitamin A: *Day 1 and 2* *Infants <12 months:* 50 000 IU injection or 100 000 IU orally *Children ≥12 months:* 100 000 IU injection or 200 000 IU orally *Day 3 onwards* = 3 000-5 000 IU orally per day				• Iron (only from Day 8 until 3 months post-discharge): 3 mg / kg / day (up to 60 mg) • Folic acid: 5 mg on day 1 and thereafter 1 mg daily • Vitamin A: Day 1 and 2 and 2 weeks after admission *Infants <6 months:* 50 000 IU orally		
Vitamin/mineral supplementation	• Vitamin K: 10 mg (not indicated whether dosage is once off or daily) • Multivitamin drops or tablets containing Vitamin C, D and B-complex (no dosage recommended)				Infants 6-12 months: 100 000 IU orally *Children >12 months:* 200 000 IU orally • Vitamin B complex, vitamins D, E and K (according to prescription for vitamin and mineral premix)		
Amount of feeds in 24 hours	Day 1 to 2	12 (2 hourly)			According to a feeding chart for F-75 (6-12 feeds: every 2-4 hours) and F-100 (6 feeds: 4 hourly).		
	Day 3 to 5	8 (3 hourly)					
	Day 6 onwards	6 (4 hourly)					
Amount of feed according to body weight	Day 1	70ml/kg/day			The amount of feed that should be administered to a child is based on weight and is prescribed according to the feeding chart for F-75 and F-100 (example 130 ml / kg / day during initial phase should be maintained).		
	Day 2 to 3	Not specified					
	Day 4 to 5	125 ml/kg/day					
	Day 6 to 8	150 ml/kg/day					
	Nutrient	Half	Full	↑Energy	Nutrient	F-75	F-100
	Energy	168 kJ	336 kJ	567 kJ	Energy	315 Kj	420 kJ

Feeding guideline	1981 WHO guidelines for the management of PEM				1999 / 2013 WHO guidelines for the management of SAM		
Nutritional content per 100 ml supplementary feed	Protein	1.5 g	3.0 g	3.0 g	Protein	0.9 g	4.2 g
Availability of recommended products	• ORS Solution: Mixed according to recipe or provided by WHO; • Milk feeds: Mixed according to recipe in WHO guidelines; • K-MIX2: Provided by UNICEF				• ReSoMal: Provided by UNICEF; • Milk feeds: Mixed according to recipe in WHO guidelines or commercially available; • Vitamin and mineral premix: Provided by UNICEF or commercially available		

Sources: WHO, 1983; WHO, 1999; WHO, 2013

(NDOH$_a$, 2015). In-patient care of IYC with SAM was based on recommendations and opinions of experts in the field (Tickell & Denno, 2016).

In the early 2000's, Puoane *et al.* (2001) conducted research in Sipetu and Mary Theresa District Hospitals in the Mount Frere Health District (Eastern Cape). The purpose of this research was to assess the treatment practices for malnourished IYC, followed by recommendations on how to improve treatment practices. The assessment and recommendations were based on the 1999 WHO 10 steps for the management of SAM. The initial rapid assessment indicated that the practices implemented at both hospitals were different from the WHO recommendations. After staff members were trained on the WHO 10 steps for the management of SAM, treatment practices were amended, and case fatality rates improved in both hospitals within 6 months (Puoane *et al.*, 2001). Following this research, treatment practices for the management of SAM started to change and the Integrated Management of Acute Malnutrition (IMAM) protocol was issued by the NDOH for implementation in SA. Nutrition intervention strategies were meticulously defined and described in this treatment guidelines, focusing on the prevention and management of hypoglycaemia, hypothermia, micronutrient deficiencies and the feeding regimes for the severely acute malnourished child (NDOH, 2015).

CONCLUSION

Despite continuous developments within the recommended feeding regimes for the management of SAM, there is limited independent evidence-based findings and adjustments to substantiate recommendations based on the WHO 10 steps in the management of SAM. The absence of applicable published data has required dependence on expert opinion. Over the last few years, major research gaps have been identified with regards to the implementation of feeding regimes in the context of managing and treating SAM, complicated by HIV infection. It should also be noted that current treatment guidelines exclude or provide limited and vague information on the management of malnourished infants younger than 6 months of age. In addition to this, more robust post-discharge treatment guidelines are needed to prevent and decrease the incidence of SAM readmissions (USAID, 2018).

In conclusion, although the feeding regimes for the management of malnourished IYC evolved significantly from the 1950's, little changes have been introduced since 1999. The current feeding recommendations are mostly focussed on in-patient management of SAM and for IYC older than six months of age. It should be noted that the purpose of presenting the information in this review, is not to criticize the WHO or the authors of these guidelines or any other subject experts. It is merely an outcry to researchers and policy makers to update, improve and strengthen current nutrition intervention strategies, based on recent research outcomes, for the management of SAM, to curb increasing levels of IYC mortality.

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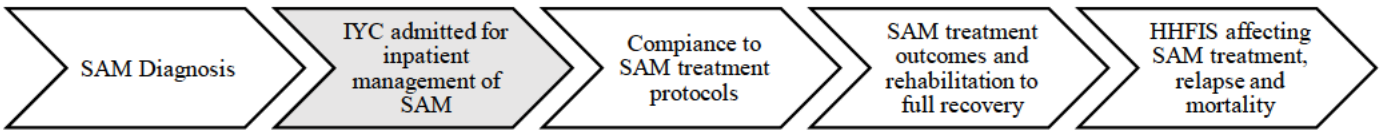
The evolution of nutrition strategies over the last five centuries simplified the inpatient management of IYC diagnosed with SAM. This evolution has brought about less complicated criteria for diagnosis of MAM and SAM, versus historic "Underweight, Marasmus, Kwashiorkor and Marasmic-Kwashiorkor" classification systems. Health professionals are now in a position to use classification criteria such as weight-for-height, MUAC and the prevalence or absence of oedema to diagnose IYC with MAM or SAM. By using the acute malnutrition algorithm, IYC with SAM can sooner be identified for hospitalization and inpatient management of SAM.



CHAPTER 5

Title of manuscript:

Nutritional status of children, hospitalized for inpatient management of severe acute malnutrition in South Africa

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Contributor statement:

MB and FV designed the research study. MB and SK conducted the literature search. FV & MB analyzed the data. MB wrote the first draft of the manuscript. All authors edited the manuscript and approved the final content. MB is primarily responsible for the paper's final content.

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Nutritional Status of Infants and Young Children Admitted for Inpatient Management of Severe Acute Malnutrition

ABSTRACT

Inadequate nutritional status of IYC threaten child survival, despite admission for inpatient management of SAM. SAM is universally diagnosed using weight-for-height, MUAC and / or the presence of oedema. This study aimed to determine nutritional status of IYC admitted to 16 hospitals in SA, for inpatient SAM management. A multi-centre prospective, descriptive and comparative observational study was employed, using a convenience sample. Weight, height, MUAC and clinical data was computed for 245 IYC with a mean age of 14 ± 8.19 months. Inpatient SAM IYC were stunted and wasted. Mean admission and discharge weight was 6.63 ± 1.89kg and 7.03 ± 2.02kg; mean admission and discharge height-for-age 66.16 ±16.06 cm and 71.29 ± 11.47 cm, and mean admission and discharge MUAC 11.38 ±2.35cm and 11.51±2.35cm. Prevalence of mild, moderate and severe oedema was 21.7%, 11.1% and 8.2%. Approximately half of IYC experienced lack of appetite (46.3%) and diarrhoea (46.9%), whilst 45.2% had a poor daily weight gain less than 5g/kg/day. Mean duration for oedema, lack of appetite and diarrhoea was 6.8 ± 4.30, 4.4 ± 3.13 and 9.0 ± 5.46 days. More boys (57.1%) were hospitalized, while the mean duration of hospitalization was 10 ± 6.42 days for the study sample. The CFR was 6.1%. SAM treatment was complicated by LARIs, sepsis, HIV, TB, anemia, herbal intoxication, vomiting, hypoglycemia and cerebral palsy. Global and national SAM treatment protocols should be revised and updated to include management of SAM complications.

KEY WORDS

Infants and young children, anthropometric status, nutritional status, hospitalization, severe acute malnutrition

KEY MESSAGES

- MUAC less than 11.5 cm, lack of appetite and the presence of diarrhoea and / or oedema increase the risk for SAM mortality;

- Medical conditions such as LARIs, sepsis, debilitating conditions such as HIV and TB in combination with anemia, herbal intoxication, vomiting and hypoglycemia complicate the management of SAM;
- SAM treatment protocols need to be reviewed and updated to include guidelines on the management of SAM complicated by herbal intoxication;
- Health professionals responsible for monitoring of daily weight gain and decision-making to determine readiness for discharge should receive extensive training on calculating and interpreting adequate daily weight gain progress against set goals.

INTRODUCTION

Infants and young children (IYC) have the right to an optimal nutritional status. Despite this human right, malnutrition remains a global challenge. IYC with a poor nutritional status have a greater risk to develop malnutrition, which threaten child survival (Bamford *et al.*, 2018; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

Mid-year population estimates in SA, indicated that more than 145 000 IYC suffered from acute malnutrition (STATS SA, 2019). Furthermore, acute malnutrition was identified as one of the major causes of mortality amongst IYC, since wasted IYC were 11 times more likely to die than well-nourished children (Bamford *et al.*, 2018; WHO, 2020).

Globally, the IYC mortality rate for children younger than five years, was reported as 21.8% in 2017 (Global Hunger Index, 2019). In SA, the reported national mortality rate for children under the age of five was 28.5% for the same year (STATS SA, 2019). Internationally and nationally, a lot was done to prevent malnutrition amongst IYC (Bamford *et al.*, 2018). As a result of SA efforts, the local SAM CFR, reduced from 12.7% in 2012 to 8% in 2017, being below the global and national target of 9.0% (NDOH, 2016; Bamford *et al.*, 2018).

The term malnutrition is used as a collective term to refer to underweight, overweight and micronutrient deficiencies (WHO, 2016), while underweight includes wasting, stunting and micronutrient deficiencies (Black *et al.*, 2008). Historically, underweight or

malnutrition was commonly referred to as protein-energy-malnutrition (PEM) and categorised as marasmus (energy deficiency), kwashiorkor (protein deficiency) or marasmic-kwashiorkor (energy and protein deficiency) (Adamu *et* al., 2016; Ghosh-Jerath *et al.,* 2017). Currently, both chronic and acute forms of severe underweight is incorporated into the blanket term "severe acute malnutrition", differentiating between SAM with or without complications (Cloete, 2015; Adamu *et al.,* 2016; Ghosh-Jerath *et al.*, 2017). Stunting develops as a result of chronic malnutrition with its origins as early as in-utero and in early childhood, especially the first two years postnatally (Briend, 2019). Stunting is identified by a low height-for-age and is associated with increased morbidity and mortality from infections such as pneumonia, diarrhoea, sepsis, meningitis, hepatitis and tuberculosis (Black *et al.*, 2008; De Onis & Branca, 2016; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). Wasting, also referred to as acute malnutrition, is a life-threatening condition requiring immediate health and nutritional intervention to improve child survival, with direct causes being related to inadequate food and nutrient intake or infectious disease. Furthermore, wasted IYC are immuno-compromised with a lack of emergency treatment resulting in IYC being at a greater risk of mortality, especially if they are severely malnourished (NDOH, 2015; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

At present, a distinction is made between SAM and moderate acute malnutrition (MAM) (NDOH, 2015; Adamu *et al*., 2016). MAM makes a larger contribution to the burden of malnutrition than SAM, in addition to the mortality risk being lower among IYC diagnosed with MAM (Briend *et al.,* 2005). A diagnosis of MAM is made when an IYCs weight-for-height is between -3 to -2 z-score between -3 to -2 below the median of the WHO z-score, or when the MUAC is between 11.5 and 12.5 cm (NDOH, 2015; Adamu *et al.*, 2016). SAM is characterised by a weight-for-height lower than -3 z-score and/or a MUAC of less than 11.5 cm and/or the presence of bilateral pitting pedal oedema. Where an IYC presents with any one of the following indicators, the IYC is classified as suffering from SAM (NDOH, 2015; Adamu *et al.*, 2016).

Furthermore, SAM is complicated by infectious diseases such as diarrhoea, LARIs and other infectious and parasitic diseases (UNICEF, WFP, WHO, UNHCR & FAO, 2020; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). The interaction between malnutrition and the development of infections are commonly known as the malnutrition-infection cycle (Darmon & Drewnowski, 2015) due to the existence of a vicious cycle between malnutrition and infectious diseases, with IYC suffering from these diseases having an increased risk of developing SAM requiring hospitalisation and vice versa. In addition, SAM increase the risk of mortality when developed in combination with IYC illnesses such as pneumonia and diarrhoea (Adamu *et al.*, 2016; Akombi *et al.*, 2017).

The aim of this study was to determine the nutritional status of IYC admitted to 16 public hospitals within SA for the inpatient management of SAM.

METHODS

A multi-centre prospective, descriptive and comparative observational study was employed.

The study setting

The study was conducted at 16 public hospitals with active SAM treatment programs, in four SA provinces. Study sites were selected, together with Provincial and Institutional Health Management. Study sites included six hospitals from the Alfred Nzo Health District in the Eastern Cape, three hospitals from the Thabo Mofutsanyana Health District in the Free State, and three hospitals in the most rural areas of the city of Tshwane municipal area. In Gauteng and Mpumalanga, four hospitals from each health district were identified as study sites.

Sampling

To determine the minimum number of study participants, a power calculation was conducted to generate 80% power, at a 0.05 level of significance. A total of 245 IYC between the ages of six months and five years, admitted to any of the 16 hospitals identified as study sites for the management of SAM, were included in the study sample. Only IYC with a first-time diagnosis and hospitalisation for the inpatient management of

SAM, were included in the study sample. IYC that were hospitalized prior to commencement of the study were not eligible for inclusion. Convenience sampling was used to cover the spectrum of treatment of IYC hospitalized for the management of SAM in Alfred Nzo, Maluti-a-Phufong, Gert Sibande, Nkangala, Ehlanzeni and Tshwane municipal areas.

Data collection instruments and data collection

Data collection instruments in the form of fieldworker administered questionnaires were used for data collection. The data collection instrument, consisting out of four questionnaires, was piloted and a reliability of 99.2% was calculated, using the Cronbach Alpha test. Local, trained fieldworkers collected socio-demographic, anthropometric and clinical data from study participants. Anthropometric measurements included body weight, length/height and MUAC. Daily clinical data included observations regarding the prevalence or absence of diarrhoea, oedema and appetite. Body weight and MUAC were measured on admission and discharge, together with daily measurements conducted at the same time one hour before or after a feed. Length/height was measured on admission and discharge.

Data interpretation and analysis

The IBM Statistical Package for Social Sciences (SPSS) version 24 was used for statistical analysis. Descriptive statistics, namely frequency distributions, percentages, means and standard deviations were used to present continuous and categorical data. Statistical significance was determined at p value lower than 0.05 with 95% confidence intervals in the final model.

WHO z-scores were used to classify anthropometric indicators according to the WHO growth standards for weight-for-age, weight-for-height and height-for-age (WHO, 2008). The WHO Anthro Plus Survey Analyser was used to analyse anthropometric indicators according to WHO z-scores to interpret underweight, stunting and wasting.

MUAC was classified as SAM if the measurement were less than 11.5cm and MAM at a measurement between 11.5 and 12.4cm (NDOH, 2015, Cashin & Oot, 2018).

Oedema was determined by gently pressing a thumb on the top of the participant's feet and classified as present when dents remained after the fieldworker's fingers were removed (NDOH, 2015; WHO, 2019). Various grades of oedema were described including absent or non-oedematous malnutrition and mild (grade +), moderate (grade ++) or severe (grade +++) oedema (NDOH, 2015; Cashin & Oot, 2018; WHO, 2019). The presence or absence of diarrhoea and appetite was determined on a daily basis, by reviewing the hospital notes of the IYC, in addition to consulting the mother/caregiver. Appetite was recorded as good or poor with it being recorded as good if the participant finished his/her feed and the participant's mother/caregiver reporting that the participant ate well (NDOH, 2015).

Daily weight gain was classified as good (10g/kg/day), moderate (5-10g/kg/day), and poor (less than 5g/kg/day) according to guidelines outlined in the SA operational guidelines for the Integrated Management of children with SAM (NDOH, 2015).

Ethical approval

Approval was obtained from the SA Health Director General for accepting the research grant from the funder as required by SA Regulations relating to foodstuffs for IYC (R991, 6 December 2012). Thereafter, approval from Provincial and Institutional Health and Research Managers was sought to include identified hospitals as study sites. Ethical approval for the implementation of the study was obtained from the Biomedical Research Ethics Committee (BREC) of the University of KwaZulu-Natal. Voluntary participation in the study was confirmed by obtaining informed consent from mothers/caregivers.

Study limitations

Study limitations included the inability to record birth weights for all participants due to the unavailability of a Road to Health Booklet and fieldworkers losing contact with participants transferred to other hospitals. The introduction of bias as a result of using a convenience sample can also be regarded as a study limitation.

RESULTS

The study sample consisted of 261 IYC admitted to the study sites for the management of SAM, of which the majority (60.8%) were male. The mean age of participants was 14.6 ±8.19 months. On admission, medical diagnosis's included SAM complicated by oedema, LARIs, sepsis, cerebral palsy, HIV, herbal intoxication, diarrhoea and/or vomiting, TB, anaemia, hypoglyceamia and dehydration. Most participants were from the Eastern Cape (49.8%), followed by Gauteng (20.3%), Mpumalanga (18%) and Free State (11.9%). Of the initial 261, data was computed for 245 IYC as data for 16 (6.2%) were excluded due to missing anthropometric data, death and transfer to next level of care.

Anthropometric indicators

Birth weight

Participants had a mean birth weight of 2.5 ± 0.98 kg, with the majority (22,2%) having a birth weight between -3 and -2 z-score while 13,4% had a birth weight of lower than -3 z-score. This was especially true for females, with 33.1% being born with a weight between -3 to less than -2 z-scores.

Weight, height and MUAC on hospital admission and discharge

On admission, mean weight was 6.6 ± 1.89 kg while mean weight upon discharge was 7.0 ± 2.02kg. Admission and discharge values for height was 66.2 ± 16.06 cm and 71.3 ± 16.06 cm while for MUAC it was 11.4 ± 2.35cm and 11.5 ± 2.57cm. IYC were admitted for a median of 10.1 ± 6.41 days, ranging between 2 and 33 days. There was a significant difference between mean admission and discharge weight (p= 0.0278) and height-for-age (p= 0.0005), with no significant difference between admission and discharge MUAC (p= 0.6533).

In the Eastern Cape, the median admission weight was 6.8 ± 1.98 kg compared to 5.2 ± 2.00 kg in the Free State, while for Mpumalanga and Gauteng it was 6.9 ± 1.34kg and 7.8 ± 9.46 kg. The mean admission height for IYC was 63.8 ± 18.96 cm in the Eastern Cape, 67.7 ± 12.20 cm in Gauteng, 70.2 ± 13.29 cm in Mpumalanga and 67.5 ± 8.28 cm in the Free State. Admission MUAC in Eastern Cape was 11.5 ± 2.29 cm, 11.0 ± 2.96 cm in

Gauteng, 11.9 ± 2.29 cm in Mpumalanga and 10.6 ± 2.80 cm in the Free State. MUAC upon discharge ranged from 11.20 ± 2.76 cm for the Free State to 12.0 ±2.06 cm in Mpumalanga. Discharge MUAC in Eastern Cape and Gauteng was 11.5 ± 2.29 cm and 11.0 ± 2.96 cm respectively. The duration of hospital admission was 3.2 ± 0.76 days in the Free State, 10.0 ± 6.79 days in Mpumalanga, 10.6 ± 5.66 days in the Eastern Cape and 12.3 ± 7.25 days in Gauteng.

Underweight (weight-for-age)

Data has been computed for 245 IYC to determine the prevalence of underweight amongst the study sample. The prevalence of underweight was 97.6% for the sample population, of which 55.2% IYC were severely underweight, 26.8% moderately underweight and 18.0% mildly underweight. As presented in table 5.1, underweight was more prevalent amongst males and IYC younger than 12 months of age. The greatest incidence of underweight was for IYC admitted for SAM management in Eastern Cape (51.4%), followed by Gauteng (20.4%), Mpumalanga (18.4%) and Free State (9.8%). Most (55.2%) of the IYC admitted for inpatient management of SAM was severely underweight. The mean weight-for-age z-score for the study population was – 3.25 ± 1.57 as indicated in table 5.2.

Acute Malnutrition (weight-for-height)

Data has been computed for 245 IYC to determine the prevalence of acute malnutrition. For the study sample, the prevalence of SAM was 89.0%, more males (54.7%) suffered from acute malnutrition than females (34.3%). More than half (51.8%) of the study sample admitted for SAM treatment was younger than 12 months, of which predominantly (55.9%) was marasmic. As reflected in table 5.3, the prevalence of marasmus, also known as SAM without oedema, was 61.0%, and for kwashiorkor, also referred to as SAM with oedema, 39.0%. The majority of IYC admitted to hospitals in the Free State (73.9%), Mpumalanga (70.7%) and Gauteng (70.8%). The prevalence of kwashiorkor and marasmus was equally amongst SAM inpatients in the Eastern Cape. The incidence of MUAC less than 11.5 cm was reported for 41% of the participants being

Table 5.1: The prevalence of underweight amongst IYC admitted for inpatient management of SAM, expressed per province, age and gender

Underweight (n=245)	Total		Severe		Moderate		Mild	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
All (IYC)	239	97.6%	132	55.2%	64	26.8%	43	18.0%
Eastern Cape	126	51.4%	64	50.8%	32	25.4%	26	20.6%
Free State	24	9.8%	15	62.5%	7	29.2%		0.0%
Mpumalanga	45	18.4%	21	46.7%	13	28.9%	11	24.4%
Gauteng	50	20.4%	31	62.0%	12	24.0%	6	12.0%
<12 months	127	51.8%	69	54.3%	32	25.2%	26	20.5%
13-24 months	91	37.1%	48	52.7%	26	28.6%	17	18.7%
25-36 months	18	7.3%	8	44.4%	4	22.2%	6	33.3%
>36 months	9	3.7%	7	77.8%	2	22.2%		0.0%
Male	150	61.2%	81	54.0%	40	26.7%	25	16.7%
Female	95	38.8%	50	52.6%	24	25.3%	18	18.9%

Table 5.2: WHO Z-Score Summary for IYC expressed per age, gender and province

WHZ (n=245)	Total	WHO Z-Score Summary					
		Height-for-Age (Stunting)		Weight-for-Age (Underweight)		Weight-for-Height (Acute Malnutrition)	
		Mean	SD	Mean	SD	Mean	SD
All (IYC)	245	-2.41	2.13	-3.25	1.57	-2.22	2.00
Male	150	-2.46	2.21	-3.37	1.52	-2.4	2.02
Female	95	-2.32	2.02	-3.08	1.63	-1.92	1.94
<12 months	112	-2.19	2.44	-3.24	1.72	-1.91	1.99
13-24 months	106	-2.36	1.87	-3.15	1.47	-2.46	2.01
25-36 months	17	-3.45	1.67	-3.53	1.31	-2.18	1.91
36-48 months	8	-3.13	1.86	-3.9	0.91	-2.75	2.01
49-60 months	2	-3.64	0.95	-4.9	1.01	-4.13	-
Eastern Cape	126	-2.61	1.85	-3.12	1.48	-1.84	2.1
Free State	24	-1.91	2.33	-3.84	1.39	-2.82	1.58
Mpumalanga	45	-2.06	2.48	-3.23	1.4	-2.8	1.41
Gauteng	50	-2.47	2.28	-3.36	1.95	-2.27	2.24

hospitalized, while 25.0% had a MUAC between 11.5 and 12.5 cm and 21.8% had a MUAC of greater than 12.5 cm. As illustrated in table 5.1, the mean weight-for-age z-score was -2 ± 2.00 and the mean weight-for-height of IYC with a weight-for-height of lower than -3 z-scores was 73.89.

Table 5.3: Prevalence of SAM, expressed per province, gender and age group

Severe Acute Malnutrition (n=245)	Total		SAM with oedema (Kwashiorkor)		SAM without oedema (Marasmus)	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
All (IYC)	218	89.0%	85	39.0%	133	61.0%
Males	134	54.7%	57	42.5%	77	57.5%
Females	84	34.3%	28	33.3%	56	66.7%
<12 months	127	51.8%	46	36.2%	71	55.9%
13-24 months	91	37.1%	34	37.4%	49	53.8%
25-36 months	18	7.3%	3	16.7%	7	38.9%
>36 months	9	3.7%	2	22.2%	6	66.7%
Eastern Cape	106	43.3%	53	50.0%	53	50.0%
Free State	23	9.4%	6	26.1%	17	73.9%
Mpumalanga	41	16.7%	12	29.3%	29	70.7%
Gauteng	48	19.6%	14	29.2%	34	70.8%

Stunting (height-for-age)

The prevalence of stunting amongst the study sample was 96.3%, of which mostly (45.8%) were severely stunted. Table 5.4 depicts that the incidence of stunting was higher in males (61.2%) and infants younger than 12 months (51.8%). The severity of stunting was comparable amongst males (44.7%) and females (43.2%). The mean height-for-age z-score was -2 ± 2.13. Of the 236 stunted IYC in the study sample, the mean height-for-age of those that were severely stunted, was 44.33 while it was 60.59 for those that were moderately stunted. The mean height-for-age below -3 z-scores was 57.14 in the age groups 24-35 months and 36-47 months. Severe stunting was more prevalent amongst IYC from the Frees State (54.2%), followed by Eastern Cape (45.2%) Gauteng (42%) and Mpumalanga (37.8%). The mean height-for-age below -3 z-scores was 49.49 in the Eastern Cape, followed by 44.44 in Gauteng, 36.59 in Mpumalanga and 33.33 in the Free State.

Table 5.4: The prevalence of stunting amongst IYC admitted for inpatient management of SAM, expressed per province, age and gender

Stunting (n=245)	Total		Severe		Moderate		Mild	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
All (IYC)	236	96.3%	108	45.8%	48	20.3%	80	33.9%
Eastern Cape	126	51.4%	57	45.2%	25	19.8%	35	27.8%
Free State	24	9.8%	13	54.2%	4	16.7%	7	29.2%
Mpumalanga	45	18.4%	17	37.8%	6	13.3%	22	48.9%
Gauteng	50	20.4%	21	42.0%	13	26.0%	16	32.0%
<12 months	127	51.8%	57	44.9%	21	16.5%	46	36.2%
13-24 months	91	37.1%	37	40.7%	25	27.5%	29	31.9%
25-36 months	18	7.3%	9	50.0%	1	5.6%	2	11.1%
>36 months	9	3.7%	5	55.6%	1	11.1%	3	33.3%
Male	150	61.2%	67	44.7%	27	18.0%	49	32.7%
Female	95	38.8%	41	43.2%	21	22.1%	30	31.6%

Clinical characteristics

Oedema

The overall presence of bilateral pitting pedal oedema was 42.9%. Table 5.5 illustrates that for the 233 study participants for which data regarding clinical characteristics were available, 100 had bilateral pitting pedal oedema, with 22.7% presenting with mild oedema (grade +), 11.6% with moderate oedema (grade ++) and 8.6% with severe oedema (grade +++). The number of days that oedema was present, ranged from one to 26 days. In the majority of cases (58.0%), oedema was resolved six days after admission.

Table 5.5: Presence of bilateral pitting pedal oedema amongst the study sample

Level of Oedema (n=233)	Frequency	Percentage	Prevalence of grades of oedema
Absent	133	57.1%	-
Present	100	42.9%	-
Mild oedema (Grade +)	53	22.7%	21.7%
Moderate oedema (Grade ++)	27	11.6%	11.1%
Severe oedema (Grade +++)	20	8.6%	8.2%

Appetite

Data on the presence or absence of appetite was available for 233 participants. Almost half (48.5%) of IYC admitted for inpatient management of SAM had a lack of appetite, that returned on day three IYC with a lack of appetite experienced this for between one and 24 days during the period of hospitalization.

Daily weight gain

Daily weight gain was analyzed for a total of 233 study participants. As illustrated in table 5.6, 119 IYC (49.2%) had a poor daily weight gain of less than 5g/kg/day, while 79 (32.6%) IYC had a good daily weight gain of 10g/kg/day or more.

Presence or absence of diarrhoea

Data was computed for 233 participants to determine the prevalence of diarrhoea. The prevalence of diarrhoea amongst IYC admitted for inpatient management of SAM was 49.4%. Acute watery diarrhoea lasted between two and 22 days, but for the majority of participants (57.7%), it resolved by day three or four.

Table 5.6: The percentage of IYC with poor, moderate or good daily weight gain during hospitalization for the management of SAM

Daily weight gain (n=242)	Frequency	Percentage of IYC with poor / moderate / good weight gain	Prevalence of poor / moderate / good daily weight gain
Good (>10g/kg/day)	242	98.8%	-
Good (>10g/kg/day)	79	32.2%	32.6%
Moderate (5-10g/kg/day)	44	18.0%	18.2%
Poor (<5g/kg/day)	119	48.6%	49.2%

IYC SAM mortality

Fifteen (15) out of the 245 participants died during the period of data collection. Most of these IYC deaths were recorded for IYC admitted to facilities in the Eastern Cape (63.0%), followed by Mpumalanga (26.0%) and Gauteng where the mortality rate was

11.0%. No deaths were reported for IYC residing in the Free State during the period of data collection.

DISCUSSION

Factors and clinical characteristics that contributed to the prevalence of SAM and increased risk for mortality was a MUAC less than 11.5cm (41.0%), lack of appetite (46.3%), the presence of oedema (41.2%) and diarrhoea (46.9%). In addition to this, SAM was complicated by LARIs, sepsis, cerebral palsy, debilitating conditions such as HIV and TB in combination with anemia, herbal intoxication, vomiting, hypoglycemia and cerebral palsy. These complications were similar to those documented in a study conducted in seven public hospitals in Limpopo, where SAM with complications such as lack of appetite (68.4%), oedema (41.0%), HIV (18.9%), LARIs (42.4%), diarrhoea (63.8%) and herbal intoxication (17.6%) was also reported Gavhi *et al.*, (2020). In a study conducted in the Eastern Cape, the use of herbal medicine was a fatal comorbidity IYC admitted for management of SAM (Muzigaba *et al.*, 2018). SAM complications reported in other African countries included HIV (27.9%) and oedema (58.2%) in Uganda (Nyeko *et al.*, 2016); LARIs (25.1%), HIV (43.8%) and dehydration (29.6%) in Cameroon (Chiabi *et al.*, 2017); and sepsis (66.7%), diarrhoea (36.4%), anaemia (37.5%) and hypoglycaemia (16.7%) in Nigeria (Babatola *et al.*, 2019). The co-occurrence between SAM and cerebral palsy reported in this study, was similar to studies conducted in Uganda (Polack *et al.*, 2018) and Saudi Arabia (Almuneef *et al.*, 2019) where malnutrition was associated with cerebral palsy amongst 58.0% and 56.4% of IYC respectively.

IYC were admitted for a mean of 10.1 days, ranging between 2 and 33 days. These 10 days are less than the 14-42-day timeframe referred to by the NDOH for the inpatient recovery from SAM (NDOH, 2015). The median length of stay for IYC admitted for inpatient management of SAM was eight days (Gavhi *et al.*, 2020). The average duration of hospitalization in Cameroon and Nigeria was 8.25 days (Chiabi *et al.*, 2017) and 4.56 days (Babatola *et al.*, 2019) respectively.

In this study, 52.7% of the IYC had a birth weight of less than -2 of the WHO z-scores, with a mean birth weight of 2.52 ± 0.95 kg. Only one out of every five IYC included in

this study sample had a normal birth weight (weight-for-age). There was a significant association between a low birth weight (LBW) (*p = 0.143*), stunting (*p = 0.129*) and wasting (*p = 0.272*). A MUAC less than 11.5cm was also associated with mortality (*p = 0.390*). The prevalence of LBW reported in this study was much higher than the 38.54% reported in Gauteng (Tshotetsi *et al.*, 2019). However, the reported mean birth weight of 2,67kg (Tshotetsi *et al.*, 2019), compared favourably to what was reported in this study. The national prevalence of LBW in 2016 was 13.3% (STATS SA, 2016). A possible reason for the higher prevalence of LBW amongst the study sample, could be attributed to the fact ~~is~~ that IYC included in this sample were diagnosed with SAM with and it is commonly known that a LBW of less than 2,49kg is a strong predictor of SAM.

The mean weight on admission and discharge for the inpatient management of SAM was 6.64kg and 7.03kg respectively. This level of weight gain is of concern, as IYC only gained a mean weight of 390g in the course of hospitalization, when taking into consideration that the mean length of hospital stay was ten days. The desirable level of weight gain in the course of hospitalization is >10g/kg/day, consistently gained over five consecutive days before an IYC can be discharged (NDOH, 2015). However, only 32.2% of the study participants gained 10g/kg/day in the course of hospitalization being lower that the 40.9% reported in Nigeria (Babatola *et al.*, 2019).

In this study sample, all IYC were underweight, with the overall prevalence of underweight being higher among males (61.2%) than females (38.8%). In Uganda, the prevalence of underweight among male IYC admitted for inpatient management of SAM was also higher (61.0%) (Nyeko *et al.*, 2016). The 2016 South Africa Demographic and Health Survey (SADHS) documented a prevalence of underweight amongst SA IYC as 5.9% (Sambu, 2019), compared to 24.8% in Ethiopia (Gebre *et al.*, 2019) and 27.5% in 35 low-middle income countries when using Demographic and Health Survey (DHS) data spanning 2007 to 2018 (Li *et al.*, 2020). However, it should be noted that data reported by Li *et al.*, (2020), refers to multi-country statistics, rendering comparisons to individual country statistics problematic.

The prevalence of stunting was 96.3% with the majority being severely stunted. However, more males were severely stunted compared to females. Severe stunting was more prevalent amongst IYC younger than 12 months. The 2016 SADHS documented that that the prevalence of underweight among SA IYC was 27.0%, with 21.0% in Mpumalanga and 34.0% for both the Free State and Gauteng (Sambu, 2019). In Ethiopia, the prevalence of underweight IYC at community level was reported as 43.1% (Gebre *et al.*, 2019), while multi-country statistics for 35 low-middle income countries using DHS data (2007-2018), documented a prevalence of 38.8% (Li *et al.*, 2020). However, it should be noted that data reported by the latter, was applicable to the prevalence of stunting amongst IYC at community level and not for those admitted for the inpatient management of SAM.

The prevalence of SAM was 89.0%, with 54.7% of males and 34.3% of females suffering from SAM. The prevalence of SAM without oedema (marasmus) and SAM with oedema (kwashiorkor) was 61.0% and 39.0% respectively. Gavhi *et al.* (2020) reported that 57.6% of IYC admitted to Limpopo public hospitals were severely malnourished, with the mean MUAC of 11.3cm documented for the current study, being similar to that reported for IYC with SAM in Limpopo (Gavhi *et al.*, 2020). Analysis of the 2016 SADHS indicated that the national prevalence of acute malnutrition was 2.5% (Sambu, 2019), while the incidence of SAM was 3.6% (STATS SA, 2016). An analysis of 2007-2018 DHS from 35 low-middle income countries, indicated that the prevalence of acute malnutrition was 12.9% (Li *et al.*, 2020). The prevalence of SAM in Cameroon was 2.7% (Chiabi *et al.*, 2017), while 16.2% was documented for Ethiopia (Gebre *et al.*, 2019). The difference between the findings of this study compared to that of other studies, can be attributed to the fact that all the participants in the current study were all diagnosed with acute malnutrition.

The overall mortality rate documented for study participants was 6.1%. This figure is in line with under-five mortality reported by Bamford *et al.* (2018), in SA, but lower than the target of lower than 10.0% outlined in the SA SAM treatment protocol (NDOH, 2015). However, it should be noted that the IYC mortality in the Eastern Cape and Mpumalanga was two to six times higher than the national target, while for Gauteng, the 10.0%

recorded, was slightly higher than the national target. Study findings of previous studies conducted in SA, reported SAM-related mortality rates of 25.9% in Limpopo (Gavhi *et al.*, 2020) and 24.4% in the Eastern Cape (Muzigaba *et al.*, 2018). The national under-five SAM mortality rates reported in 2016 was 25.9%, with the SAM mortality rate reported for the Eastern Cape, Free State, Mpumalanga and Gauteng, being 9.4%, 8.8%, 6.9% and 9.6% respectively (STATS SA, 2016). In Africa, SAM mortality rates described were higher than that reported for local studies at 11.9% in Uganda (Nyeko *et al.*, 2016); 15.0% in Cameroon (Chiabi *et al.*, 2017), 12.0% in Nigeria (Babatola *et al.*, 2019) and 14.8% in Kenya (Gachau *et al.*, 2018).

CONCLUSION

More male IYC were admitted for the inpatient management of SAM. As a LBW and a MUAC of less than 11.5cm increases the risk of IYC to suffer from SAM, it was not surprising that in the current study 13.4% IYC had a low body weight and MUAC less than 11.5 cm, while all participants were stunted and wasted. The CFR was 6.1%, which is lower than the national target of 10.0%. IYC were admitted for inpatient management with a mean/median duration 10.1 ± 6.42 days, making it lower than the national SAM treatment protocol of 14-42 days. IYC were discharged despite their daily weight gain being less than the desired >10g/kg/day. The inpatient management of SAM amongst IYC is complicated by medical conditions such as LARIs, sepsis, cerebral palsy, debilitating conditions such as HIV and TB in combination with anemia, herbal intoxication, vomiting and hypoglycemia. This was also true for IYC admitted to the study sites for inpatient management of SAM. The prevalence of lack of appetite, oedema and diarrhoea, further complicates the management of SAM. IYC admitted for inpatient management of SAM in Eastern Cape, Free State, Mpumalanga and Gauteng presented with oedema, lack of appetite and diarrhoea. Global and national SAM treatment protocols do not include the management of SAM amongst IYC, complicated by herbal intoxication and should be revised to guide health professionals to improve treatment outcomes.

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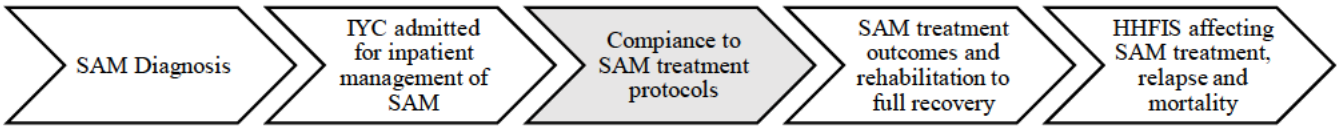
The nutritional status of IYC is an important indicator in determining treatment of IYC with SAM. Current SAM treatment protocols, based on the WHO ten steps in the management of SAM, provide step to step guidance to health professionals on the inpatient management of SAM. Various standards for admission, treatment and discharge are described in the SAM treatment protocol, as presented by the SA DOH.



CHAPTER 6

Title of manuscript:

Compliance with Treatment Protocols for Inpatient Management of Severe Acute Malnutrition in South Africa

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MB and FV designed the research study. MB and SK conducted the literature search. FV & MB analyzed the data. MB wrote the first draft of the manuscript. All authors edited the manuscript and approved the final content. MB is primarily responsible for the paper's final content.

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Compliance with Treatment Protocols for Inpatient Management of Severe Acute Malnutrition in South Africa

ABSTRACT

Inpatient management of SAM for IYC remains a global challenge due to non-compliance to SAM treatment protocols. The aim of this study was to determine compliance with the national SAM treatment protocol in 16 public hospitals. Results from this study can strengthen and improve the inpatient management of IYC with SAM. A multi-centre prospective, descriptive and comparative observational study was employed with a convenience sample. 245 IYC admitted for SAM treatment, were included in the study sample, of which 150 were male (61.2%) and 95 females (38.8%). The mean age was 14.6 ± 8.2 months. Overall compliance with the SAM treatment protocol was average (63.1%), with compliance to admission and discharge standards 98.6% and 4.4% respectively. RUTF appetite testing to determine admission was only conducted amongst 16.1% IYC. Therapeutic feeds were available and used in all hospitals. Breastfeeding was only encouraged amongst 16.4% mothers with breastfed IYC. High protein, soft meals were not provided as part of the rehabilitation phase in 43.8% hospitals. Half (48.5%) of the IYC were discharged with a daily weight gain of less than 5g/kg/day. The mean number of days for consecutive daily weight gain more than 10g/kg/day was 2.5 ± 1.8 days. 7.9% IYC were discharged despite oedema and diarrhoea still prevalent. 5.3% IYC has inadequate appetite at discharge. Compliance with the SAM treatment protocol was average, increasing the risk for relapse, readmission and death. IYC were discharged prematurely without SAM complications being resolved. Hospitalization for full recovery and rehabilitation from SAM was inadequate.

KEY WORDS

Compliance, SAM treatment protocol, SAM, inpatient management, severe acute malnutrition

KEY MESSAGES

- Compliance with SAM treatment protocols are inadequate and increase the risk for relapse, readmission and IYC mortality after discharge;
- Breastfeeding is not encouraged as part of the inpatient management of SAM for IYC;
- High protein, soft meals and snacks are not used in addition to food supplements to support catch-up growth during the rehabilitation phase;
- IYC were prematurely discharged with daily weight gain less than 5g/kg/day and oedema, diarrhoea and inadequate appetite not always resolved before discharge.

INTRODUCTION

The inpatient management of SAM for IYC remains a global challenge because of weak health systems and inadequate compliance with SAM treatment protocols (Tickell & Denno, 2016). SAM is a life-threatening condition requiring immediate health and nutritional intervention to improve IYC survival (UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020).

Inadequate healthcare services were identified as a worldwide underlying factor contributing to the prevalence of SAM and IYC mortality (UNICEF, 2015). Five UN Agencies developed and published a collective framework known as the "GAP on Child Wasting: A Framework" to fast-track progress in global reduction of IYC acute malnutrition. One of the focus points of the GAP Framework is to improve inpatient management of IYC with SAM through radical and rapid upscaling of inferior quality health services (UNICEF, WFP, WHO, UNHCR & FAO, 2020).

Treatment protocols for the inpatient management of SAM have been globally available since 1982, based on ten steps described by the WHO (WHO, 1999). Many countries, including SA, developed SAM treatment protocols based on the WHO ten steps that were amended in 1999 and 2013 (WHO, 1999; WHO, 2013; NDOH, 2015). The SA NDOH published the SA SAM treatment protocol in 2015, with the purpose to provide standardized guidelines to health professionals for the inpatient and outpatient management of acute malnutrition, including MAM and SAM (NDOH, 2015). However,

compliance with SAM treatment protocols is unsatisfactory (UNICEF, WFP, WHO, UNHCR & FAO, 2020).

In response to the need to evaluate and strengthen gaps in the delivery of health service for the inpatient management of SAM, the aim of this study was to determine compliance with the national SAM treatment protocol in 16 public hospitals located in Eastern Cape, Free State, Mpumalanga and Gauteng, SA. The contextual framework for this study, is illustrated in figure 6.1. Inadequate inpatient management of SAM results in relapse after hospital discharge, leading to a vicious cycle between hospital admission, recovery, discharge and relapse, thereby increasing the risk for IYC mortality (Stobaugh *et al.*, 2018). The purpose of both international and local SAM treatment protocols is to break the cycle and thereby improving IYC survival (UNICEF, WFP, WHO, UNHCR & FAO, 2020).

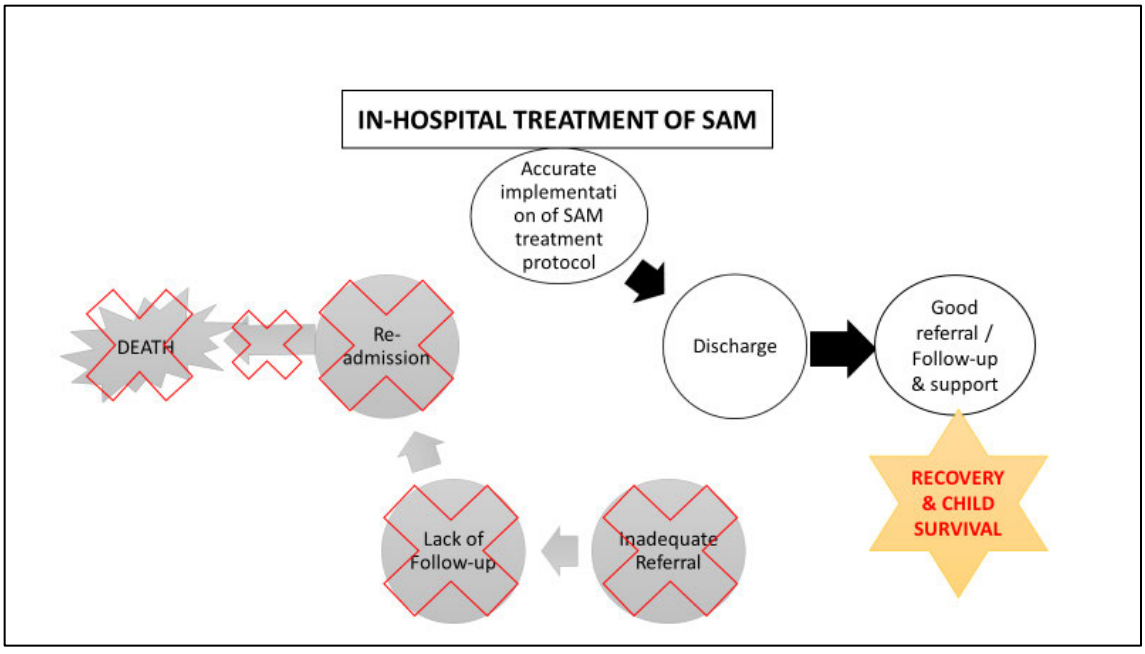

Figure 6.1: Breaking the cycle of IYC SAM to improve child recovery and survival

Source: UNICEF, WFP, WHO, UNHCR & FAO, (2020)

For the purpose of this paper, the following indicators were used to measure compliance with the SAM treatment protocol (NDOH, 2015):

- Availability of SAM treatment protocol;

- All health professionals involved in the multidisciplinary team, caring and treating the severely malnourished child, must be trained on the SAM treatment protocol;
- A ready-to-use-therapeutic-food (RUTF) appetite test must be conducted to determine whether the child should be admitted or referred to OPD;
- Availability of both F-75 and F-100 formulas;
- A strategy must be in place for short supply of F-75 and F-100;
- Recipes as prescribed in the SAM treatment protocol must be followed to prepare F-75 and F-100 formula when used;
- A commercial vitamin and mineral mix must be added to the manually mixed feeds;
- F-75 formula must be administered to the IYC before hospitalisation or upon arrival at the ward;
- The feeding regime must transition from F-75 formula to F-100 formula within five to seven days after admission;
- A high protein, soft diet must be provided during the rehabilitation phase, in addition to food supplements;
- The length of hospital stay for recovery must be two to six weeks;
- Daily weight gain of more than 10g/kg/day for at least five consecutive days before discharge must be attained;
- Nutrition supplements must be prescribed and issued as treatment to take out (TTO) at discharge;
- TTO nutrition supplements must be adequate for a week after discharge;
- The infant must be referred for follow-up at the OPD of the discharging hospital or to the local clinic.

It should be noted that neither the amount of feed nor prescribed medication as part of SAM treatment was evaluated to determine compliance with the SAM protocol.

METHODS

A multi-centre prospective, descriptive and comparative observational study was employed.

Study setting

The study was conducted at 16 government hospitals across SA with active SAM management programmes. This included six hospitals from the Alfred Nzo Health District in the Eastern Cape, three hospitals from the Thabo Mofutsanyana Health District in the Free State, and three hospitals in the most rural areas of the city of Tshwane municipal area. In Gauteng and in Mpumalanga, four hospitals from each health district were identified as study sites.

Sampling

To determine the minimum number of study participants, a power calculation was conducted to generate 80% power, at a 0.05 level of significance. A total of 245 IYC between the ages of six months and five years, admitted to any of the 16 hospitals identified as study sites for the management of SAM, were included in the study sample. Only IYC who were newly hospitalised with a diagnosis of SAM and/or who had a first-time diagnosis and hospitalisation for SAM and/or who were admitted for stabilisation, were included in the study sample. IYC that were hospitalised prior to commencement of the study were excluded. Convenience sampling was used to cover the spectrum of treatment of IYC hospitalised for the management of SAM in Alfred Nzo, Maluti-a-Phufong, Gert Sibande, Nkangala, Ehlanzeni and Tshwane municipal areas.

Data collection instruments and process

Fieldworker administered questionnaires were used data collection instruments. The data collection instrument, consisting of four questionnaires, was piloted and a reliability of 99.2% was calculated, using the Cronbach Alpha test. Local, trained fieldworkers collected socio-demographic, anthropometric and clinical data from study participants. Anthropometric measurements included body weight, length/height and MUAC. Daily clinical data included observations and/or a review of patient records to determine the prevalence or absence of diarrhoea, oedema and appetite. Body weight, length/height and MUAC were measured on admission and discharge, together with daily measurements both conducted one hour before or after a feed.

Data analysis

The IBM SPSS version 24 was used for statistical analysis. Descriptive statistics, namely frequency distributions, percentages, means and standard deviations were used to present continuous and categorical data. Logistic regression analysis and multivariate analysis was conducted to investigate the relationship between outcome measures and their associations. Statistical significance was determined at p value less than 0.05 with 95% confidence intervals in the final model.

Anthropometric hospitalization data

Weight (kg), and MUAC (cm), was measured daily as well as upon admission and discharge. These measurements were used as baseline and discharge measurement to calculate daily weight gain. Daily weight gain for each IYC was calculated using the following steps (NDOH, 2015):

Step 1: Subtract child's weight yesterday (W1) from IYC's weight today (W2):
W2 – W1 = "x" kg
"x" kg x 1000 = x grams gained
Step 2: Divide grams gained by yesterday's weight
Grams gained ÷ W1 = "x" g/kg/day
(whereby "x" refers to the numerical value of the IYC's weight

Interpretation of daily weight gain: "good" if an IYC gained more than 10g/kg/day; "moderate" between 5-10g/kg/day; and "poor" when less than 5g/kg/day as outlined in the SA operational guidelines for the Integrated Management of IYC with SAM (NDOH, 2015).

SAM compliance scoring scale

In the absence of a national or global evaluation tool to determine compliance with standards for the inpatient management of SAM, evaluation tools were developed by the researcher. Treatment protocol Standards and implementation thereof were based on the DOH SAM treatment protocol and analysed using a scoring scale. The response scoring scale was designed based on a Likert quality scoring scale, where neutrality was

represented by “average compliance” (Likert, 1932; Joshi *et al.*, 2015); with outcomes rated as follows on a scale of one to five (Likert, 1932; Joshi *et al.*, 2015):

- 5 represented 90-100% compliance = excellent;
- 4 represented 75-89% compliance = good;
- 3 represented 50-75% compliance = average;
- 2 represented 35-50% compliance = poor; and
- 1 represented <35% compliance = very poor

A score of zero was interpreted as “non-compliant”. Percentage compliance with SAM admission, treatment and discharge standards were presented as a mean for the study and per province.

Compliance with admission standards for inpatient management of SAM

Compliance with standards for admission of IYC with SAM for inpatient management, was analysed based on determining the frequency of admission. However, data did not comply with any of the following admission standards: WHZ lower than -3 z-scores, MUAC less than 11.5cm and/or RUTF appetite test failure. Meaning a “yes” response represented compliance, while “no” represented non-compliance.

Recovery from SAM complications

SAM clinical complications monitored daily were appetite, diarrhoea and oedema. Fieldworkers conducted observations, reviewed hospital records of study participants and used reporting from mothers/caregivers to determine the absence or presence of clinical complications. It was also recorded when these complications were resolved and how long after admission it took place. Clinical complications were reported as “yes” if resolved or “no” if not yet resolved.

Oedema was measured by pressing a thumb gently on the top of the participant’s feet and classified as present if the dents remained after the fieldworker’s fingers were removed (NDOH, 2015; WHO, 2019). Various grades of oedema were described, namely mild (grade +), moderate (grade ++) or severe (grade +++) oedema (NDOH, 2015; Cashin & Oot, 2018; WHO, 2019). The presence or absence of diarrhoea and appetite was determined daily, by reviewing the participant’s hospital notes and from the

mother/caregiver feedback. Appetite was recorded as good if the participant finished his /her feed without coercion (NDOH, 2015). If present, diarrhoea was recorded as acute, watery, dysentery and persistent (Irena *et al.*, 2011; NDOH, 2015)

Compliance with the SAM treatment protocol

Compliance with the SAM treatment protocol was analysed using a predesigned evaluation tool based on the SAM treatment protocol standards as prescribed in the national protocol. A "yes" response represented compliance, based on the SAM compliance scoring scale. A score was allocated using the number of study participants or dietitians reported complying with SAM treatment protocol standards.

Compliance with discharge standards in the SAM treatment protocol

Compliance with discharge standards was analysed based on and categorised according to the evaluation standards as defined in the national protocol. Compliance to discharge standards included daily weight gain more than 10g/kg/day, for more than five consecutive days before discharge, return of appetite and subsided oedema and diarrhoea (NDOH, 2015). An answer of "Yes" represented compliance and scoring based on the SAM compliance scoring scale; determined by the number of study participants reported to comply to the identified SAM discharge standards.

Ethical approval

Approval was obtained from the SA Health Director General for accepting the research grant from the funder as required by SA Regulations relating to foodstuffs for IYC (R991, 6 December 2012). Thereafter, approval from Provincial and Institutional Health and Research Managers was sought to include identified hospitals as study sites. Ethical approval for the implementation of the study was obtained from the Biomedical Research Ethics Committee (BREC) of the University of KwaZulu-Natal. Voluntary participation in the study was confirmed by obtaining informed consent from mothers/caregivers.

Study limitations

Study limitations included an inability to record birth weights for all participants due to the unavailability of a Road to Health Charts and fieldworkers losing contact with participants due to them being transferred to other hospitals. Compliance to treatment of medical treatment such as the prescription and use of antibiotics and micronutrients and the treatment of hypothermia, hypoglycaemia and shock was not measured. More research is needed to determine compliance to these treatment steps in the management of SAM. The introduction of bias due to convenience sampling of study participants can also be regarded as a study limitation. HIV and TB status of IYC as an underlying cause of malnutrition, was not included / determined in this study.

RESULTS

A total of 245 IYC admitted to the study sites for the management of SAM, were included in the study sample, of which 150 were male (61.2%) and 95 females (38.8%). All participants were aged between six months and five years, with a mean age of 14.6 ± 8.2 months. Most participants (n=245) admitted for the inpatient management of SAM were from Eastern Cape (49.8%), followed by Gauteng (20.3%), Mpumalanga (18%) and Free State (11.9%). Data for 27 IYC was excluded due to incomplete anthropometric data, demise and transfer-to other health facilities. The mean birth weight of participants was 2.5 ± 0.95kg, while mean weight upon admission and discharge was 6.6 ± 1.38kg and 7.0 ±2.02kg respectively. The mean admission and discharge MUAC were 11.38 ± 2.35cm and 11.51 ± 2.57cm.

Compliance with admission standards for inpatient management of SAM

Only three of the 218 (1.4%) participants, did not comply with the SAM admission standards, as their WHZ z-scores were between < -2 z-score and median zero with a MUAC of more than 11.5cm. RUTF appetite testing was only conducted amongst 35 (16.1%) of malnourished IYC before admission.

Compliance with the SAM treatment protocol

As presented in table 6.1, overall compliance with the SAM treatment protocol was average (63.1%), while compliance in Mpumalanga, Free State, Eastern Cape and

Gauteng was 56.7%, 53.3%, 50.6% and 48.9% respectively. F-75 and F-100 therapeutic feeds were available at all facilities at the time of data collection. Training for management of IYC SAM was only conducted for dietitians and nurses. Seven hospitals implemented the RUTF test to determine the return of appetite as an indicator to commence catch-up feeding. Only 18 of 110 breastfeeding mothers (16.4%) were encouraged to continue breastfeeding during admission. The lowest rate of continued breastfeeding occurred in Free State (6.4%), followed by Mpumalanga (12.7%) and Gauteng (13.6%). Nasogastric and parenteral feeding was administered to six IYC. Seven hospitals indicated that infant formula was used when F-75 and F-100 were out of stock. At this time, only two hospitals prepared therapeutic milks using the recipe prescribed in the SAM treatment protocol. No commercial vitamin and mineral mix were added to these prepared therapeutic milks. The majority (78.0%) of IYC received F-75 in casualty or immediately upon arrival in the pediatric ward. In Mpumalanga, 51.1% of 41 IYC received F-75 in casualty or immediately upon arrival in the pediatric ward, hence being classified as average compliance. Eleven IYC received F-100 immediately upon arrival in the pediatric ward, while 24 (9.8%) received infant formula or a specialized semi-elemental enteral feed. Just over six out of ten (63.8%; n=155) of participants progressed from F-75 to F-100 within three to seven days after hospital admission (average compliance). The mean duration for transitioning from F-75 to F-100 was 5.8 ± 3.3 days. F-75 to F-100 transition in the Eastern Cape was 6.2 ± 3.1 days, 5.1 ± 3.0 days in the Free State, 5.6 ± 4.4 days in Mpumalanga and 5.6 ± 2.7 days in Gauteng. The lowest prevalence of transition from F-75 to F-100 was reported for Eastern Cape hospitals at 48.4% (poor performance). Seven (43.8%; poor compliance) hospitals served only RUTF and enriched maize meal to IYC with no additional food or meals from the pediatric ward diet. The other nine (56.3%; good compliance) hospitals, added food from a high protein, soft diet to support catch-up growth. Overall length of hospital stay was 10.1 ± 6.4 days. Mean hospital stay for participants in Eastern Cape was 9.8 ± 6.5 days, 10.5 ± 7.3 days for Free State, 8.4 ± 4.1 days for Mpumalanga, and 12.3 ± 7.3 days for Gauteng. Almost all facilities (15 out of 16) issued food supplements as take-out treatment upon discharge, which was enough for at least one week. Only one hospital did not issue food supplements upon discharge. All facilities referred discharged IYC to the hospital's out-patient department or local clinic for support and monitoring after discharge.

Table 6.1: Compliance with the SAM treatment protocol

Standard described in SAM treatment protocol	Results				
	SAM study	Eastern Cape	Free State	Mpumalanga	Gauten
Total score for compliance with SAM treatment protocol (out of 30)	18.94	15.17	16.00	17.00	14.67
Percentage compliance with SAM treatment protocol (out of 100%)	63.13%	50.56%	53.33%	56.67%	48.89%

Recovery from SAM complications

Oedema

Frequency distributions were calculated to determine the prevalence of oedema for 233 IYC. Data for 12 IYC were excluded due to demise, transferral to the next level of care and incomplete data. The overall presence of bilateral pitting pedal oedema was 42.9%, of which 22.8% had mild oedema (grade I), 11.6% moderate oedema (grade II) and 8.6% severe oedema (grade III). Oedema was present for a mean of 6.8 ± 4.3 days (minimum 1, maximum 26) In most cases (58%), oedema was resolved within six days after admission.

Appetite

Presence of appetite was calculated as frequency distributions for 222 IYC. The data for 23 participants was excluded due to demise, transfer and incomplete data. A lack of appetite was prevalent in 113 (59.91%) IYC. The mean number of days within which appetite returned was 4.4 ± 3.1 days (minimum 2; maximum 24).

Diarrhoea

The presence of diarrhoea was calculated for 233 IYC. Data for 11 participants was excluded due to demise, transfer to the next level of care and incomplete data. The prevalence of acute watery diarrhoea was 49.4%, with a duration of 5.1 ± 3.2 days (minimum 2; maximum 22). For majority of the participants (57.7%), diarrhoea was resolved by day three.

Compliance with discharge standards in the SAM treatment protocol

Only 10 (4.4%) of participants complied with all five discharge criteria as described in the SAM protocol, with the majority (n=7) being from Mpumalanga. Compliance with discharge standards was good for most participants (67.8%; n=154) or average (58.6%; n=133). As seen in table 6.2, compliance with discharge standards was classified as average in all provinces, ranging from 50.0% to 65.1%. No cases of very poor or non-compliance were reported. In all provinces, almost half (48.5%; n=110) of IYC were discharged while daily weight gain was less than 5g/kg/day. In nearly one out of five (19.4%) participants, IYC daily weight gain was 5-10g/kg/day, with the mean number of days for consecutive weight gain of more than 10g/kg/day being 2.5 ± 1.8 days, compared to the five consecutive days prescribed. The least consecutive days of weight gain was documented in Free State with a mean of 1.1 days, followed by Eastern Cape's 2.2 days and Gauteng's 2.3 days. In 7.9% (n=18) of cases, IYC were discharged without oedema and diarrhoea having been resolved. This was primarily the case for IYC that were discharged from Free State hospitals. Twelve (5.3%) participants were discharged with a lack of appetite, mostly from hospitals in Eastern Cape and Gauteng.

DISCUSSION

In SA, SAM is one of the major causes of death amongst IYC (Bamford *et al.*, 2018). In this study, more males than females were affected by SAM, with 61.2% of IYC admitted for inpatient management of SAM being male as opposed to 38.8% females. Since inadequate compliance with treatment protocols for the inpatient management of SAM contributes to the increased risk of IYC mortality and multiple readmissions after discharge (NDOH, 2015), the aim of this study was to determine compliance with the national SAM treatment protocol as a factor affecting treatment outcomes and mortality.

For the current study, the prevalence of SAM was 92.2%, with 61.0% of participants identified as suffering from SAM without oedema (marasmus), 39.0% suffering from SAM with oedema (kwashiorkor) and 1.4% having MAM.

SAM without oedema (marasmus) was more prevalent amongst females, while SAM with oedema (kwashiorkor) was more prevalent amongst males. These findings compared

Table 6.2: Compliance with discharge standards as described in the SAM treatment protocol

Compliance Grade	SAM study	Eastern Cape	Free State	Mpumalanga	Gauteng
	n=227	**n=110**	**n=24**	**n=46**	**n=50**
Excellent (compliance to 5 out of 5 criterium)	4.4% (n=10)	0.9% (n=1)	-	-	4.0% (n=2)
Good (compliance to any 4 out of the 5 criterium)	28.6% (n=65)	28.2% (n=31)	33.3% (n=8)	30.2% (n=13)	26.0% (n=13)
Average (compliance to any 3 out of the 5 criterium)	58.6% (n=133)	64.6% (n=71)	29.2% (n=7)	65.1% (n=28)	54.0% (n=27)
Poor (compliance to any 2 out of the 5 criterium)	4.9% (n=11)	6.4% (n=7)	37.5% (n=9)	4.7% (n=2)	16.0% (n=8)

favourably with that of an Ethiopian study where the prevalence of marasmus was 63.4%, kwashiorkor 34.4% and MAM 2.3% (Kabalo & Seifu, 2017).

The treatment of SAM was complicated by other medical conditions such as oedema, LARIs, sepsis, debilitating conditions such as HIV and TB, herbal intoxication, diarrhoea and/or vomiting, anemia, hypoglyceamia and dehydration. The occurrence of SAM and other medical complications increased the risk for delayed recovery from SAM and mortality. This finding was similar to outcomes of a SAM study conducted in the Eastern Cape (Muzigaba *et al.*, 2018). In addition, it should be highlighted that herbal intoxication plays a vital role in complicating SAM treatment and recovery, which may result in death (Muzigaba *et al.*, 2018). In Ethiopia, Malawi and Bangladesh, it was reported that diarrhoea, vomiting, fever and cough correlated positively with inpatient management of SAM (Binns *et al.*, 2015; Kabalo & Seifu, 2017). Complications such as oedema, diarrhoea, lack of appetite, hypoglycemia, anemia, sepsis, LARI, TB and HIV prolonged recovery from SAM (Tadesse *et al.*, 2017; Gebre *et al.*, 2019; Desyibelew *et al.*, 2020).

Weight gain during inpatient recovery was associated with increased SAM recovery rates in Ethiopia, Malawi and Bangladesh. Furthermore, a close relationship exists between improved discharge MUAC and SAM recovery (Binns *et al.*, 2015). The average weight gain from admission until discharge, was 0.390kg, which was associated with an increased risk for mortality ($r = 0.272$; $p < 0.01$). A minimal increase was reported in this

study from a mean admission MUAC of 11.38 ± 2.35cm to a mean discharge MUAC of 11.51 ± 2.57cm. Data from sub-Saharan Africa indicated that a MUAC of ≤ 11.5cm was associated with an increased risk for relapse and mortality from SAM (Desyibelew *et al.*, 2020).

Bilateral pitting oedema was prevalent amongst 42.9% of study participants, of which 22.8% was classified as mild (grade I), 11.6% as moderate (grade II) and 8.6% as severe (grade III). The prevalence of oedema amongst IYC admitted to Ethiopian hospitals for the management of SAM was 20.5% (Tadesse *et al.*, 2017) and 34.4%, with 54.6%, 40.7% and 4.8% classified as grade I, II and III respectively (Kabalo & Seifu, 2017). In the majority of cases (58%) oedema was resolved within six days after admission. A lack of appetite was reported for 59.9% of IYC lasting two to 24 days. The prevalence of acute watery diarrhoea was 49.4%, with a mean duration of 5.1 days. In Ethiopia, 11.9% of IYC admitted for inpatient management of SAM had diarrhea, with study outcomes suggesting that IYC with diarrhoea were 4.6 times more likely to be severely malnourished (Gebre *et al.*, 2019).

Compliance with admission standards for inpatient management of SAM was in accordance with the standards of the SAM treatment protocol, including WHZ <-3SD and/or MUAC of less than 11.5cm and the presence of oedema, irrespective of WHZ and MUAC. In Ethiopia, admission MUAC of less than 11.5cm was much higher at 63.3% (Kabalo & Seifu, 2017) and 73.3% (Tadesse *et al.*, 2017), than the prevalence of 44.0% in the current study.

The successful implementation of SAM treatment protocols and resultant treatment and recovery outcomes, is affected by the unavailability of food supplements, not adding a vitamin and mineral mix to prepared therapeutic feeds and inadequate professional training (Muzigaba *et al.*, 2018). For this study, compliance with the implementation of the SAM treatment protocol was average (63.1%), despite SAM treatment protocols being available at all study sites. Despite global and national recommendations that all members of the multidisciplinary team involved in treating IYC with SAM should be trained on operational guidelines for the inpatient management of SAM (WHO, 1999; NDOH,

2015), only dietitians and nurses received relevant training. Regular training of health professionals and monitoring of compliance with SAM treatment protocols can improve the quality-of-service delivery, resulting in increased SAM recovery rates (Choi *et al.*, 2018; Muzigaba *et al.*, 2018).

The majority of hospitals (93.8%) used commercial ready-to-use therapeutic feeds, with F-75 and F-100 therapeutic feeds being available at all facilities when the study was conducted. If F-75 and F-100 was not available, it was borrowed from other neighboring hospitals. Alternatively, infant formula or self-prepared therapeutic feeds were used in the absence of F-75 and F-100. However, despite the prescribed recipe in the SAM treatment protocol, a commercial vitamin and mineral mix was not added to self-prepared therapeutic milks. Although the SAM treatment protocol encourages continuous breastfeeding as part of inpatient management of SAM, only 16.4% mothers were encouraged to continue breastfeeding. This was much lower than the 37.3% reported in Ethiopia (Kabalo & Seifu, 2017). Nasogastric and parenteral feeding was not routinely administered (2.8%). In accordance with the SAM treatment protocol, the majority of participants (78.0%) received F-75 upon arrival at casualty or the pediatric ward. F-100, infant formula and a specialized semi-elemental enteral feed was administered to 35 IYC immediately after admission. The mean duration of administering F-75 before progressing to F-100 was 5.8 days. This is in line with the recommended three to seven days indicated in the SAM treatment protocol. In Ethiopian hospitals, RUTF was prescribed for IYC as part of the feeding regime. (Kabalo & Seifu, 2017). However, more than half (56.3%) of hospitals included in the study sample served a high protein, soft diet in addition to F-100 to support catch-up growth, RUTF and enriched maize meal were served in addition to F-100.

The SAM treatment protocol recommends that the duration of inpatient management should be two to four weeks. However, in this study, the mean duration of hospitalization was only 10.1 days. For the majority of participants, compliance witch discharge standards were good (67.8%) and exceeded the 32.7% compliance to discharge criteria reported in Ethiopia (Tadesse *et al.*, 2017). The biggest area of concern documented was that IYC were discharged at a level of weight gain that was less than 5g/kg/day, compared

to the recommended desirable daily weight gain of more than 10g/kg/day. This finding was in line with SAM studies conducted in Ethiopia and Cameroon where daily weight gain was 4.2 and 4.4g/kg/day (Kabalo & Seifu, 2017; Ndzo & Jackson, 2018). In addition, where IYC had a daily weight gain of more than 10g/kg/day, it only held true for a mean of 2.5 consecutive days, being lower than the standard of five consecutive days. Upon discharge, complications such as oedema, diarrhoea and a lack of appetite was unresolved in 13.2% of cases. The implication of these findings suggests that IYC were discharged before full recovery from SAM, making them vulnerable to relapse, readmission and ultimately an increased risk of mortality (Stobaugh *et al.*, 2018).

Sufficient food supplements translating to a week's supply were provided by more than 90% of the hospitals upon participant discharge. On discharge, IYC were referred to the hospital's out-patient department or local clinic for support and monitoring. As indicated, non-compliance with the treatment protocol for the inpatient management of SAM increases the risk of mortality during recovery and rehabilitation. This was especially true when F-75 therapeutic feeds were not fed immediately upon admission if F-75 was not followed by changing it to F-100 within three to seven days after admission and when in-hospital weight gain was less than desired. IYC that are not followed-up post discharge for rehabilitation support, also have a higher risk of mortality and readmission. A systematic review of 26 SAM-related studies, indicated that poor compliance with SAM treatment protocols increased the risk of relapse and readmission, including non-compliance with admission and discharge criteria (Stobaugh *et al.*, 2018).

Monitoring tools to assess levels of compliance at operational level, should form part of inpatient SAM treatment protocols (UNICEF, WFP, WHO, UNHCR & FAO, 2020). More research is needed to determine the relationship between compliance with SAM treatment protocols recovery, and IYC survival.

CONCLUSION

Compliance with the SAM treatment protocol standards was average, increasing the risk for relapse, readmission and death. IYC were discharged from inpatient SAM management despite poor daily weight gain and before clinical complications such as

oedema, poor appetite and diarrhoea were resolved. Hospitalization for full recovery and rehabilitation from SAM was inadequate. Since one of the biggest indicators of non-compliance with discharge standards was related to daily weight gain of more than 10g/kg/day for five consecutive days, it is recommended that a screening tool should be developed to assist health professionals with determining and the interpretation of daily weight gain, depicted as four colour coded areas in red, orange, yellow and green. This screening tool should be accessible via an application or medical device that can provide a daily algorithm-based recommendation regarding readiness for discharge, linked to progress towards desirable daily weight gain and resolving of clinical signs and symptoms. It can thus be concluded that inpatient management of SAM in public hospitals included in this study sample did not support adequate recovery from SAM before discharge, increasing IYC risk for relapse, readmission and mortality.

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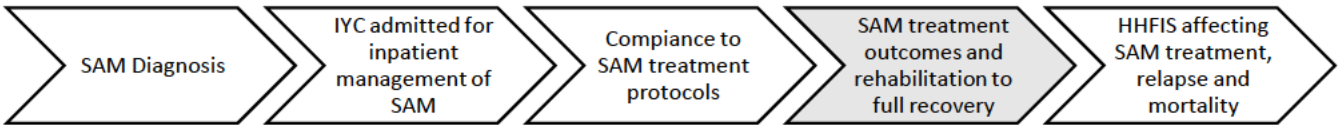
Compliance to the standards of the SA SAM treatment protocol are essential for SAM recovery and treatment outcomes. A lack of complying to the treatment and discharge criteria is associated with poor SAM treatment outcomes and recovery and premature discharge of IYC from hospital care, with an increased risk for relapse, readmission and IYC mortality.



CHAPTER 7

Title of manuscript:

Treatment outcomes for the inpatient management of severe acute malnutrition in South Africa

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MB and FV designed the research study. MB and SK conducted the literature search. FV & MB analyzed the data. MB wrote the first draft of the manuscript. All authors edited the manuscript and approved the final content. MB is primarily responsible for the paper's final content.

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Treatment Outcomes for the Inpatient Management of Severe Acute Malnutrition in South Africa

ABSTRACT

Treatment outcomes for the inpatient management of SAM is affected by the implementation of a SAM treatment protocol. Despite the implementation of these protocols, inpatient malnourished IYC are still at risk for death. Feeding practices prescribed to support stabilization, transition and rehabilitation phases of inpatient SAM treatment is related to SAM recovery and mortality outcomes. The aim of this study was to determine treatment outcomes and risk factors associated SAM treatment within SA. A multi-centre prospective, descriptive and comparative observational study approach were employed. A total of 245 inpatient IYC with SAM, with a mean age of 14.6 ± 8.19 months, were included in the study. The prevalence of SAM without oedema (marasmus) and SAM with oedema (kwashiorkor) was 61.0% and 39.0%, respectively. SAM was complicated by oedema (40.8%), LARIs (6.5%), HIV (5.7%), herbal intoxication (5.7%) and diarrhoea (6.5%). SAM recovery rate was 89.0%, with 3.7% readmissions and 6.1% deaths. Increased risk for IYC mortality was associated with SAM complicated by other medical conditions (X^2= 30.518; 0.001), MUAC less than 11cm (r = 0.390; p <0.01, CI 95%), hospital duration (r = 0.149; p < 0.05, CI 95%), no or delayed intake of F-75 (X^2= 24.948; 0.002) and F-100 (X^2=16.877; 0.018); early or delayed transmission from F-75 to F-100 (X^2= 24.490; 0.017), daily weight gain less than 10g/kg/day (X^2= 20.912; 0.000) and timeframe of followed-up after discharge (X^2= 71.946; 0.000). Ongoing monitoring and strengthening of SAM treatment protocols for inpatient management of SAM can improve SAM cure rates and decrease IYC relapse, readmission and mortality.

KEY WORDS

Case fatality rate, inpatient management and treatment of severe acute malnutrition, refeeding syndrome, hospitalized, SAM treatment outcomes, SAM cure rate, SAM recovery rate, SAM mortality rate

KEY MESSAGES

- SAM recovery, defaulter and mortality rates fell within International standards as described by the Sphere Association;

- Feeding regimes prescribed for management of SAM during stabilization, transmission and rehabilitation phases should be critically implemented, controlled and monitored as it may increase risk for death;
- IYC are discharged from hospital despite not meeting all discharge criteria, increasing their vulnerability for relapse, readmission and death;
- SAM treatment protocols and the implementation thereof should continuously be monitored and reviewed to strengthen standards for the inpatient management of SAM, resulting in improved IYC survival outcomes.

INTRODUCTION

SAM treatment outcomes must be monitored and evaluated on a regular basis to continuously identify ways on how to improve SAM recovery, mortality and defaulter rates. Mortality amongst IYC admitted for inpatient management of SAM remain a challenge, nationally and globally (NDOH, 2015; Rytter *et al.*, 2020). Although IYC mortality rates in SA decreased in the last decade to less than the global standard of 8%, mortality rates amongst inpatient SAM IYC can be as high as 60% in the absence of or inadequate implementation of SAM treatment protocols (NDOH, 2015; Bamford *et al.*, 2018; Girum *et al.*, 2018).

The implementation of the feeding regime for the management of SAM must be meticulously planned, implemented and monitored. The appropriate administration of therapeutic feeds during the stabilization, transition and rehabilitation phases is vital to the treatment outcome. F-75, F-100 and RUTF are specialized therapeutic feeds commercially manufactured or in-hospital prepared according to product specifications and recipes prescribed by the WHO and NDOH (WHO, 1999; NDOH, 2015). F-75 is administered fist during the stabilization phase of SAM to treat hypoglycemia, shock and dehydration. The target is to prevent death, which can occur within the first few days after admission (NDOH, 2015; Wagnew *et al.*, 2018). Cautious introduction of F-100 is necessary to support catabolic and anabolic metabolic functions in order to prepare the IYC for rehabilitation feeding. This phase should gradually be implemented over 3-7 days after admission to prevent refeeding syndrome. Introduction of F-100 before or after this recommended time frame increases the risk of death (NDOH, 2015; Mbethe & Mda,

2017). Poor adherence to these feeding regimes which are essential for inpatient management of SAM, result in delayed recovery, development of complications and increased IYC mortality (Girum *et al.*, 2018).

The envisaged benchmark for the recovery from SAM, mortality and defaulter rates have been defined by the Sphere Association (2018). Standard 2.2. for the management of SAM describe a mortality rate of lower than 10% amongst SAM inpatients, a defaulter rate of less than 15% and recovery rate of more than 75% when the SAM treatment plan is successfully implemented (Sphere Association, 2018). Predictable risk factors and co-morbidities associated with delayed SAM recovery and increased SAM mortality is not yet well understood and requires further investigation (Girum *et al.*, 2018). Limited data on the outcomes of inpatient SAM management in SA is available. Data is mostly restricted to prevalence statistics. The primary aim of this study, therefore, was to determine treatment outcomes of the inpatient management of SAM amongst IYC admitted to 16 SA public hospitals. Secondary to this, the study aimed to determine the possible association between various SAM treatment practices as possible risk factors and how they relate to mortality.

METHODS

A multi-centre, prospective, descriptive and comparative observational study including a mixed methods approach was employed.

The study setting

The study was conducted at 16 government hospitals in four SA provinces, with hospitals with active programmes for the management of SAM being selected for inclusion in the SAM study, together with Provincial and Institutional Health Management and the Provincial Ethical Committees/Research Departments. This included six hospitals from the Alfred Nzo Health District in the Eastern Cape, three hospitals from the Thabo Mofutsanyana Health District in the Free State, and three hospitals in the most rural areas of the city of Tshwane municipal area. In Gauteng and in Mpumalanga, four hospitals from each health district were identified as study sites.

Sampling

To determine the minimum number of study participants, a power calculation was conducted to generate 80% power, at a 0.05 level of significance. A total of 245 IYC between the ages of six months and five years, admitted to any of the selected 16 hospitals, were included in the study sample. Only IYC who were newly hospitalized with a diagnosis of SAM and/or who had a first-time diagnosis and hospitalisation for SAM and/or who were admitted for stabilisation, were included in the study sample. IYC that were hospitalized prior the study was not eligible for inclusion. Convenience sampling was used to cover the entire management of SAM in Alfred Nzo, Maluti-a-Phufong, Gert Sibande, Nkangala, Ehlanzeni and Tshwane municipal areas.

Data collection instruments and process

Data collection instruments in the form of fieldworker administered questionnaires were used for data collection. Four questionnaires were used to collect data through interviews, record reviewing and observations. The data collection instrument was piloted and a reliability of 99.2% was calculated, using the Cronbach Alpha test. Local, trained fieldworkers collected socio-demographic, anthropometric and clinical data from study participants. Anthropometric measurements included body weight, length / height and MUAC. SAM complications included daily observations regarding the prevalence or absence of diarrhoea, oedema and appetite. Body weight was determined on admission, followed by daily measurements conducted at the same time one hour before or after a feed, and before discharge. IYC aged six to 23 months, were weighed while only wearing a dry nappy. Children aged 24-50 months were weighed wearing only underwear. Weight was measured using an electronic baby scale or an electronic floor scale, depending on the age of the child. Scales were calibrated before each measurement was conducted. Length/height was measured on the day of admission and upon discharge. An infantometer was used to measure the length of IYC between 6 and 24 months with the mother/caregiver assisting the health professional conducting the measurement by holding the IYCs head and ensuring that the legs were straight, while the fieldworker documented the length. The height of children aged two to five years was measured using a stadiometer, with children taller than 85cm also measured in a standing position. MUAC was measured upon admission, followed by daily measurements till discharge. MUAC

was measured at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromium) of the upper left upper arm, using a colour coded tape or measuring tape in cm (CDC, 2007; Cashin & Oot, 2018).

Data analysis

The IBM Statistical Package for Social Sciences (SPSS) version 24 was used for statistical analysis. Descriptive statistics, namely frequency distributions, percentages, means and standard deviations were used to present continuous and categorical data. Logistic regression analysis and multivariate analysis was conducted to investigate the relationship between outcome measures and their associations. Categorical variables were compared using the Chi-square test. Statistical significance was determined at p value < 0.05 with 95% confidence intervals in the final model.

Anthropometric data before and upon admission

Weight, expressed in kilogram (kg), and MUAC, expressed in centimetre (cm), was measured upon admission and discharge. These measurements were used as baseline and end measurement to calculate daily weight gain as a result of the feeding interventions.

Daily weight gain for each IYC has been calculated by using the following steps (NDOH, 2015):

Step 1: Subtract IYC's weight yesterday (W1) from IYC's weight today (W2):
W2 – W1 = "x" kg
"x" kg x 1000 = x grams gained
Step 2: Divide grams gained by yesterday's weight
Grams gained ÷ W1 = "x" g/kg/day
(whereby "x" refers to the numerical value of the IYC's weight)

Interpretation of daily weight gain was defined as "Good" if an IYC gained more than 10g/kg/day; "Moderate" when an IYC gained 5-10g/kg/day; and "Poor" when an IYC gain less than 5g/kg/day according to guidelines outlined in the SA operational guidelines for the Integrated Management of children with SAM. Desirable daily weight gain was described as more than 10g/kg/day (NDOH, 2015).

Prevalence of SAM with or without oedema

SAM was classified as either SAM with oedema or SAM without and was used to determine admission Standards for inpatient management of SAM. IYC with oedema was categorised as SAM with oedema, also referred to as kwashiorkor, and admitted to hospital for inpatient management of SAM irrespective of WHZ and MUAC measurements. On the other hand, SAM without oedema, also known as marasmus, was classified according to WHZ lower than -3 WHO z-score and / or a MUAC of less than 11.5cm. In addition to this, IYC with WHZ lower than -2SD and / or a MUAC of higher than 11.5cm, with no oedema, was classified as moderately acute malnourished (NDOH, 2015, Cashin & Oot, 2018).

Recovery from SAM complications

The SAM complications that have been monitored daily was appetite, diarrhoea and oedema. Fieldworkers conducted observations, reviewed hospital records from study participants and used reporting from mothers / caregivers to determine absence or prevalence of these clinical complications. In addition to this, it has been recorded when these complications were resolved. Resolving of clinical complications have been reported as "Yes" for resolved or "No" if not yet resolved for each of these conditions. The number of days after admission when these clinical complications have been resolved was also recorded individually.

Oedema was measured by pressing a thumb gently on the top of the participant's and classified as present when dents remained in the participant's feet after the fieldworker's fingers were removed (NDOH, 2015; WHO, 2019). Various grades of oedema were described as absent or non-oedematous malnutrition and mild (grade +), moderate (grade ++) or severe (grade +++) oedema. These grades were used to describe nutritional status as SAM (NDOH, 2015; Cashin & Oot, 2018; WHO, 2019). The presence or absence of diarrhoea and appetite was determined daily, by reviewing hospital notes of the IYC and by the mother / caregiver reporting on this.

Appetite was recorded as good (1) or poor (2). Appetite was recorded as *good* if the participant finished his / her feed and the participant's mother / caregiver reported that the participant ate well (NDOH, 2015).

Diarrhoea was recorded as absent or prevalent, categorised as acute watery, dysentery and persistent diarrhoea (Irena *et al.*, 2011; NDOH, 2015).

SAM cure rate

Sphere standard 2.2. for the management of SAM has been used to calculate the SAM cure rate. The following formula has been used for the calculation:

$$\text{SAM cure rate} = \frac{\text{Number of IYC admitted for inpatient management of SAM that has been discharged}}{\text{Number of IYC admitted for inpatient management of SAM}} \times 100$$

Interpretation of the SAM cure rate was described as IYC mortality (percentage of IYC that passed away), defaulters (percentage of IYC that was transferred to other facilities and for which data was incomplete) and percentage recovery. Outcomes were interpreted according to the following standards as defined in Sphere standard 2.2. for the management of SAM: Died less than 10%; Recovered more than 75%; Defaulted less than 15% (Sphere Association, 2018).

Risk factors for mortality amongst SAM IYC

Chi-square tests was performed to determine correlations between mortality and categorical data such as the period when F-75 and F-100 was administered, the administration of therapeutic feeds during stabilization and rehabilitation phases, the prevalence of oedema, daily weight gain, daily MUAC and number of weeks that IYC was followed-up after discharge. Pearson coefficient was used to determine associations between mortality and continuous data such as weight and MUAC on admission and the number of days admitted for SAM management.

Ethical approval

Approval was obtained from the SA Health Director General for accepting the research grant from the funder as required by SA Regulations relating to foodstuffs for IYC (R991, 6 December 2012). Thereafter, approval from Provincial and Institutional Health and

Research Managers was sought to include identified hospitals as study sites. Ethical approval for the implementation of the study was obtained from the Biomedical Research Ethics Committee (BREC) of the University of KwaZulu-Natal. Voluntary participation in the study was confirmed by obtaining informed consent from mothers/caregivers, including an explanation of the study objectives and the use of the results in their home language, in addition to being assured that refusal to participate in the study would not compromised the medical treatment of their IYC and that all data would be treated as confidential during and following the data collection period by allocating all participating IYC a number for identification purposes.

Study limitations

Limitations encountered during the data collection process was the inability to record birth weights for all participants due to unavailability of a Road to Health Chart and fieldworkers lost contact with participants transferred to other hospitals. It should also be noted that compliance to feeding regimens, which include volume of feeds prescribed and information on treatment of hypoglycaemia, shock, hypothermia, dehydration and micronutrient deficiencies were not evaluated. The biasness of using a convenience sample can also be regarded as a study limitation. Underlying causes of malnutrition and TB was not included / determined in this study.

RESULTS

A total of 245 IYC admitted to the study sites for the management of SAM, were included in the study sample, of which more male (150; 61.2%) than females (95; 38.8%). All of these IYC were between the ages of 6 months and five years, with a mean age of 14.6 ± 8.2 months. Medical diagnoses upon admission included SAM (87; 35.5%) and SAM complicated by oedema (100; 40.8%), lower acute respiratory infections (LARIs) (16; 6.5%), sepsis (1; less than 1.0%), HIV (14; 5.7%), herbal intoxication (14; 5.7%), diarrhoea and / or vomiting (8; 3.3%), TB (8; 3.3%), anemia (2; less than 1.0%), hypoglycemia (1; less than 1.00%) and dehydration (8; 3.3%). Most of the study participants (n=245) were admitted to hospitals from Eastern Cape (49.8%), Gauteng (20.3%), Mpumalanga (18.0%) and Free State (11.9%) for the inpatient management of SAM. Data for 27 IYC was excluded due to incomplete anthropometric data, death and

transferral of IYC to other health facilities. The mean birth weight was 2.5 kg (SD ± 1.0). The mean weight upon admission and discharge was 6.6 ± 1.4 kg and 7.0 ± 2.0 kg. The mean admission MUAC was 11.4 ± 2.4 cm and discharge MUAC was 11.5 ± 2.6 cm. Dated was computed for 218 IYC as 27 were excluded due to death, transferal to next level of care and incomplete data.

Prevalence of SAM with oedema (kwashiorkor) and SAM without oedema (marasmus)

WHZ was measured and computed for 218 IYC. As reflected in table 7.1, the prevalence of marasmus, also known as SAM without oedema, was 61.0%, and for kwashiorkor, also referred to as SAM with oedema, 39.0%. The highest prevalence of SAM with oedema was amongst males (42.5%), whilst for SAM without oedema was more prevalent amongst female participants (66.7%). The majority of IYC admitted to hospitals in the Free State (73.9%), Mpumalanga (70.7%) and Gauteng (70.8%) was admitted for inpatient management of SAM without oedema. The prevalence of SAM with oedema and SAM without oedema was equally amongst SAM inpatients in the Eastern Cape.

SAM cure rate

As shown in table 7.2, the overall recovery rate from SAM amongst the study participants were 89.0% with a 4.9% defaulting rate.

From the 218 IYC that was discharged, eight (3.7%) was readmitted for inpatient SAM treatment. New diagnoses for SAM treatment included failure to thrive (50.0%); SAM complicated by coughing (25.0%); HIV (12.5%) and heart conditions (12.5%). Most of these IYC (5; 62.5%) were in the Eastern Cape, with only two from Mpumalanga and one from Gauteng. Only four of these IYC were brought back to the OPD by mothers / caregivers for follow-up. This follow-up period was between one and three weeks. During follow-up calls / visits three mothers reported that the IYC was no better after discharge and sought treatment from the local clinics. In only one case did the mother / caregiver reported that the IYC is “not eating well”. Other IYC were not brought back to the OPD for follow-up on the indicated dates and fieldworkers were unable to conduct home visits or reach mothers / caregiver via phone since incorrect contact numbers and physical

Table 7.1: Prevalence of SAM with oedema (kwashiorkor) and SAM without (marasmus)

SAM admission Standards (NDOH, 2015)	SAM Study		Eastern Cape		Free State		Mpuma-langa		Gauteng		Males		Females	
	n=218		n=106		n=23		n=41		n=48		n=134		n=84	
SAM with oedema (kwashiorkor)	85	38.0%	53	50.0%	6	26.1%	12	29.3%	14	29.2%	57	42.5%	28	33.3%
SAM without (marasmus)	133	61.0%	53	50.0%	17	73.9%	29	70.7%	34	70.8%	77	57.5%	56	66.7%
SAM without oedema: WHZ <-3SD and MUAC <11.5cm	35	16.1%	9	8.5%	7	30.4%	7	17.1%	12	25.0%	19	14.2%	16	19.1%
SAM without oedema: WHZ <-3SD	71	32.6%	23	21.7%	12	52.2%	18	43.9%	18	37.5%	43	32.1%	28	33.3%
SAM without oedema: MUAC <11.5cm	36	16.5%	29	27.4%	10	43.5%	13	31.7%	19	39.6%	35	26.1%	36	42.9%
SAM without oedema & Appetite test conducted before admission	35	16.1%	9	8.5%	7	30.4%	7	17.1%	12	25.0%	19	14.2%	16	19.1%
Non-compliance to any of the admission standards	3	1.38%	3	1.38%	-	-	-	-	-	-	-	-	-	-

addresses were provided upon discharge or IYC has been “send home” to stay with the grandmother in rural areas.

Table 7.2: SAM cure rate categorized according to the Sphere Standard 2.2

Standard (Sphere Association, 2018)	SAM Study		Eastern Cape		Free State		Mpuma-langa		Gauteng	
	n=227		n=110		n=24		n=46		n=50	
Recovered >75%	218	89.0%	111	88.1%	24	100.0%	43	93.5%	50	100.0%
Defaulted <15%	27	4.9%	3	2.4%	-	-	-	-	-	-
Died <10%	15	6.1%	12	9.5%	-	-	3	6.5%	-	-

IYC mortality

The overall IYC mortality rate for the entire cohort of patients was 6.1%. Fifteen of the 245 participants deceased during the period of data collection. Most of these IYC deaths occurred in hospitals from the Eastern Cape (12 IYC; 4.9%). No deaths were reported from facilities in the Free State and Gauteng for the timeframe of data collection.

Risk factors for mortality amongst SAM IYC

Chi-square tests were used to estimate the relationship between medical diagnosis and IYC mortality. The results showed that there exist a significant association between SAM complicated by other medical conditions (X^2= 30.518; 0.001), and the presence of oedema (X^2= 19.699; 0.001). A significant association exist between mortality and a delayed intake of F-75 after admission (X^2= 24.948; 0.002), inclusion of F-100 in the feeding regime (X^2=16.877; 0.018), changed over from F-75 to F-100 after 3-7 days of admission (X^2= 24.490; 0.017), daily weight gain less than the desired weight gain of >10g/kg/day (X^2= 20.912; 0.000) and inadequate followed-up and support of IYC after discharge (X^2= 71.946; 0.000).

Using the Pearson coefficient, a positive correlation was measured between mortality and discharge weight (r = 0.272; p <0.01; CI 95%), discharge MUAC (r = 0.390; p <0.01, CI 95%) and duration of hospital stay (r = 0.149; p < 0.05, CI 95%). The Pearson coefficient indicated a negative correlation between death and discharge height (r = -0.129; p <0.05, CI 95%).

DISCUSSION

IYC mortality related to inadequate inpatient management of SAM remains a global challenge (Rytter *et al.*, 2017). This is also true in SA as SAM is one of the major causes

of under-5 mortality (Bamford *et al.*, 2018). Yet, sufficient data exists to show that the proper implementation of SAM treatment protocols can improve SAM treatment outcomes and SAM recovery rates (NDOH, 2015; Stobaugh *et al.*, 2018).

More males are affected by SAM than females (Gebre *et al*., 2019). This was also true for IYC included in this study, where 61.2% males and 38.8% females were admitted for inpatient management of SAM. The overall prevalence of malnutrition amongst inpatients was 92.2%, sub-classified as 61.0% marasmus (SAM without oedema), 39.0% kwashiorkor (SAM with oedema) and 1.4% MAM. SAM without oedema affected females more, whilst SAM without oedema affected more of the males. Similar findings were described in Ethiopia, with prevalence of marasmus, kwashiorkor and MAM reported to be 63.4%, 34.4% and 2.3%, respectively (Kabalo & Seifu, 2017). Recovery from marasmus was lower when compared to that for kwashiorkor (Teshome *et al.*, 2019).

The overall recovery and mortality rates for IYC includes in this study was 88.9% and 6.1%, respectively. This was lower when compared to the Sphere standard for SAM recovery (Sphere Association, 2018). The defaulter rate of 4.9%, included both transfers and missing data. This was also lower when compared to the Sphere standard (Sphere Association, 2018). This SAM recovery rate was higher when compared to that reported in other African countries. The SAM recovery rate amongst IYC admitted for SAM inpatient management in Ethiopian hospitals ranged from 64.9% (Kabalo & Seifu, 2017) to 76.8% (Massa *et al.*, 2016), with a mortality rate of 1.2% (Kabalo & Seifu, 2017) and defaulter rate of 17.5%). A SAM mortality rate of 14% was reported in Uganda (Rytter *et al.*, 2017). A systematic review from 54 observational SAM studies reported the pooled SAM recovery rate as 71.2%. SAM recovery rate reported for Eastern Africa was 71.4%, Central Africa 84.7%, Northern Africa 78.9%, Western Africa 60.9% and Southern Africa 64.7% (Desyibelew *et al.*, 2020). The SAM recovery rate in Cameroon was 72.8% (Ndzo & Jackson, 2018). The mortality rate reported in this study was lower when compared to 25.9% reported in Limpopo (Gavhi *et al.*, 2020).

In this study, the treatment of SAM was complicated by other medical conditions such as oedema, LARIs, sepsis, debilitating conditions such as HIV and TB, herbal intoxication,

diarrhoea and / or vomiting, anemia, hypoglyceamia and cerebral palsy. The concurrence of SAM and other medical complications increased the risk for delayed recovery from SAM and increased mortality. This was similar to the outcomes of a SAM study conducted in the Eastern Cape and Limpopo, both provinces within SA. It should also be highlighted that studies conducted in SA also report increased IYC mortality associated with herbal intoxication (Muzigaba *et al.*, 2018; Gavhi *et al.*, 2020). This requires more local research to determine the impact of herbal toxication in complicating SAM treatment outcomes and an increase in mortality. These findings were in line with findings of studies conducted in Ethiopia, Malawi and Bangladesh. Furthermore, diarrhoea, vomiting, fever and cough correlated positively with inpatient management of SAM (Binns *et al.*, 2015; Kabalo & Seifu, 2017). Complications such as oedema, diarrhoea, poor appetite, hypoglycemia, anemia, sepsis, LARI, HIV and TB prolonged recovery or increase the risk for mortality (Tadesse *et al.*, 2017; Gebre *et al.*, 2019; Desyibelew *et al.*, 2020).

The implementation of the appropriate feeding regime as described in the SAM treatment protocol is closely related to the risk for IYC mortality (Wagnew *et al.*, 2018). The timeous administration of F-75 and F-100 therapeutic feeds is essential for treating shock, hypoglyceamia and dehydration and to prevent refeeding syndrome (Wagnew *et al.*, 2018). These conditions increase the risk for mortality amongst IYC admitted for the inpatient management of SAM (Mbethe & Mda, 2015; Wagnew *et al.*, 2018). Outcomes of this study indicated noteworthy associations between an increased risk for mortality and the administration of therapeutic feeds, as well as the timeframe for administering these feeds since arrival and admission up to the changeover from stabilizing feeding to rehabilitation feeding. A delay in initiating F-75 feeding were associated with an increased risk for death. The duration of changing over from F-75 to F-100 also posed an increased risk for IYC mortality. A delicate balance, therefore, exists in the timing of introducing rehabilitation therapeutic feeds. IYC that were initiated on F-100 immediately after admission or those that received F-100 earlier than 3 days after admission, or later than 7 days after admission, were all at risk for death. This phenomenon may be related to the development of refeeding syndrome. These finding were similar to studies conducted in Uganda and Ethiopia. In Uganda it was reported that no or delayed intake

of F-75 (AHR: 6.6; 95% CI: 2.9, 14.7) and F-100 (AHR: 3; 95% CI: 1.6, 5.4) were independent predictors of mortality (Wagnew *et al.*, 2018). An increased mortality rate was associated with transitioning from F-75 to feeds with a higher carbohydrate content in Ethiopia (Rytter *et al.*, 2017). Mbethe & Mda (2015) reported the incidence of refeeding syndrome in a SA hospital as 15.0% amongst IYC admitted for management of SAM. It is suspected that refeeding syndrome is under-diagnosed and reported, hence a desperate need to conduct more research in SAM inpatients to improve SAM recovery rates and IYC survival.

Weight gain during inpatient recovery was associated with increased SAM recovery rates in Ethiopia, Malawi and Bangladesh. A close relationship exists between improved discharge MUAC and SAM recovery (Binns *et al.*, 2015). The average weight gain from admission until discharge was only 0.390kg, which was associated with and increase risk for mortality. Changes in MUAC upon admission and discharge (from 11.3cm to 11.5cm) was nominal, whereas a MUAC less than 11.5cm was associated with risk for death (Gavhi *et al.*, 2020). Underweight, stunting, wasting and a MUAC below 11.5 cm was identified as risk factors for mortality (Desyibelew *et al.*, 2020). The extent of daily weight gain (more than 10g/kg/day for 5 consecutive days), the MUAC (more than 11.5cm) and resolved oedema and diarrhea, in contrast, could be used to confirm SAM recovery and readiness for discharge (NDOH, 2015). Daily weight gain for most IYC in this study was reported as less than 5g/kg/day for a mean of 2.5 days, with MUAC remaining less than 11.5cm. In 13.2% cases neither oedema nor diarrhoea were resolved by time of discharge. A strong association was also measured amongst these failures and an increased risk for mortality. These findings were aligned with SAM studies conducted in Ethiopia and Cameroon where daily weight gain was also between 4.2 and 4.4g/kg/day (Kabalo & Seifu, 2017; Ndzo & Jackson, 2018). These findings indicate that IYC are set-up for failure after SAM recovery if they are discharged before full recovery, making them vulnerable to relapse, readmission and ultimately an increased risk for death.

The national SAM treatment protocol requires that inpatients should be admitted to hospitals for a period of 4-6 weeks in order to provide adequate support and treatment to allow full recovery before discharge (NDOH, 2015). However, IYC included in this study

was only admitted for a mean of 10.1 days, which is less when compared to the SAM treatment protocol. A strong association was reported between early discharge and relapse, readmission and IYC mortality. In Ethiopia, the average duration of hospital admission was reported to be 12 days (Wagnew *et al.*, 2018), 24.5 days (Ndzo & Jackson, 2018) and 6.4 weeks (Kabalo & Seifu, 2017) which was longer than reported in this study. Teshome *et al.* (2019) also reported that approximately 36 days is an adequate SAM recovery time, before discharge. The duration of inpatient recovery, therefore, plays a vital role in SAM recovery as a short hospital stay was associated with an increased risk for death (NDOH, 2015) and it is recommended that the SA SAM protocol be adhered to. The readmission rate amongst IYC in this study, was 3.7%. This was lower when compared to the 10.8% reported in Ethiopia (Tadesse *et al.*, 2017). Reasons for readmission for inpatient SAM treatment was failure to thrive (50.0%); coughing (25.0%); HIV (12.5%) and heart conditions (12.5%). Despite referral of IYC to the hospital's OPD for follow-up after discharge, this remained a challenge as mothers / caregivers did not return with their IYC for rehabilitative treatment after discharge. Efforts to trace defaulters from OPD should be emphasized and strengthened (Massa *et al.*, 2016).

Results from this study emphasizes the need for more research to investigate the relationship between inadequate implementation of SAM protocols standards and recovery, relapse and mortality in SA.

CONCLUSION

In this study, the international Standards for SAM recovery and mortality were met, with SAM recovery, defaulter and mortality rates reported to be aligned with the Sphere Association recommendations. Non-compliance to the local SAM treatment protocol standards however, increased the risk for relapse, readmission and death. The implementation of feeding regimes and timeous feeding of applicable therapeutic feeds to support stabilization and rehabilitation phases of SAM recovery, without posing the risk for developing refeeding syndrome, can reduce the risk for mortality during inpatient care. Daily monitoring and evaluation of weight gain, MUAC and resolved oedema and diarrhoea should be closely monitored to not only improve SAM recovery rates, but also

to increase the chance of IYC survival after discharge. It is therefore, advised that hospital staff always adhere to the SA SAM protocol.

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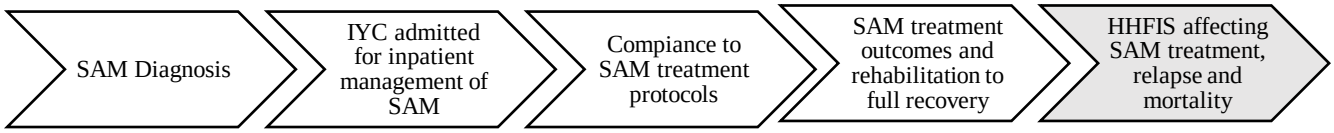
In order to improve SAM treatment outcomes during inpatient management of SAM, it is important to understand the role that household food insecurity play in the recovery and rehabilitation of IYC, living in food insecurity. Being aware of the association between inadequate food intake and SAM recovery will increase an understanding of delayed recovery and a need for enhanced inpatient management of SAM to support full recovery and rehabilitation from SAM.



CHAPTER 8

Title of manuscript:

Household Food Security Status of inpatient children with severe acute malnutrition in South Africa

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Contributor statement:

MB and FV designed the research study. MB and SK conducted the literature search. FV & MB analyzed the data. MB amended the household food insecurity access scale scoring scale to address the needs for the SAM study. MB wrote the first draft of the manuscript. All authors edited the manuscript and approved the final content. MB is primarily responsible for the paper's final content.

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Household Food Security Status of inpatient children with severe acute malnutrition in South Africa

ABSTRACT

Food security remains a global challenge. This is especially true for IYC living in low and low-medium income countries such as SA. HHFIS is an underlying factor for the development of severe acute malnutrition (SAM) amongst IYC, resulting in hospital admission for inpatient management of SAM. HHFIS is a predive factor for SAM recovery, treatment outcomes, relapse and mortality. The aim of this study was to investigate the association between HHFIS and SAM recovery and treatment outcomes. A total of 261 IYC, admitted to 16 public hospitals within SA, with a mean age of 14 ± 18.19 months was included in the study. The HFIAS was used to determine food insecurity, defined by inadequate food quantity and quality. A total of 27.2% households were food insecure, of which 14.6% moderately and 10.7% severely. Prevalence of HHFIS amongst males (28.2%), IYC younger than 12 months of age (26.6%) and those from rural areas (30.0%) were the greatest. Consuming a limited variety of foods were associated with delayed return of appetite (X^2= 0.141; 0.028) and increased visits to clinics after discharge (X^2= -0.255; 0.026). Inadequate or a lack of food intake was associated with SAM complicated by other medical conditions (X^2= 0.167; 0.009), delayed recovery from oedema (X^2= -0.235; 0.035) and diarrhoea (X^2= -0.199; 0.037), inadequate daily weight gain less than 10g/kg/day (X^2= -0.190; 0.003) and IYC mortality (X^2= -0.131; 0.522). These strong associations define HHFIS as a predictable risk factor for inadequate SAM treatment outcomes and recovery, followed by relapse and possible mortality. A cyclic link between HHFIS and inpatient management of SAM exists, which should be addressed when SAM treatment protocols and poverty relief programs are planned, implemented and monitored.

KEY WORDS

Household food insecurity, inpatient management of severe acute malnutrition, treatment outcomes, household food insecurity access scale (HFIAS), inadequate food intake, predictable risk factors for recovery

KEY MESSAGES

- HHFIS is a predictable risk factor, not only for the manifestation of SAM, but also for prolonged recovery and poor treatment outcomes;
- IYC from households with HHFIS are at risk of relapse and mortality following discharge, since nutrition education and post-treatment support does not improve feeding practices at household level;
- Poverty alleviation projects should be designed with the aim of not only preventing SAM, but also to improving recovery rates of IYC that are admitted for inpatient management of SAM.

INTRODUCTION

All IYC have a right to life and food, irrespective of their race, gender, or the political, cultural or religious orientation of their parents [United Nations Children's Fund (UNICEF), 1998; SA Parliament, 2019]. Despite this human right, IYC malnutrition remains a global challenge, threatening child survival, with IYC from food insecure households being at a greater risk of developing malnutrition (Bamford *et al.*, 2018; UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). Globally, 14.3 million are severely malnourished, of which 3.5 million live in Africa (UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). UNICEF developed a conceptual framework outlining the factors contributing to the development of SAM (UNICEF, 2015; Black *et al.*, 2020). Household food insecurity, characterised by a limited intake and access to food was found to be an underlying factor contributing to SAM amongst IYC (Adamu *et al., 2016)*. Daily consumption of a diverse diet contributes to the general health and wellbeing of IYC. It is widely accepted that acceptable dietary diversity reflects nutrient adequacy, necessary for optimal health and general wellbeing (Kennedy *et al.*, 2013; Akombi *et al.*, 2017). Adequate food intake needs to commence during gestation and be sustained during the first 1000 days of life. This includes maternal nutrition during pregnancy and lactation, protection, promotion and support of adequate breastfeeding practices and the introduction of appropriate and timeous complimentary feeding (Akombi *et al.*, 2017; WHO, 2019; UNICEF, WFP, WHO, UNHCR & FAO, 2020*).*

Poverty, nutrition transition associated with urbanisation, and high food prices contribute to a lack of consuming adequate quantities and varieties of food (Shisana *et al.*, 2013; Mkhawani *et al.*, 2016). This results in the development of SAM, complicated by other infectious diseases and an increased need for inpatient management of SAM amongst IYC (Darmon & Drewnowski, 2015). Household food insecurity (HHFIS) is a predictor of poor SAM recovery and treatment outcomes, relapse, and mortality (Chaturvedi *et al.*, 2018; Atnafe *et al.*, 2019). In the light of this association and a lack of studies investigating this relationship the aim of the study was to investigate the association between HHFIS and admission for inpatient management of SAM, SAM treatment outcomes, mortality and relapse following discharge.

METHODS

A multi-centre prospective, descriptive and comparative observational study including a mixed methods approach was employed.

The study setting

The study was conducted at 16 government hospitals in four SA provinces. Hospitals eligible for inclusion in the study sample had active programmes for the management of SAM, in addition to approval that had to be obtained from the Provincial and Institutional Health Management and the Provincial Ethical Committees/Research Departments. Of the 16 hospitals, six were from the Alfred Nzo Health District in the Eastern Cape, three from the Thabo Mofutsanyana Health District in the Free State, while three were located in the most rural areas of the city of Tshwane municipal area. In Gauteng and in Mpumalanga, four hospitals from each health district were identified as study sites.

Sampling

To determine the minimum number of study participants, a power calculation was conducted to generate 80% power, at a 0.05 level of significance. A total of 261 households were included in the study sample. Data was collected for IYC that were newly hospitalized with a diagnosis of SAM and/or who had a first-time diagnosis and hospitalization for SAM and/or who were admitted for stabilisation of the condition. IYC that were hospitalized prior to commencement of the study were not eligible for inclusion.

Convenience sampling was used to cover the spectrum of household food security for IYC hospitalized for the management of SAM in Alfred Nzo, Maluti-a-Phufong, Gert Sibande, Nkangala, Ehlanzeni and Tshwane municipal areas.

Data collection instruments and process

Data collection instruments in the form of fieldworker administered questionnaires were used for data collection with fieldworkers conducting interviews, reviewing hospital records and conducting observations. The data collection instruments were piloted and a reliability of 99.2% was calculated, using the Cronbach Alpha test. Locally recruited, trained fieldworkers collected data that included anthropometric measurements, SAM complications and household food insecurity data from mothers and caregivers of IYC that were hospitalized with SAM served as study participants. Anthropometric measurements included body weight, length/height and MUAC. SAM complications included daily observations regarding the prevalence or absence of diarrhoea, oedema and appetite. Body weight was determined on admission, followed by daily measurements conducted at the same time one hour before or after a feed, and before discharge.

Operational definition of household food security

Household food security (HHFS) is defined as a situation where all household members can access food daily according to individual requirements to meet their nutritional requirements and attain optimum health. Food access can be hindered by an inability to be economically/agriculturally? productive or due to the unavailability of funds to access food at a household level (Coates *et al.*, 2007). For this study, HHFS was determined using the household food insecurity access scale (HFIAS).

Using the guidelines of the HFIAS, 10 questions were included in the data collection instruments to determine the IYCs access to food. The intention of these questions was to measure an occurrence of an experience related to HHFIS, followed by a response (rarely, sometimes or often) to determine the frequency of that specific occurrence. The reflection of experiencing HHFS was focused on the 30 days prior to interviewing the

mother/caregiver (Coates *et al.*, 2007). The questions included in the data collection instruments for this study are outlined in table 1.

Data analysis

The IBM SPSS version 24 was used for statistical analysis. Descriptive statistics, namely frequency distributions, percentages, means and standard deviations were used to present continuous and categorical data. Logistic regression analysis and multivariate analysis was conducted to investigate the relationship between outcome measures and their associations. Categorical variables were compared using the Chi-square test. Statistical significance was determined at p value < 0.05 with 95% confidence intervals in the final model.

Household food security

The HFIAS aims to measure various indicators associated with HHFIS including HHFIS access related conditions and domains and HFIAS score and prevalence (Coates *et al.*, 2007).

Ethical approval

Approval was obtained from the SA Health Director General for accepting the research grant from the funder as required by SA Regulations relating to foodstuffs for IYC (R991, 6 December 2012). Thereafter, approval from Provincial and Institutional Health and Research Managers was sought to include identified hospitals as study sites. Ethical approval for the implementation of the study was obtained from the Biomedical Research Ethics Committee (BREC) of the University of KwaZulu-Natal. Voluntary participation in the study was confirmed by obtaining informed consent from mothers/caregivers, including an explanation of the study objectives and the use of the results in their home language, in addition to being assured that refusal to participate in the study would not compromised the medical treatment of their IYC and that all data would be treated as confidential during and following the data collection period by allocating all participating IYC a number for identification purposes.

Study limitations

Study limitations included incomplete anthropometric data for 16 participants. Limited data on socio-economic and socio-demographic variables of the household was collected, since the study aim was to determine the association between HHFIS as a risk factor for SAM recovery, mortality, relapse and readmission. The HIV status of study participants as a possible contributor to malnutrition was not determined since SAM treatment protocols and standards do not differ for this group of malnourished IYC. The introduction of bias by using a convenience sample can also be regarded as a study limitation.

RESULTS

HFIAS calculations were computed for 261 households to determine frequencies of HHFIS domains, scale scores and prevalence. Associations between HHFIS domains and categorical or continuous data was determined using 2 tailed Pearson Chi-square tests. A total of 217 IYC and their related HHFIS data was calculated to identify associations between HHFIS, anthropometric indicators and SAM treatment practices. Data for 43 households were excluded in these calculations due to missing data, death or transfer of the IYC to another hospital.

SAM treatment outcomes, recovery and mortality

Anthropometric data was computed for 245 IYC admitted to the study sites for the management of SAM, of which 61.2% were male and 38.8% female with a mean age of 14.64 ± 8.19 months. Apart from SAM as a medical diagnosis upon admission, SAM was complicated by oedema (40.8%), lower acute respiratory infections (LARIs) (6.5%), HIV (5.7%), herbal intoxication (5.7%), diarrhoea, dehydration and / or vomiting (6.5%), TB (8; 3.3%), anemia, sepsis and (1.63%). The mean admission and discharge weight were 6.6 ± 1.38 kg and 7.0 ± 2.02 kg respectively: mean admission and discharge MUAC 11.4 ± 2.35 cm and 11.5 ±2.57 cm and mean admission and discharge length/ height 66.2 ± 16.06 cm and 71.3 ± 11.47. SAM without oedema (marasmus) and SAM with oedema (kwashiorkor) incidences were 61.0% and 39.0%. Prevalence of mild, moderate and severe oedema was 21.7%, 11.1% and 8.2%, respectively, that resolved on day six for all IYC. Nearly half (46.3%) of IYC had a lack of appetite that returned on day three for all

IYC. A similar proportion, 45.2% had an inadequate daily weight gain of less than 5g/kg/day, while diarrhoea was present among 46.9% of the study sample with a mean duration of 9 ± 5.46 days. The SAM recovery rate was 89.0% and mortality rate 6.1%. Only eight IYC (3.7%) were readmitted for inpatient SAM treatment.

Prevalence of household food insecurity

A total of 136 households out of the 261 indicated that they experienced some form of HHFIS according to the HFIAS domains and categories. As described in table 8.1, 27,2% of all households were food insecure, classified as mild (1.9%), moderate (14.6%) or severe (10.7%) food insecure. The highest incidence of HHFIS was reported in Mpumalanga (29.8%) and Eastern Cape (29.2%). Food insecurity in the Eastern Cape was reported as 30.0%, with 16.9% of participants being severely food insecure. Mild food insecurity was prevalent in Free State (16.13%) and Mpumalanga (17.0%). The prevalence of food security was 28.3% in Gauteng. The highest prevalence of a food insecurity category was recorded for male participants (28.2%), while the prevalence of moderate food insecurity among males was 16.8% and severe food insecurity among females was 12.6%. The prevalence of moderate (13.3%) or severe (13.3%) food insecurity was the highest amongst IYC younger than 12 months. The incidence of moderate HHFIS amongst IYC between one and two years of age was 14.9%. The prevalence of food security amongst children between two and three years and three and five years was 35.7% and 44.4% respectively.

Suboptimal food quality

As illustrated in table 8.4, inadequate food quality was reported for 184 out of the 261 households (70.5%) surveyed, of which the majority (43.3%) experienced this phenomenon often in the four weeks before the IYC was admitted for inpatient management of SAM. The highest incidence (80.6%) of not consuming a variety of food was reported in households from the Free State. However, the unavailability of food of an acceptable quality was only experienced sometimes (61.3%) in month prior to the IYC being hospitalized for SAM treatment. Suboptimal food quality was often experienced by households in Eastern Cape (53.9%) and Gauteng (45.3%). Suboptimal food quality was often insufficient for both males (47.7%) and females (40.0%) below two years of age

Table 8.1: Prevalence of Household Food Insecurity, categorized per province, gender and age groups

Household Food Security Category			1. Household Food Secure	2. Mildly Food Insecure	3. Moderately Food Insecure	4. Severely Food Insecure	Total amount of households with a food insecurity category
All IYC	n=261	Frequency	65	5	38	28	71
		Percentage	24.9%	1.9%	14.6%	10.7%	27.2%
Male	n=149	Frequency	34	3	25	14	42
		Percentage	22.8%	2.0%	16.8%	9.4%	28.2%
Female	n=95	Frequency	26	2	10	12	24
		Percentage	27.4%	2.1%	10.5%	12.6%	25.3%
6-12 months	n=128	Frequency	29	3	17	17	37
		Percentage	22.7%	2.3%	13.3%	13.3%	28.9%
13-24 months	n=94	Frequency	22	2	14	9	25
		Percentage	23.4%	2.1%	14.9%	9.6%	26.6%
25-36 months	n=14	Frequency	5	-	3	-	3
		Percentage	35.7%	-	21.4%	-	21.4%
37-60 months	n=9	Frequency	4	-	1	-	1
		Percentage	44.4%	-	11.1%	-	11.1%
Eastern Cape	n=130	Frequency	33	1	15	22	38
		Percentage	25.4%	0.8%	11.5%	16.9%	29.2%
Free State	n=31	Frequency	5	1	5	1	7
		Percentage	16.1%	3.2%	16.1%	3.2%	22.6%
Mpumalanga	n=47	Frequency	11	2	8	4	14
		Percentage	23.4%	4.3%	17.0%	8.5%	29.8%
Gauteng	n=53	Frequency	15	1	10	1	12
		Percentage	28.3%	1.9%	18.9%	1.9%	22.6%

(mean value 46.0%). Using the 2 tail Pearson Chi-Square test, a strong association was found between consuming a limited variety of foods and stunting (X2= 0.154; p=0.017), a mean weight of 6.6 ±1.8 kg (X2= 0.190; p=0.003), lack of appetite (X2= 0.141; p=0.028), MUAC less than 11.5cm (X2= -0.157; p=0.014) and clinic visits after discharge (X2= -0.255; p=0.026).

Table 8.2: Prevalence of insufficient food quality and severities, categorized per province, gender and age groups

		Households where IYC ate limited types and amount of food	Rarely	Sometimes	Often
All IYC	n=261	184	1	70	113
		70.5%	0.4%	26.8%	43.3%
Male	n=149	109	1	37	71
		73.2%	0.7%	24.8%	47.7%
Female	n=95	63	-	25	38
		66.3%	-	26.3%	40.0%
6-12 months	n=128	89	-	33	56
		69.5%	-	25.8%	43.8%
13-24 months	n=94	69	-	23	46
		73.4%	-	24.5%	48.9%
25-36 months	n=14	9	-	6	3
		64.3%	-	42.9%	21.4%
37-60 months	n=9	5	-	5	-
		55.6%	-	55.6%	-
Eastern Cape	n=130	95	1	24	70
		73.1%	0.8%	18.5%	53.9%
Free State	n=31	25	-	19	5
		80.7%	-	61.3%	16.1%
Mpumalanga	n=47	28	-	14	14
		59.6%	-	29.8%	29.8%
Gauteng	n=53	37	-	13	24
		69.8%	-	24.5%	45.3%

Households where the mother / caregiver worried about not having enough food for IYC

Of the 261 households surveyed, 68.6% of mothers/caregivers indicated that they worried about not having enough food to feed their IYC. This concern was predominantly (58.1%) among mothers/caregivers from households in the Free State. More than half of the mothers/caregivers of children aged between two years (50.0%) and five years (55.6%), were concerned about the unavailability of food to feed their IYC four weeks prior to being admitted for inpatient management of SAM. Using the 2 tail Pearson Chi-Square test, a strong association was found between the unavailability of adequate quantities of

food and cessation of breastfeeding (X2= -0.199; p= 0.002), stunting (X2= 0.128; p=0.046), mean admission weight of 6.6 ±1.8 kg (X2= 0.204; p=0.002), duration of hospital stay (X2= -0.130; p=0.043), number of days it took for oedema to be resolved (X2= -0.247; p=0.027), inadequate lack of appetite (X2= p=0.131; 0.041), MUAC less than 11,5cm (X2= -0.126; p=0.050), clinic visits post discharge (X2= -0.224; p=0.026) and IYC mortality (X2= -0.131; p= 0.522).

Households where IYC had to eat smaller meals than required

A total of 159 out of 261 (60.9%) IYC had to consume a meal that was smaller than what was required. The highest prevalence of consuming meals that were smaller than IYC requirements, was among IYC residing in the Free State (71.0%) and Eastern Cape (67.7%). The frequency with which this occurred was sometimes in the Free State (54.8%) and rarely in Eastern Cape (27.7%). More males (63.1%) often consumed (14.1%) less food than what was required. Children aged two to three years (64.8%) were rarely (29.8%) or sometimes (42.9%) affected by eating smaller meals than what was required. A strong association was found between eating smaller meals than required and medical diagnosis of complicated SAM? (X2= 61.524; p=0.016), cessation of breastfeeding (X2= -0.213; p=0.001), stunting (X2= 0.151; p=0.018), underweight (X2= 0.143; p=0.025), mean admission weight of 6.6 ±1.8 kg (X2= 0.136; p= 0.037), weight gain during admission (X2= -0.190; p= 0.003), lack of appetite (X2= 0.149; p=0.020), clinic visits post discharge (X2= -0.277; p= 0.006) and mortality (X2= -0.141; p=0.023).

Households where IYC ate fewer meals due to of a lack of food

As presented in table 5, 60.5% of IYC had to consume fewer meals than required daily due to a lack of food in the household. IYC residing in the Eastern Cape and Free State had to consume fewer meals more often than those in Mpumalanga and Gauteng at 70.8% and 67.7% respectively. Both males (59.7%) and females (59.0%) were equally affected due to the unavailability of food. IYC under the age of three years (61.2%) consumed fewer meals than older children (45.2%) because of a lack of food in the household. A strong association was found between the consumption of fewer meals due to unavailability of food at household level and medical diagnosis (X^2= 61.073; 0.018), cessation of breastfeeding (X^2= -0.206; 0.001), stunting (X^2= 0.130; 0.043);

Table 8.3: Prevalence of household food insecurity conditions and severities, categorized per province, gender and age groups

HFIAS Condition	SAM Study		Eastern Cape		Free State		Mpumalanga		Gauteng		Male		Female		6-12 months		13-24 months		25-36 months		37-60 months	
	n=261		n=130		n=31		n=47		n=53		n=149		n=95		n=128		n=94		n=14		n=9	
Households where the mother / caregiver worried about not having enough food for IYC	179	68.6%	93	71.5%	26	83.9%	29	61.7%	31	58.5%	105	70.5%	62	65.3%	85	66.4%	69	73.4%	9	64.3%	5	55.6%
Rarely	63	24.1%	40	30.8%	1	3.2%	5	10.6%	17	32.1%	36	24.2%	21	22.1%	23	18.0%	34	36.2%	1	7.1%	5	55.6%
Sometimes	66	25.3%	23	17.7%	18	58.1%	16	34.0%	9	17.0%	42	28.2%	22	23.2%	31	24.2%	21	22.3%	7	50.0%	-	-
Often	50	19.2%	30	23.1%	7	22.6%	8	17.0%	5	9.4%	27	18.1%	18	19.0%	31	24.2%	13	13.8%	1	7.1%	-	-
Households where IYC had to eat smaller meals than needed	159	60.9%	88	67.7%	22	71.0%	21	44.7%	28	52.8%	94	63.1%	54	56.8%	75	58.6%	61	64.9%	9	64.3%	3	33.3%
Rarely	52	19.9%	36	27.7%	1	3.2%	4	8.5%	11	20.8%	36	24.2%	16	16.8%	20	15.6%	28	29.9%	1	7.1%	3	33.3%
Sometimes	66	25.3%	24	18.5%	17	54.8%	12	25.5%	13	24.5%	37	24.8%	22	23.2%	34	26.6%	19	20.2%	6	42.9%	-	-
Often	41	15.7%	28	21.5%	4	12.9%	5	10.6%	4	7.6%	21	14.1%	16	16.8%	21	16.4%	14	14.9%	2	14.3%	-	-
Households where IYC ate fewer meals because of a lack of food	158	60.5%	92	70.8%	21	67.7%	19	40.4%	26	49.1%	89	59.7%	56	59.0%	75	58.6%	60	63.8%	8	57.1%	3	33.3%
Rarely	60	22.99 %	38	29.23 %	3	9.68%	4	8.51%	15	28.30 %	40	26.85 %	19	20.00 %	24	18.75 %	31	32.98 %	1	7.14%	3	33.3%

HFIAS Condition	**SAM Study**		**Eastern Cape**		**Free State**		**Mpumalanga**		**Gauteng**		**Male**		**Female**		**6-12 months**		**13-24 months**		**25-36 months**		**37-60 months**	
	n=261		**n=130**		**n=31**		**n=47**		**n=53**		**n=149**		**n=95**		**n=128**		**n=94**		**n=14**		**n=9**	
Sometimes	64	24.5%	29	22.3%	17	54.8%	10	21.3%	8	15.1%	33	22.2%	21	22.1%	30	23.4%	18	19.2%	7	50.0%	-	-
Often	34	13.0%	25	19.2%	1	3.2%	5	10.6%	3	5.7%	16	10.7%	16	16.8%	21	16.4%	11	11.7%	-	-	-	-
Households where there was no food for IYC to eat	116	44.4%	74	56.9%	17	54.8%	10	21.3%	15	28.3%	64	43.0%	43	45.3%	57	44.5%	43	45.7%	6	42.9%	2	22.2%
Rarely	51	19.5%	36	27.7%	6	19.4%	2	4.3%	7	13.2%	33	22.2%	17	17.9%	23	18.0%	22	23.4%	3	21.4%	2	22.2%
Sometimes	32	12.3%	14	10.8%	10	32.3%	5	10.6%	3	5.7%	15	10.1%	11	11.6%	14	10.9%	11	11.7%	2	14.3%	-	-
Often	33	12.6%	24	18.5%	1	3.2%	3	6.4%	5	9.4%	16	10.7%	15	15.8%	20	15.6%	10	10.6%	1	7.1%	-	-

underweight (X^2= 0.129; 0.043), mean admission weight of 6.6 ±1.81 kg (X^2= 0.186; 0.043), number of days for diarrhoea to resolve (X^2= -0.199; 0.037), visits to clinics after discharge (X^2= -0.309; 0.002) and mortality (X^2= -0.142; 0.021).

Households where there was no food for IYC to eat

More than 53.7% (116 out of 216) mothers / caregivers reported a lack of food at household level. The occurrence of a lack of food for the IYC to eat occurred often (18.5%) in the Eastern Cape. More households in Eastern Cape (56.9%) and Free State (54.8%) had a lack of food than those in Gauteng (28.3%) and Mpumalanga (21.3%). Males (43.0%) and females (45.3%) were equally affected by the unavailability of food in the household. The highest prevalence (44.9%) of a lack of food at household level was reported for IYC younger than three years of age. The lack of food for IYC was associated with medical diagnosis of complicated SAM (X2= 0.167; p=0.009), cessation of breastfeeding (X2= -0.221;p< 0.000), stunting (X2= 0.175; p=0.006), underweight (X2= 0.195; p=0.002); mean admission weight of 6.6 ±1.8 kg (X2=0.144.; p=0.027), MUAC less than 11.5 cm (X2= 0.165; p=0.011), number of days it took for oedema to resolve during inpatient treatment of SAM (X2= -0.235; p=0.035), number of days it took for appetite to return in the course of SAM treatment (X2= -0.207; p=0.044), clinic visits post discharge (X2= -0.325; p=0.0001).

DISCUSSION

More male than female IYC, with a mean age of 14 months, was admitted to the study sites for the inpatient management of SAM. This trend was similar to what was reported in other SAM studies conducted in various parts of Ethiopia and SA (Asres *et al.*, 2018). SAM was complicated by other medical conditions such as oedema, LARI, HIV, TB, anemia, diarrhoea, vomiting and dehydration (Asres *et al.*, 2018). This presence of SAM and conjunction with other medical conditions increase the risk for delayed SAM recovery, relapse, and mortality. REF This synchronicity was also demonstrated by the outcomes of studies conducted in Ethiopia whereby the co-existence of SAM and oedema, diarrhoea, pneumonia, anaemia, TB and HIV delayed recovery time (Derseh *et al.*, 2018; Baraki *et al.*, 2020; Wondim *et al.*, 2020). Herbal intoxication is another medical condition that complicates the treatment and outcomes of IYC admitted for inpatient management of SAM (Muzigaba *et al.*, 2018). This condition was also reported as a risk factor for delayed SAM treatment outcomes by Muzigaba *et al.* (2018) and Gavhi *et al.* (2020) in the Eastern Cape and Limpopo, respectively.

In the current study, HHFIS was also associated with stunting, underweight and SAM, with IYC from food insecure households being more likely to have mean admission weights of less than 7kg and a MUAC of less than 11.5 cm. This was comparable to findings in Ethiopia, where IYC with SAM with an admission weight of more than 7kg had a higher probability of a faster SAM recovery rate (AHR = 1.73, 95% CI: 1.41–2.14) (Atnafe *et al.*, 2019). It can therefore be assumed that HHFIS is predictive of delayed recovery from SAM during inpatient management.

The prevalence of HHFIS was 27.2%, with a higher prevalence of severe food insecurity among males, IYC younger than 12 months and those residing in rural areas. Nearly 15% (14.6%) of the study sample came from moderately food insecure households, while 10.7% were severely food insecure. This prevalence was in line with the 26.0% food insecurity reported in the SANHANES-1 study, with higher incidences of food insecurity reported in rural areas (Shisana *et al.*, 2013). A high prevalence of food insecurity was also reported amongst infants younger than 12 months with SAM in Nepal (Ghimire *et al.*, 2020). These findings were higher than what was reported in Canada, where the prevalence of HHFIS was reported as 17%, of which 8.6% was moderate and 2.9% severe (Orr *et al.*, 2018), highlighting the difference in food security between middle income countries like SA and high-income countries like Canada (Global Hunger Index, 2019).

The early cessation of breastfeeding was not only related to admission for SAM treatment, but also to delayed recovery and poor treatment outcomes amongst malnourished IYC. These findings were like research outcomes from Canada, whereby mothers from food insecure households cease breastfeeding before the infant reached four months (Orr *et al.*, 2018). Globally, breastfeeding is regarded as a HHFI intervention for IYC under two years of age. The benefit of breastfeeding in the context of serving as a source of nutrition and therefor provision of food security for IYC is underestimated. As a result, a renewed focus should be placed on linking knowledge and practices of mothers to that of health professionals in the fight to improve child survival rates (NDOH, 2013; Venu *et al.*, 2017; WHO, 2020). This result emphasizes the need for mothers to improve breastfeeding practices in an attempt to increase the likelihood of IYC surviving beyond their second birthday. In SA, breastfeeding rates remain low. REF? The Tshwane declaration, regulation R991 of 6 December 2012 and the national IYC feeding policy have been developed to protect, promote, and support breastfeeding practices, with the aim of increasing IYC survival rates. Other policies and programs are also implemented nationally to

support the first 1000 days of a child's life (NDOH, 2013). It can therefore be concluded that the availability of robust policies and programs do not serve as a barrier in the prevention of IYC deaths, but rather the ongoing implementation, monitoring and strengthening thereof (Derseh *et al.*, 2018; WHO, 2020). More research and evidence-based evaluations at implementation level are needed to identify strengths, weaknesses and threats of these policies and programs in order to identify corrective or strengthening measures to improve the quality of care for breastfeeding mothers (UNICEF 2011; Baraki *et al.*, 2020; WHO, 2020).

When considering the household factors and domains of the HFIAS, significant associations were found between each domain and SAM recovery and treatment outcomes. Inadequate food intake was defined by a lack of food intake due to the unavailability of food in the household or eating fewer meals or less food due to limited food quantities. IYC with a history of inadequate food intake in terms of both quality and quantity the month prior to hospital admission, were more likely to be in need for inpatient treatment of SAM that was complicated by other medical conditions. Inadequate or no food intake was a predictable risk factor for poor treatment outcomes, such as increased length of hospital stay, delayed recovery from SAM complications such as oedema, diarrhoea, lack of appetite and an inadequate daily weight gain of less than 10g/kg/day. Insufficient dietary intake also increases the risk for increased return clinic visits for management of illness/malnutrition and readmission after exiting SAM rehabilitation. A strong association exists between no or inadequate food intake and IYC mortality. These finding were similar to what was reported by other researchers. In Ethiopia, food insecurity was associated with a poor daily weight gain of less than 8g/kg/day (Atnafe *et al.*, 2019).

A strong association was found between malnutrition in all its forms i.e. stunting, underweight and SAM and HHFIS. Although the effect of micronutrient deficiencies was not studied, literature describes the association between a monotonous diet and malnutrition, including micronutrient deficiencies (Christian *et al.*, 2019). Eating a limited variety of foods was a predictable risk factor for IYC hospitalization for inpatient management of SAM that presented with a lack of appetite and delayed return of appetite during inpatient treatment. This association was also reported by Musa *et al*. (2017) where an association was found between SAM recovery and a lack of consuming a balanced diet.

CONCLUSION

The results from this study indicated that inadequate food intake and a diet that lacks variety, not only increases the risk of IYC suffering from for malnutrition, but also increases their risk for hospital admission for the inpatient management of SAM, characterized by delayed and poor recovery outcomes and an increased risk for relapse and mortality following discharge. This suggests a cyclic association between HHFIS, SAM and an increased risk for mortality. IYC from food insecure households, irrespective of the severity thereof, have an increased risk for failed recovery from SAM and mortality. However, the data underscoring this relationship is limited, hence requiring further investigation.

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CHAPTER 9

SYNTHESIS, CONCLUSIONS AND RECOMMENDATIONS

9.1 INTRODUCTION

The inpatient management of SAM remains a global challenge. Worldwide 14.3 million IYC suffer from SAM with 75% living in low and low-middle income countries, including SA (UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). Despite continuous developments within the recommended feeding regimes for the management of SAM, there is limited independent evidence-based findings and amendments to substantiate recommendations based on the WHO Ten Steps in the management and treatment of SAM (Sphere Association, 2018). In the absence of relevant published data, recommendations for the management and treatment of SAM have required reliance on expert opinion. When it comes to the implementation of feeding regimes in the context of managing and treating SAM complicated by HIV infection and herbal intoxication, a significant paucity of data has been identified (Muzigaba *et al.*, 2018). It should also be noted that current treatment guidelines lack or provide limited and vague information on the management and treatment of malnourished infants younger than six months of age. In addition, more robust post-discharge treatment guidelines are needed to prevent and decrease the incidence of SAM readmissions (USAID, 2018).

Nationally and internationally, many interventions have been implemented to prevent the manifestation of malnutrition amongst IYC (Bamford *et al.,* 2018). As a result of SA efforts, the local SAM CFR deceased from 12,7% in 2012 to 8% in 2017, hence bringing the CFR to below the global and national target of 9% (NDOH, 2016; Bamford *et al.*, 2018). Various factors contribute to SAM treatment outcomes and recovery, of which inadequate healthcare services and household food insecurity forms an integral part (Akombi *et al.,* 2017). Compliance with standards outlined in SAM treatment protocols can improve treatment outcomes, recovery and survival of IYC that grow up in food insecure households that are admitted for inpatient management of SAM. These IYC require prolonged care during hospitalizations as well as post-discharge to improve treatment outcomes and rehabilitation until full recovery is achieved. Premature hospital discharge is detrimental to full recovery from SAM, as it results in relapse, readmission and IYC mortality (Stobaugh *et al.,* 2018). In order to fully comprehend the manifestation of SAM, treatment and support required for full recovery and nutrition

intervention strategies aimed at improving SAM, should be revised and strengthened (UNICEF, WHO, International Bank for Reconstruction and Development/The World Bank, 2020). The "GAP" framework was developed by five UN Agencies with the aim of reducing IYC mortality by 5% in 2025 and 3% by 2030 respectively, thereby supporting the concept that the SDG targets can be achieved separately by 2025 and 2030 by addressing the concepts of reducing the incidence of low birth weight, improving child health, improving IYC feeding and improving treatment of IYC with SAM (UNICEF, WFP, WHO, UNHCR & FAO, 2020).

9.2 SYNTHESIS

The study aim was based on the hypothesis that compliance with standards outlined in the current national SAM treatment protocol of the SA DOH will result in improved nutritional and clinical status, as well as improved hospital recovery rates among IYC diagnosed with SAM.

To attain the study aim, the following objectives were formulated:

- Determine the nutritional status of IYC hospitalized for the inpatient management of SAM;
- Determine the clinical status of IYC hospitalized for the inpatient management of SAM;
- Determine which therapeutic feeds were used as part of the SAM Treatment Protocol at selected facilities;
- Determine compliance with the SAM Treatment Protocol and compare the recovery rate by assessing duration of hospital stay, reduced oedema and diarrhoea, return of appetite and adequate weight gain of IYC admitted for inpatient management of SAM;
- Determine SAM recovery rate and follow-up practices, as well as IYC readmission following hospital discharge;
- Determine the association between household food insecurity and IYC SAM recovery.

For the purpose of the study, the following hypotheses were formulated:

- **H_0**: Non-compliance with the feeding regimes outlined in the current SAM Treatment Protocol will not result in improved nutritional and clinical status as well as improved hospital recovery rate among IYC diagnosed with SAM.

- **H_1**: Compliance with the feeding regimes outlined in the current SAM Treatment Protocol will result in improved nutritional and clinical status as well as improved hospital recovery rate among IYC diagnosed with SAM.

Although available literature describes various factors contributing to the development of SAM, there is a paucity of data describing the impact of non-compliance with SAM treatment protocols on SAM treatment outcomes, recovery, relapse and IYC mortality. The relationship between HHFIS and the development of SAM is well described, however limited data outlining the impact of HHFIS on an IYC's ability to recover from SAM during hospitalization and rehabilitation following discharge is available. Hence an additional objective of the current study was to determine the association between HHFIS, compliance with SAM treatment protocols and SAM recovery, relapse, readmission and IYC mortality.

Inadequate compliance with SAM treatment protocols results in the premature discharge of IYC suffering from SAM, resulting in increased subsequent visits to local clinics to seek medical care, in addition to increased risk of relapse, readmission and IYC mortality (Lenters *et al.*, 2016). Hence, inadequate compliance with SAM treatment protocols can be translated into the provision of inadequate healthcare services, an underlying factor resulting in the manifestation of SAM relapse and IYC mortality. Furthermore, HHFIS not only increases the risk of IYC developing SAM, but also is also negatively associated with SAM treatment outcomes, as HHFIS is associated with delayed remission of complications associated with SAM such as oedema, diarrhoea and a lack of appetite (Betebo, Ejajo, Alemseged & Massa, 2017).

In the light of the above, current SAM treatment protocols based on anecdotal feeding recommendations that were formulated over two decades ago, should be reviewed and updated to include recent evidence and risk factors for the development of SAM described in scientific literature to guide health professionals in the management of SAM in IYC. Furthermore, roles and responsibilities of all health professionals involved in the management of SAM should be defined and included in SAM treatment protocols.

The findings of this study can be used to guide policy makers in identifying shortcomings in current SAM treatment protocols and the implementation thereof. By addressing these

shortcomings to improve and strengthen SAM treatment protocols, improved implementation of treatment protocols by a multidisciplinary team can be advocated with the ultimate goal of improving the delivery of healthcare services. In addition, the association between HHFIS and inadequate inpatient SAM recovery, highlights the importance of liaising with other government departments and non-government organisations to improve living conditions of malnourished IYC and their mothers/caregivers. Furthermore, political support is needed to facilitate decision making and legislate programme and policy changes.

In addition to study findings, further research is required to determine whether the current SAM treatment protocols and standards are appropriate for the management of SAM and to identify shortcomings in the current SAM treatment guidelines.

9.3 CONCLUSION

Nutritional and clinical status of IYC hospitalized for inpatient management of SAM

A higher percentage of male IYC were admitted for the inpatient management of SAM. As a low body weight and a MUAC of less than 11.5cm increases the risk of IYC to suffer from SAM, it was not surprising that in the current study, 13.4% of IYC included in the study sample had a low body weight and MUAC of less than 11.5 cm, while all participants were stunted and wasted. The recorded CFR was 6.1%, which is lower than the national target of 9%. The median duration of hospital stay was 10.1 ± 6.4 days, making it lower than the national SAM treatment protocol of 14 to 42 days. It was therefore not unexpected that IYC were discharged despite their daily weight gain being less than the desired weight gain of more than 10g/kg/day. The inpatient management of SAM amongst IYC included in the study sample was complicated by medical conditions such as LARIs, sepsis, cerebral palsy and debilitating conditions such as HIV and TB in conjunction with anaemia, herbal intoxication, vomiting and hypoglyceamia. The prevalence of a lack of appetite, oedema and diarrhoea further complicated the management of SAM among IYC admitted for inpatient management of SAM in Eastern Cape, Free State, Mpumalanga and Gauteng.

Therapeutic feeds used for inpatient management of SAM

Commercially available therapeutic feeds, including F-75, F-100 and RUTF, were predominantly used (93.8%) for the inpatient management of SAM. Where these therapeutic

feeds were unavailable, stock was borrowed from neighbouring hospitals, depending on availability. Despite the inclusion of a standard recipe for the preparation of these therapeutic feeds (using locally available ingredients) in the national SAM treatment protocol, infant formula was the preferred replacement feed when F-75 and F-100 was unavailable. In hospitals where the standard recipe was used to prepare therapeutic feeds, a commercial vitamin and mineral mix was not added to in-house prepared therapeutic milks. A cause for concern was the finding that in almost half of the hospitals included in the study sample, only nutritional supplements including F-75, F-100 and RUTF, were used for nutrition support with no additional high protein, soft foods or snacks being served to study participants. Although the SAM treatment protocol encourages continuation with breastfeeding as part of inpatient management, only 16.4% of mothers were encouraged to continue breastfeeding.

RUTFs were predominantly provided as a take home ration to take home for further nutrition rehabilitation. Other food supplements that were issued on discharge, included fortified maize meal, high energy supplementary drinks, paediatric enteral feeds and infant formula. Sufficient food supplements translating to a week's supply were provided by more than 90% of the hospitals upon participant discharge.

Compliance with the SAM treatment protocols

Compliance with the SAM treatment protocol standards was average, with a mean compliance score for public hospitals included in the study sample ranging between 50% and 75%, thereby increasing the risk for relapse, readmission, and mortality. IYC were discharged despite inadequate daily weight gain and before clinical complications such as oedema, lack of appetite and diarrhoea had resolved. Hence hospitalization for full recovery and rehabilitation from SAM was inadequate. It can thus be concluded that inpatient management of SAM in public hospitals included in this study sample did not support adequate recovery from SAM before discharge, increasing IYC risk of relapse, readmission and mortality.

SAM recovery rate, follow-up practices and readmission of IYC following hospital discharge

In this study, the international standards for SAM recovery and mortality were met, with SAM recovery, defaulter and mortality rates reported to be aligned with the Sphere Association (2018) recommendations. Non-compliance with the local SAM treatment protocol standards however, increased the risk for relapse, readmission and mortality. The implementation of feeding

regimes and timeous feeding of appropriate therapeutic feeds to support the stabilisation and rehabilitation phases of SAM recovery, without posing a risk for developing refeeding syndrome, can reduce the risk of mortality during inpatient care. Daily monitoring and evaluation of weight gain, MUAC and resolved oedema and diarrhoea should be closely monitored to not only improve SAM recovery rates, but also increase the likelihood of IYC survival and prevention of relapse following discharge. It is therefore recommended that hospital staff should adhere to the SA SAM protocol.

The association between HHFIS and SAM recovery

Study findings pointed towards the fact that inadequate food intake and a lack of dietary diversity not only increases the risk of IYC malnutrition, but also the risk for readmission for inpatient management of SAM, with delayed and poor recovery outcomes and an increased risk for relapse and mortality following discharge. This suggests a cyclic association between HHFIS, SAM and increased risk for mortality as illustrated in figure 9.1. IYC from food insecure households, irrespective of the severity thereof, have an increased risk of failing to recover from SAM and increased risk of mortality. However, as there is a paucity of data investigating this relationship, more research is needed (Asres *et al.*,2018). Research outcomes from India suggested that IYC were readmitted for inpatient management of SAM due to relapse after discharge. Despite the provision of nutrition education and regular follow-up support visits with mothers/caregivers, home-based feeding practices did not change, and food supplements issued for home consumption were inadequate to support full recovery (Chaturvedi *et al.*, 2018).

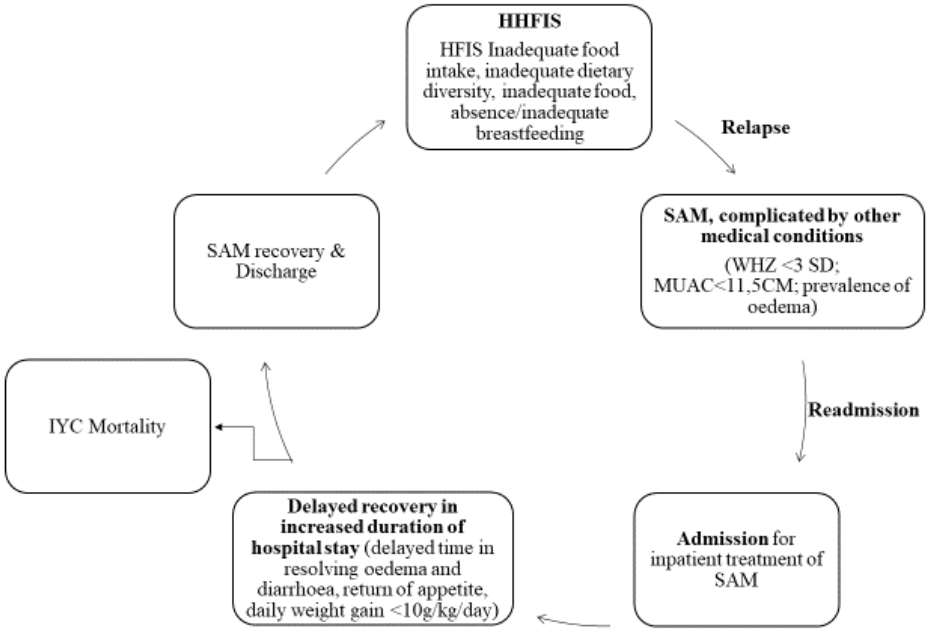

Figure 9.1: Vicious cycle between HHFIS, poor and delayed SAM recovery, relapse and IYC mortality

9.4 RECOMMENDATIONS

Although feeding regimes for the management of SAM have significantly evolved over several decades, very few changes have been introduced since 1999 and 2013. The current feeding recommendations are predominantly focussed on in-patient management of SAM and on IYC older than six months of age. This recommendation does not have the intention of criticising the WHO, authors of these guidelines or any other subject experts, but serves as a call for action to researchers and policy makers to update, improve and strengthen current nutrition intervention strategies, based on available evidence for the management and treatment of SAM in order to curb IYC mortality. The following recommendations can strengthen existing nutrition intervention strategies for the management of SAM in the public health domain, through an integrated multidisciplinary and public-private-partnership approach:

Nutritional and clinical status of IYC admitted for inpatient management of SAM

- Global and national SAM treatment protocols do not include the management of SAM amongst IYC complicated by cerebral palsy and herbal intoxication and should be revised to guide health professionals to improve treatment outcomes.

Therapeutic feeds used for inpatient management of SAM

- A standardised soft, high protein menu consisting of meals and snacks should be described in the national SA SAM treatment protocol as part of the SAM management steps. Although the inclusion of high protein/energy snacks are described in the SAM treatment protocol, it is added as an addendum and is left open for interpretation. By including it as part of the ten steps in the successful management of SAM, the important role of food in the recovery and rehabilitation of SAM is emphasised.
- In SA, a lot of effort has been put into protecting, promoting and supporting breastfeeding practices. Healthcare professionals and healthcare workers should be made aware of the importance of breastmilk as a nutritive food for providing optimal nutrition to IYC from food insecure households, the health benefits associated with breastfeeding and its impact on IYC survival. More research is needed to gain an understanding of the perceptions and personal beliefs among health professionals that could serve as barriers to encouraging and supporting breastfeeding as part of the SAM treatment protocol.
- To improve child survival as part of the management of SAM, high fat energy dense supplements are provided over for an extended period of time (Sphere Association, 2018).

The consumption of high fat, energy dense foods and snacks by children younger than five years, increases the risk for the development of childhood and adolescent obesity and metabolic syndrome (Asghari *et al.*, 2016). Since both under- and overnutrition is prevalent among the SA population, more research is needed to determine (i) the appropriate timeframe to provide high fat energy dense supplements without it contributing to the development of overweight and obesity in subsequent years; and (ii) the effect of food supplements with a high sugar and fat content on the development of childhood obesity and metabolic syndrome in adulthood.

Compliance with SAM treatment protocols

To improve compliance with the current national SAM treatment protocol, the following recommendations are made:

- Monitoring tools that can be used by hospital managers to measure compliance with SAM treatment protocol standards, should be included as part of the SAM treatment protocol and made available electronically for documentation, analysis, interpretation and reporting purposes.
- Ongoing monitoring of compliance with the national SAM treatment protocol should be encouraged and supported by provincial and national programme directors. Quarterly reports that include compliance scores, barriers to implementation and compliance, as well as corrective measures that have been implemented, should be compiled for strategic feedback sessions at district, provincial and national level.
- Since one of the biggest indicators of non-compliance with discharge standards in the current study was related to the absence of a daily weight gain of more than 10g/kg/day for five consecutive days, it is recommended that a screening tool should be developed to assist health professionals to determine and interpret daily weight gain, depicted as four colour coded areas in red, orange, yellow and green. This screening tool should be accessible via a dashboard application or medical device that can provide a daily algorithm-based recommendation regarding readiness for discharge, linked to progress towards a desirable daily weight gain and resolving clinical signs and symptoms.

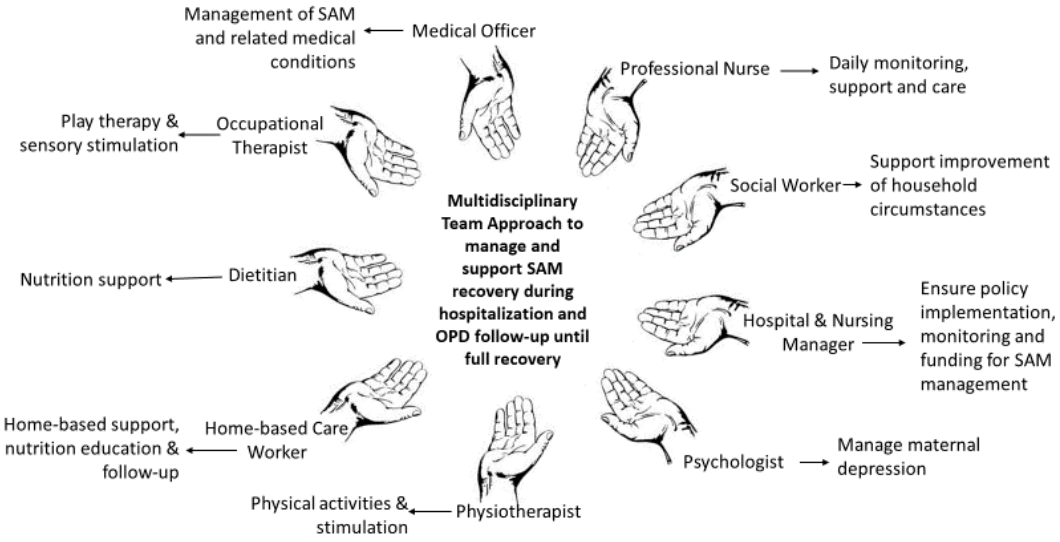

Figure 9.2: Example of health professionals involved in a multidisciplinary team approach to treat and support SAM rehabilitation during hospitalization and OPD follow-up until full recovery

- Encourage a multidisciplinary team approach by identifying and clarifying the roles and responsibilities of all health professionals involved in SAM management and support during hospitalization and outpatient discharge (OPD) rehabilitation for inclusion in the SAM treatment protocol. To illustrate this recommendation, refer to figure 9.2 as an example of
- Sensory stimulation, play and loving care is associated with improved SAM treatment outcomes and rehabilitation (NDOH, 2015). A study conducted in Jaipur indicated that obstacles to the implementation of sensory stimulation, play and loving care included a lack of time from nursing staff to attend to these activities, perceptions amongst nursing staff and mothers/caregivers that malnourished IYC are lethargic and uninterested in these activities, lack of awareness of nursing staff and mothers/caregivers that sensory stimulation through play and physical activities improve SAM treatment outcomes and a lack of toys or raw materials to create toys as illustrated in the WHO guidelines (Talikoti & Rathore, 2020). Occupational Therapists and Physiotherapist play a major role in driving this activity and should be included as partners in the multidisciplinary team (Moore & Lynch, 2018; Ooi *et al.*, 2020).

- Hospitals can form public-private-partnerships to obtain raw materials to be used for toy-making to improve sustainability of IYC stimulation activities. IYC should be discharged with toys made by mothers/ caregivers during hospitalization to continue play activities at home. An example of a public-private-partnership is an outreach activity that includes the elderly living old age homes in the vicinity of the hospital or SAM treatment centre to create soft toys that can be used as part of SAM rehabilitation activities in exchange for e.g. foodservice administration/evaluation. The effect of ongoing play activities from admission until full recovery from SAM should be evaluated to determine the effect of ongoing play, sensory stimulation and loving care following discharge as a risk factor for SAM relapse and readmission.
- Include mental health support for mothers/caregivers in the management of SAM. An integral part of the multidisciplinary approach should be to routinely screen and treat maternal depression amongst mothers/caregivers. Findings of a study conducted in the Mbarara Regional Hospital, Uganda, suggested a strong association between maternal depression and the incidence of SAM amongst IYC (Ashaba *et al.,* 2015). The inclusion of a Psychologist or mental health councillor is essential to diagnose and treat maternal depression and assist with attaining coping strategies that may strengthen SAM treatment and rehabilitation to prevent relapse, readmission and IYC mortality (Sphere Association, 2018). More studies are needed to determine: (i) the association between SAM and maternal depression, (ii) risk factors contributing to maternal depression, and (iii) the impact of the management of maternal depression on SAM treatment outcomes.
- Review the GAP framework and include valid recommendations and actions in the current national SAM treatment protocol to strengthen interdepartmental and public-private-partnerships in the fight against IYC mortality as a result of SAM.

SAM recovery rate, follow-up practices and readmission of IYC following hospitalization and discharge

The following recommendations will assist in improving SAM recovery rates and rehabilitation during and following hospital discharge:

- Health professionals responsible making decisions regarding readiness for discharge should receive in-depth training on discharge standards presented in the national SAM treatment protocol. Training should be expanded beyond that of health professionals employed in public hospitals to academic institutions and professional associations. Sustainability will

be ensured by expanding the training of these target groups to newly appointed health professionals or private practicing health professionals rendering sessional services to IYC in public health facilities.

- SAM recovery rates should be included as an indicator in the DHIS and interpreted in conjunction with compliance with the SAM treatment protocol.
- Home-based carers can involve lodging mothers/caregivers in meal preparation for IYC admitted for inpatient management of SAM, using food preparation demonstrations and participation as a platform for nutrition education. The purpose of these food preparation demonstrations will be to teach mothers/caregivers how to prepare food for IYC at home, using locally available ingredients, and to encourage mothers/caregivers to feed IYC from the family pot, eradicating the assumption that IYC need "special, commercially available" foods for optimal growth.
- Food technologists and scientists or academic departments can develop recipes for use by poor households, without the addition of expensive micronutrient mixes, food supplements and ingredients. These recipes can be used in food preparation demonstrations for mothers/caregivers during IYC hospitalization, while take home pamphlets including these recipes can be made available to mothers/caregivers for home use.
- Department of Agriculture and Agricultural colleges and schools can embark on outreach programmes that focus on teaching individuals in poor and food insecure villages, suburbs and informal settlements how to grow and harvest vegetables in limited spaces as home grown vegetables will contribute to improved dietary diversity and food intake of IYC.

The association between HHFIS and SAM recovery

"The biggest enemy of health in the developing world is poverty" was the opening statement made by Kofi Annan, former Secretary-General of the United Nations, in 2001 at the World Health Assembly (UN, 2001).

- In order to gain political power, collective political actors and institutions should join forces to use unions, political parties and power resources to alleviate poverty. Since most single mothers are impoverished, political actors target these women to support elections by increasing the electoral power of women (Brady *et al.*, 2016). As poverty is associated with HHFIS, inadequate food and dietary practices, SAM and IYC mortality, more research is needed to determine the relationship between political involvement in alleviating HHFIS as a main to gain electoral power in SA.

- An annual campaign should be conducted to discourage the misuse of social grants. Mothers/ caregivers who receive child support grants should receive information on how to spend the money wisely to support IYC health. A mobile phone application should be designed and made available to mothers/caregivers to guide them on monthly budgeting and planning of household expenditure. This application should also be linked to local food suppliers, indicating special offers on basic foods.
- The government should establish a committee or task team at national level, to liaise with the Chamber of Commerce and Industry to compile guidelines for the maximum allowed increase in annual food prices. The factors influencing food prices should be identified and the percentage contribution to food price increases should be linked to these factors. In addition, the relationship between these factors and food price increases should be defined on a sliding scale, allowing both food price increases and reductions, depending on changes affecting these contributing factors. A regulatory body should be established or appointed to control, and monitor food prices based on these guidelines.
- In addition to food price increase guidelines, a basic food basket for poor households should be recommended, with an average set price per annum. By capping the average price for a basic food basket, the government can ensure that basic food baskets remain affordable throughout the year. Apart from these basic foods being excluded from value-added tax (VAT), a maximum allowed price increase per annum should also be determined.

9.4. PUBLIC HEALTH RELEVANCE

The global and national public health implications of malnutrition in all its forms are well described in the literature. When focusing on malnutrition, it is important to consider both the short-term and long-term consequences for IYC, their families and SA. The adoption of the SDGs has placed SA under the obligation to provide adequate opportunities for IYC not only to survive, but to thrive. The current target for SGD 3.2 is to reduce the under-five mortality rate to at least or less than 25 deaths per 1000 live births by 2030. The most recent under-five mortality rate in SA, as reported in 2019, was 34.5 deaths per 1000 live births, which is higher than the global target (UN IGME, 2020).

Although the under-five mortality rates within SA have improved from 79.4 deaths per 1000 live births in 2006, to 34.5 per 1000 live births in 2019, the impact of the 2019 coronavirus (COVID-19) pandemic cannot be disregarded. A thorough investigation should be conducted in

SA to determine the impact of COVID-19 on IYC mortality and its possible contribution to increasing the prevalence of SAM among IYC. Recently published literature, study outcomes and case series presented on COVID-19 indicate the impact of COVID-19 on increased unemployment, poverty, women and IYC abuse, interruption of immunization schedules and growth monitoring practices of IYC in addition to reduced inpatient care of IYC suffering from SAM due to the unavailability of beds (STATS SA, 2020; UN IGME, 2020; UNFPA, 2020). In addition, the negative impact of COVID-19 on protecting, promoting and supporting breastfeeding practices should also be considered by including clear and concise COVID-19 guidelines and recommendations within the SA breastfeeding and infant feeding policies and protocols, since breastfeeding provides food security within at least the first two years of an IYC life (Spatz, Davanzo, Müller, Powell, Rigourd, Yates, Geddes, van Goudoever, & Bode, 2021). The devastating impact of COVID-19 on IYC mortality, access to adequate healthcare services and increased HHFIS, cannot be ignored and should be addressed as soon as possible.

In addition to child survival, SA is also obligated to provide adequate health services, prosperity, peace and freedom for IYC to thrive. This means that IYC must be given the opportunity to reach their full potential in life, ultimately having families of their own, being financially stable and contributing to society. Due to impaired cognitive development amongst IYC suffering from SAM in the early years of their lives, these IYC have an increased risk of being illiterate, which in later life will result in poverty, unemployment and establishing of an impoverished family with a greater likelihood of malnourished offspring (UN IGME, 2020). This must raise concern for politicians and the Minister of Finance as the result of the above is a reduction in productivity among the SA labour force, with fewer members of society contributing to the financial wellbeing of the country, leading to an increase in SA's debt and a decrease in fiscal income (The World Bank, 2018).

Another long-term consequence of malnutrition, especially that of stunting, is the development of obesity amongst malnourished IYC in later life (Symington, Gericke, Nel & Labadarios, 2016). Obesity, together with an increased risk for the development of metabolic syndrome, type 2 diabetes, heart disease and cancer, will increase healthcare costs for these individuals as well as an increased burden on national healthcare funds. In addition, it will also have a negative impact on productivity due to absenteeism from work.

Apart from public health consequences, the increased risk for poverty and unemployment amongst malnourished IYC in later life can result in an increase in crime rates as a result of household food insecurity (Caughron, 2016). Thus, resulting in an increased budget for an adequate police force, justice services and correctional services and facilities.

As with all other research outcomes, the findings of the current study need to be considered by policy makers, program designers and implementers to strengthen and correct current malnutrition policies, protocols and implementation standards, not only to decrease mortality rates, but to increase the ability of IYC to thrive. Various recommendations have been proposed under the "Recommendations" section within this chapter in a plea for strengthening of services and SAM treatment protocols. However, the findings and recommendations of this study should be viewed in conjunction with the outcomes and findings of other research conducted within SA over the last five years to strengthen the management of acute malnutrition within SA amongst IYC. A renewed focus should be placed on providing standards and guidelines regarding the prevention and management of MAM and SAM, differentiating between treatment guidelines for SAM complicated by LARIs, debilitating conditions such as TB and HIV, cerebral palsy and herbal intoxication. Health professionals at all levels of care and within both the public and private sector should be thoroughly educated on these treatment standards and guidelines to ensure SAM is prevented and that IYC admitted for the inpatient management of SAM reach full recovery before they are discharged to prevent relapse and readmission, resulting in mortality.

Policies and protocols must contain clear statements and recommendations regarding inter-and intradepartmental and sectoral collaboration to prevent and manage acute malnutrition. The main focus of program development, implementation, monitoring, evaluation and improvement should not only be to reach the set SDG 3.2. targeting to reduce child mortality, but to generate long-term, sustainable solutions regarding the prevention and manifestation of malnutrition, with the ultimate goal being to preserve the lives of IYC and also the independence and life of SA society at large.

9.5. STUDY STRENGHTS AND LIMITATIONS

The following strengths and limitations have been identified for the current study:

Study strengths

- The public hospitals included as study sites already implemented SAM treatment protocols prior to the study being conducted;
- Operational managers, involved in the implementation, monitoring and evaluation of SAM was involved in the planning and monitoring of this study;
- Fieldworkers were qualified health professionals (nurses and dietitians), familiar with conducting clinical and anthropometric measurements and assessments;
- All members of the research team, including research assistants, provincial study coordinators and fieldworkers were trained to gain an understanding of the study aim, objectives, hypothesis, data collection tools and data collection methods, thereby standardising the level of understanding, knowledge and methods employed by the research team across all provinces and sampled hospitals;
- Fieldworkers resided in local communities and were therefore able to visit study sites on a daily basis for data collection purposes;
- Using convenience sampling ensured that all IYC admitted for inpatient treatment of SAM, were screened for inclusion in the study;
- Global standards and measuring protocols were used to collect anthropometric data including weight, length / height and MUAC, as well as the prevalence of clinical indicators of SAM such as oedema, diarrhoea and a lack of appetite;
- Global and national standards such as the Sphere SAM recovery rates and WHO / SA SAM treatment standards were used for comparative purposes to present and interpret study outcomes.

Study limitations

The execution of this study posed the following limitations:

- Since current SAM treatment protocols and standards do not differ for IYC with a known HIV status, HIV as an underlying cause of malnutrition was not HIV status was not included/ determined within the scope of this study (Mambulu-Chikankheni, Eyles, Eboreime & Ditlopo, 2017);
- The predominant study limitation was an inability to collect data from 30 participants per hospital due to low admission rates;

- Fieldworkers only collected data on weekdays, resulting in clinical data not being collected over weekends;
- Birth weights of all participants could not be collected due to unavailability of a Road-to-Health Booklet;
- Appetite tests were not conducted during hospitalization;
- Fieldworkers lost contact with participants that were transferred to other hospitals;
- Fieldworkers were unable to track participants referred to local clinics for follow-up following discharge as mothers/caregivers only brought study participants to clinics for follow-up a month after discharge;
- Mothers/caregivers provided incorrect telephone numbers and/or home addresses thus hampering follow up and home visits;
- Study participants living with siblings or caregivers were sent to live with grandparents residing in other areas/provinces;
- Employed mothers/caregivers sent study participants to live with grandparent(s);
- Fieldworkers did not have the necessary airtime to contact mothers/caregivers to monitor study participants following discharge and hospitals did not allow them to use official telephones to contact mothers/caregivers;
- Fieldworkers did not have transport to conduct home visits;
- Fieldworkers who found permanent employment were unable to continue with participant monitoring following discharge;
- Study participants were transferred to other health facilities with fieldworkers not being granted access to the contact details of mothers/caregivers;
- Fieldworkers were not granted access to patient admission files to determine if any of the study participants were re-admitted, with little or no assistance from hospital personnel in gaining access to patient files for data collection purposes, resulting in the possibility that some study participants that were readmitted for inpatient management were excluded from the study due to limited access to patient files;
- The introduction of bias as a result of using a convenience sample of study participants, can also be regarded as a study limitation as it may misrepresent the target population, i.e. malnourished IYC (Jager, Putnick & Bornstein, 2017).

9.6. REFERENCES

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QUESTIONNAIRE 1 (To be completed in Ward)

TITLE:

THE EFFECT OF READY-TO-USE THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN HOSPITALISED CHILDREN IN SOUTH AFRICA AND SWAZILAND

RESPONDENT NUMBER: ☐☐☐☐

Name of Fieldworker: _____ **Date of Data Collection:** _____

Name of Hospital: _____ **Province:** _____

SECTION A: DEMOGRAPHIC DATA

	Please circle the correct answer for each of the questions below.	FOR OFFICE USE ONLY
	Collect the following information from the Patient Ward File:	
	Date of admission:	
	Medical diagnosis of 1the child:	
	Weight on admission:	
	Collect the following information from the Road To Health Booklet:	
	Date of Birth:	
	Gender: 1. Boy 2. Girl	
	Birth Weight:	
	Collect the following information by asking the Mother / Caretaker:	
	Relationship to the child 1. Mother 2. Grandmother 3. Sister 4. Aunt/Cousin 5. Other (specify: _____)	
	Age of the lodger mother/caregiver: _____ years	

SECTION B. HOUSEHOLD FOOD INSECURITY ACCESS SCALE

	Collect the following data through interviewing the mother / caretaker. Please circle the correct answer for each of the questions below.	**FOR OFFICE USE ONLY**
1.	In the last month, did you worry that you and your household members would not have enough food? 1. Yes 2. No (skip to question 12)	
2.	How often did you worry about this? 4. Rarely (once / twice in the last month) 5. Sometimes (3-10 times in the last month) 6. Often (>10 times in the last month)	
3.	In the last month, did you and your household eat limited types and amounts of food because of a shortage of money? 1. Yes 2. No (skip to question 14)	
4.	How often did this happen? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)	
5.	In the last month did your child have to eat a smaller meal than you felt he / she needed because there was not enough food? 1. Yes 2. No (skip to question 16)	
6.	How often did this happen? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)	
7.	In the last month, did your child have to eat fewer meals because of a lack of food at home? 1. Yes 2. No (skip to question 18)	
8.	How often did this happen? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)	
9.	In the last month, was there ever a situation where there was no food of any kind for your child to eat? 1. Yes 2. No (skip to Section C)	
10.	How often did this happen? 1. Rarely (once / twice in the last month) 2. Sometimes (3-10 times in the last month) 3. Often (>10 times in the last month)	

SECTION C. ANTHROPOMETRY DATA

	Please take the measurements and record the data below.	FOR OFFICE USE ONLY
11.	Height (centimetres – to the nearest decimal) **Baseline (Date of 1st data collection)**: cm **After Nutrition Intervention (Before discharge)**: Cm	
12.	Weight (kilogram – to the nearest decimal) **Baseline (Date of 1st data collection)**: kg **After Nutrition Intervention (Before discharge)**: kg	
13.	Mid-Upper Arm Circumference (MUAC) (centimetres – to the nearest decimal) **Baseline (Date of 1st data collection)** **After Nutrition Intervention (Before discharge)**	

SECTION D: IN-PATIENT MONITORING SHEET

	Please circle the correct answer for each of the questions below.	FOR OFFICE USE ONLY
	Collect the following information by interviewing the mother / caretaker:	
14.	Is your child receiving a milk feed? 1. Yes 2. No 3. Don't know 4. Not anymore	
15.	If answered "no" in question 22, do your child receive breastmilk? 1. Yes 2. No 3. Not anymore	
16.	When did your child receive the milk feed? 1. Casualty 2. Ward (immediately) 3. Ward (after a few days) 4. Not receiving any milk feed 5. The child gets breastmilk 6. Other: _____	
17.	Is your child receiving a peanut butter paste? 1. Yes 2. Only once 3. No 4. Not anymore	

	Collect the following information by reviewing the information in the ward file:	
18.	When was F-75 started? 1. Before admission 2. Upon arrival in the ward 3. A few days after admission 4. Never 5. Other: _____	
19.	When was F-100 started? 1. Transition from F-75 to F-100 (Day _____ after admission) 2. Upon arrival in the ward 3. Never 4. Other: _____	

DAILY MONITORING SHEET

	Oedema	Weight	Appetite*	MUAC	Diarrhoea
Day 1					
Day 2					
Day 3					
Day 4					
Day 5					
Day 6					
Day 7					
Day 8					
Day 9					
Day 10					
Day 11					
Day 12					
Day 13					
Day 14					
Day 15					

* Appetite is not tested at this facility:
Reason for not testing appetite?

QUESTIONNAIRE 2 (To be completed through interview with Dietitian)

TITLE:
THE EFFECT OF READY-TO-USE THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN HOSPITALISED CHILDREN IN SOUTH AFRICA AND SWAZILAND

RESPONDENT NUMBER: ☐☐☐☐

Name of Fieldworker: _____ **Date of Data Collection:** _____
Name of Hospital: _____ **Province:** _____

	Please complete the following questions below or circle the correct answer.	FOR OFFICE USE ONLY
1.	Number of children admitted to this hospital for SAM during the past month.	
2.	Number of SAM children excluded from the study according to the set criteria.	
3.	Main reasons for exclusion from the study:	
4.	A SAM / Malnutrition Policy is available at the hospital. 1. Yes 2. No	
5.	Which of the following SAM / Malnutrition Policies / Protocols are used for implementation in this facility? 1. 2015 Operational Guidelines on the Integrated Management of Acute Malnutrition from National Department of Health 2. Provincial Policy / Protocol 3. Institutional Policy / Protocol 4. WHO Documents 5. Other (specify: _____)	
6.	All health professionals working with SAM children have received training on the SAM / Malnutrition Policy in the last 2 years. 1. Yes 2. No 3. Not everyone	
7.	Which health professionals receive training on the SAM / Malnutrition Policy? *(can be more than one group)* 1. Dietitians 2. Nurses 3. Doctors 4. Allied Health Workers 5. Other (specify: _____)	
8.	Do you use a commercial F-75 feed or do you mix it yourself? 1. Commercial F-75 feed (skip to question 9) 2. F-75 mixed at hospital (skip to questions 10 and 11)	
9.	What is the name of the F-75 product that you buy? (skip to question 12)	
10.	Which recipe do you use for mixing the F-75 formula? 1. WHO recipe 2. Recipe described in national / provincial department of health documents 3. Our own recipe 4. Other (specify: _____)	
11.	Do you add a commercial vitamin & mineral premix when you mix the F-75 feed at the hospital? 1. Yes 2. No 3. Sometimes	

	Please complete the following questions below or circle the correct answer.	FOR OFFICE USE ONLY
12.	Do you use a commercial F-100 feed or do you mix it yourself? 1. Commercial F-100 feed (skip to question 13) 2. 2. F-100 mixed at hospital (skip to questions 14 and 15)	
13.	What is the name of the F-100 product that you buy? (skip to question 16)	
14.	Which recipe do you use for mixing the F-100 formula? 1. WHO recipe 2. Recipe described in national / provincial department of health documents 3. Our own recipe 4. Other (specify: _____)	
15.	Do you add a commercial vitamin & mineral premix when you mix the F-100 feed at the hospital? 1. Yes 2. No 3. Sometimes	
16.	Do you currently have F-75 stock to use? 1. Yes 2. No	
17.	Do you currently have F-100 stock to use? 1. Yes 2. No	
18.	What do you do when you run out of F-75 stock?	
19.	What do you do when you run out of F-100 stock?	
20.	Do you give RUTF (peanut-paste) as part of the management of SAM? 1. Yes 2. No 3. Sometimes	
21.	When do you start the RUTF?	
22.	How do you test for the appetite?	
23.	Which food is provided to the child as part of the management of SAM?	
24.	Which supplement are you providing as a TOT upon discharge?	
25.	For how long will this supply last the child after discharge? 1. One week 2. Two weeks 3. A month 4. Other (specify: _____)	
26.	To whom do you refer the child for follow-up after discharge? 1. Come back to hospital 2. Local Clinic 3. Not referred 4. Other (specify: _____)	

IMPORTANT NOTICE!

Please add a copy of the recipe used for mixing F-75 and F-100 feeds in cases where these feeds are mixed at hospital.

QUESTIONNAIRE 3 (3 months follow-up after discharge)

TITLE:
THE EFFECT OF READY-TO-USE THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN HOSPITALISED CHILDREN IN SOUTH AFRICA AND SWAZILAND

RESPONDENT NUMBER: □□□□

Name of Fieldworker: _____ Date of Data Collection: _____
Name of Hospital: _____ Province: _____

TO BE COMPLETED BEFORE THE CHILD LEAVES THE HOSPITAL:
Contact Person at Home: _____ Relationship to child: _____
Physical Address: _____
Tel #: _____ Best time for home visit: _____

WEEKLY MONITORING

WEEK	HOME VISIT	TELEPHONE CALL	APPETITE	VISIT TO CLINIC?	RE-ADMITTED TO HOSPITAL?	CHILD STILL NOT WELL	CHILD BETTER / "HEALTHY"
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							

DURING HOME VISIT:

Date	Previous Weight	Current Weight	Previous MUAC	Current MUAC

QUESTIONNAIRE 4 (To be completed for children on re-admission)

TITLE:
THE EFFECT OF READY-TO-USE THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN HOSPITALISED CHILDREN IN SOUTH AFRICA AND SWAZILAND

Name of Fieldworker: _____ **Date of Data Collection:** _____
Name of Hospital: _____ **Province:** _____

Respondent Number	Discharge Date	Re-admission Date	Previous Diagnosis	Current Diagnosis

DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA

PRETORIA
Private Bag X828, PRETORIA, 0001. 27th Floor, Room 2710, Civitas Building, Cnr Thabo Sehume & Struben Street, PRETORIA, 0001 Tel: 012 395 8000, Fax: 012 395 8422
CAPE TOWN
P.O. Box 3875, CAPE TOWN, 8000, 6th Floor, Room 617, 103 Parliament Towers, Plain Street, CAPE TOWN, 8000 Tel: 021 461 2040, Fax: 021 461 6864

Mr Noel Guliwe
Chief Executive Officer: Aspen Pharmacare South Africa
P O Box 1587
Gallo Manor
WOODMEAD
1587

Dear Mr Guliwe

PERMISSION FOR ASPEN PHARMACARE TO ADMNISTER RESEARCH GRANT ON TREATMENT OF MALNUTRITION AND SEVERE ACUTE MALNUTRITION

The National Department of Health (NDoH) acknowledges receipt of a letter dated 4 April 2017 requesting approval for Aspen Pharmacare to administer a research grant which would aid the Sefako Makgatho Health Sciences University (SMU) in conducting training of postgraduate students.

It is my understanding that the proposed research study will not use infant formula and therefore does not violate Regulation 991. Approval is granted on condition that the University shall use the grant provided by Aspen to conduct observational activities only and the study will be further subject to the consideration and approval of the University's Health Research Ethics Committee.

Submission of the progress report on research initiative to address severe acute malnutrition to the Department of Health is encouraged.

Yours sincerely

[redacted]

MS MP MATSOSO
DIRECTOR-GENERAL: HEALTH
DATE: 11/9/2017

ADDENDUM F

Province of the
EASTERN CAPE
HEALTH

Enquiries: Zonwabele Merile Tel no: 083 378 1202

Email: zonwabele.merile@echealth.gov.za Fax no: 043 642 1409

Date: 07 December 2018

RE: THE EFFECT OF THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MULNTRITION IN CHILDREN IN SOUTH AFRICA AND SWAZILAND. (EC_201809_004)

Dear Mrs A. Ngqaka

The department would like to inform you that your application for the abovementioned research topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.

2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.

3. The Department of Health expects you to provide a progress update on your study every 3 months (from date you received this letter) in writing.

4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Eastern Cape Health Research Committee secretariat. You may also be invited to the department to come and present your research findings with your implementable recommendations.

5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

[redacted]

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

health
Department of Health
FREE STATE PROVINCE

04 October 2018

Ms. MM Botha
School of Agriculture, Earth and Science
UKZN

Dear Ms. MMS Botha

Subject: The effect of therapeutic feed in the management of severe acute malnutrition in children in South Africa and Swaziland

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent by each participant must be obtained.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of the Elizabeth Ross, Thebe and Mofumahadi Manapo Mopeli Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of KwaZulu-Natal and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the KwaZulu-Natal and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** sebeelats@fshealth.gov.za or lithekom@fsheatlh.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day

[redacted]

Dr D Motau
HEAD: HEALTH
Date: 23/10/18

Head : Health
PO Box 227, Bloemfotein, 9300
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health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

Indwe Building, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
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Litiko Letemphilo | Departement van Gesondheid | UmNyango WezeMaphilo

Enq: 013 766 3766/3511
Ref: MP_201809_002

Provincial Research Approval Letter

TO: **Ms Magda Botha**
Molotlegi Street
Ga-Rankuwa
Pretoria
0208

TITLE: THE EFFECT OF THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN CHILDREN IN SOUTH AFRICA AND SWAZILAND

The provincial health research committee has approved your research proposal in the latest format you sent.

- Approval Reference Number: MP_201809_002
- Data Collection Period: January 2019 – May 2019
- Approved Data Collection Facilities:

KwaMhlanga Hospital	Shongwe Hospital	Standerton Hospital	Middelburg Hospital

Kindly ensure that the study is conducted with minimal disruption and impact on our staff, and also ensure that you provide us with a soft or hard copy of the report once your research project has been completed.

Kind regards

[redacted]

MR. JERRY SIGUDLA
MPUMALANGA PHRC

MPUMALANGA PROVINCE
DEPARTMENT OF HEALTH
28 -01- 2019
PRIVATE BAG X11285
NELSPRUIT 1200

28/01/2019
DATE

MPUMALANGA
THE PLACE OF THE RISING SUN

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Enquiries: Mpho Moshime-Shabagu
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TSHWANE RESEARCH COMMITTEE: CLEARANCE CERTIFICATE

DATE ISSUED: 07/12/2018
PROJECT NUMBER: 84/2018
NHRD REFERENCE NUMBER: GP_201809_013

TOPIC: The effect of therapeutic feed in the management of severe acute malnutrition in children in South Africa and Swaziland

Name of the Researcher:	Ms. Magda Botha
Name of Supervisor:	Prof Frederick J Veldman
Facility:	Jubilee District Hospital ODI District Hospital Dr. George Mukhari Academic Hospital
Name of the Department:	University Kwazulu-Natal

NB: THIS OFFICE REQUEST A FULL REPORT ON THE OUTCOME OF THE RESEARCH DONE AND

NOTE THAT RESUBMISSION OF THE PROTOCOL BY RESEARCHER(S) IS REQUIRED IF THERE IS DEPARTURE FROM THE PROTOCOL PROCEDURES AS APPROVED BY THE COMMITTEE.

DECISION OF THE COMMITTEE: APPROVED

[redacted]
Ms. Mpho Moshime-Shabangu **Date** 07/12/2018
Acting Chairperson: Tshwane Research Committee

[redacted]
Mr. Mothomone Pitsi **Date:** 2018.12.07
Chief Director: Tshwane District Health

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Enquiries: Mpho Moshime-Shabagu
Tel: +27 12 451 9036
E-mail: Mpho.Moshime@gauteng.gov.za

TSHWANE RESEARCH COMMITTEE: CLEARANCE CERTIFICATE

DATE ISSUED: 10/04/2019
PROJECT NUMBER: 84/2018
NHRD REFERENCE NUMBER: GP_201809_013

TOPIC: The effect of therapeutic feed in the management of severe acute malnutrition in children in South Africa and Swaziland

Name of the Researcher:	Ms. Magda Botha
Name of Supervisor:	Prof Frederick J Veldman
Facility:	Jubilee District Hospital ODI District Hospital Dr. George Mukhari Academic Hospital
Name of the Department:	University Kwazulu-Natal

NB: THIS OFFICE REQUEST A FULL REPORT ON THE OUTCOME OF THE RESEARCH DONE AND

NOTE THAT RESUBMISSION OF THE PROTOCOL BY RESEARCHER(S) IS REQUIRED IF THERE IS DEPARTURE FROM THE PROTOCOL PROCEDURES AS APPROVED BY THE COMMITTEE.

DECISION OF THE COMMITTEE: APPROVED

[redacted]

Mr. Peter Slwimba
Deputy Chairperson: Tshwane Research Committee

Date 10/4/19

[redacted]

Mr. Mothomone Pitsi
Chief Director: Tshwane District Health

Date: 2019.04.10

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

06 February 2019

Ms MM Botha (217080804)
School of Agricultural, Earth and Sciences
College of Agriculture, Engineering and Science
magsbotha@gmail.com

Protocol: The Effect of Therapeutic Feed in the Management of Severe Acute Malnutrition in Children in South Africa and Swaziland. Degree: PhD
BREC Ref No: BE603/17

EXPEDITED APPLICATION: APPROVAL LETTER

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received 05 October 2018.

The study was provisionally approved pending appropriate responses to queries raised. Your response received on 25 January 2019 to BREC correspondence dated 15 June 2018 has been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have been met and the study is given **full ethics approval for the South African site only** and may begin as from 06 February 2019. Please ensure that site permissions are obtained and forwarded to BREC for approval before commencing research at a site.

This approval is valid for one year from **06 February 2019.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **noted** by a full Committee at its next meeting taking place on **12 March 2019.**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

[redacted]

Professor V Rambiritch
Chair: Biomedical Research Ethics Committee

cc postgraduate administrator:ntulis@ukzn.ac.za
cc supervisor:Frederick.veldman@smu.ac.za
cc co supervisor:Kassiers@ukzn.ac.za

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
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RESEARCH OFFICE
Biomedical Research Ethics Administration
Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

24 May 2019

Ms MM Botha (217080804)
School of Agricultural, Earth and Sciences
College of Agriculture, Engineering and Science
magsbotha@gmail.com

Previous Protocol Title: The Effect of Therapeutic Feed in the Management of Severe Acute Malnutrition in Children in South Africa. Degree: PhD **BREC Ref No: BE603/17**

NEW TITLE:
Protocol: The Effect of Therapeutic Feed in the Management of Severe Acute Malnutrition in Children in South Africa and Swaziland. Degree: PhD
BREC Ref No: BE603/17

We wish to advise you that your application for Amendments received on 08 May 2019 to change the title to the above for the already BREC above study has been **noted and approved** by a sub-committee of the Biomedical Research Ethics Committee.

The committee will be notified of the above approval at its next meeting to be held on 11 June 2019.

Yours sincerely

[redacted]

pp Prof V Rambiritch
Chair: Biomedical Research Ethics Committee

INFORMATION LEAFLET AND INFORMED CONSENT FOR PARENTS

TITLE OF STUDY:

THE EFFECT OF READY-TO-USE THERAPEUTIC FEED IN THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN HOSPITALISED CHILDREN IN SOUTH AFRICA AND SWAZILAND

RESPONDENT NUMBER: □□□

Name of Fieldworker: _____ **Date of Data Collection:** _____

Name of Hospital: _____ **Province:** _____

We invite you to participate in a research study entitled "The effect of ready-to-use therapeutic feed in the management of severe acute malnutrition in hospitalised children." If you have any questions that this leaflet does not fully explain, please do not hesitate to ask. The aim of the study is to determine the effect of, ready-to-use, therapeutic feed in the management of SAM in hospitalized children on their weight gain, mid-upper arm circumference (MUAC) improvement, the reduction of diarrhoea, and their recovery rates (hospital length of stay).

The study involves the measurements of weight, height, and MUAC and palpating the child's feet to check for oedema. There are no risks in the study as it is a non-invasive evidence-based research. Your participation in this study is entirely voluntary. You can refuse to participate in the study; this will not affect you or your child in any way. Although you will not benefit directly from the study, the results of the study will enable us to inform the better product to be used in treating Severe Acute Malnutrition. All information will be kept strictly confidential. Research reports and articles in scientific journals will not include any information that may identify your child but may include the hospital name and district and province.

Consent to Participate in the Study

I confirm that I have been adequately informed/read this information leaflet about the nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I am willing to participate in this study. I have had time to ask questions and have no objection to provide. Therefore, I choose to participate in the study.

I realize that by returning a signed copy of this form I am agreeing to participate in the study.

Parent's* signature: .....…… Date.....

(or that of guardian)

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

Student No: 217080804

24 April 2017

Miss MM Botha
174 Waggel Street
La Montagne
PRETORIA
0184

Dear Miss Botha

Application: PhD: Dietetics

I have pleasure in confirming that you have been accepted as a full time PhD candidate, in the College of Agriculture, Engineering & Science, at this University, for the 2017 academic year.

Your admission as a candidate is subject to your compliance with the University's rules and regulations, which are available online on the University website 'www.ukzn.ac.za Student Portal).

At least **three** months before the thesis is to be presented, you are requested to give **written** notice to that effect to the College Dean of Research submitting at the same time the proposed title. You are required to register every semester until your degree is complete and the maximum registration period allowed for a full time PhD is four years (eight semesters). Any suspension of registration must be applied for in advance and approved by the College Dean of Research.

In terms of a recent Senate decision, you will be granted full fee remission (tuition fees only) for the first three academic years of your registration which is the minimum duration of the degree. Thereafter the prevailing fees policy of the University will apply.

In closing, I confirm that:

1. Your subject of study is "Dietetics"
2. Your supervisor is Professor JF Veldman and the co-supervisor is Dr SM Kassier

Should you have any queries regarding your registration or the administration relating to your postgraduate degree please do not hesitate to contact this office.

Yours Sincerely

[redacted]

Mrs S Khuzwayo
HIGHER DEGREES

Cc: School Academic Leader Research
Supervisor
School Higher Degrees Office