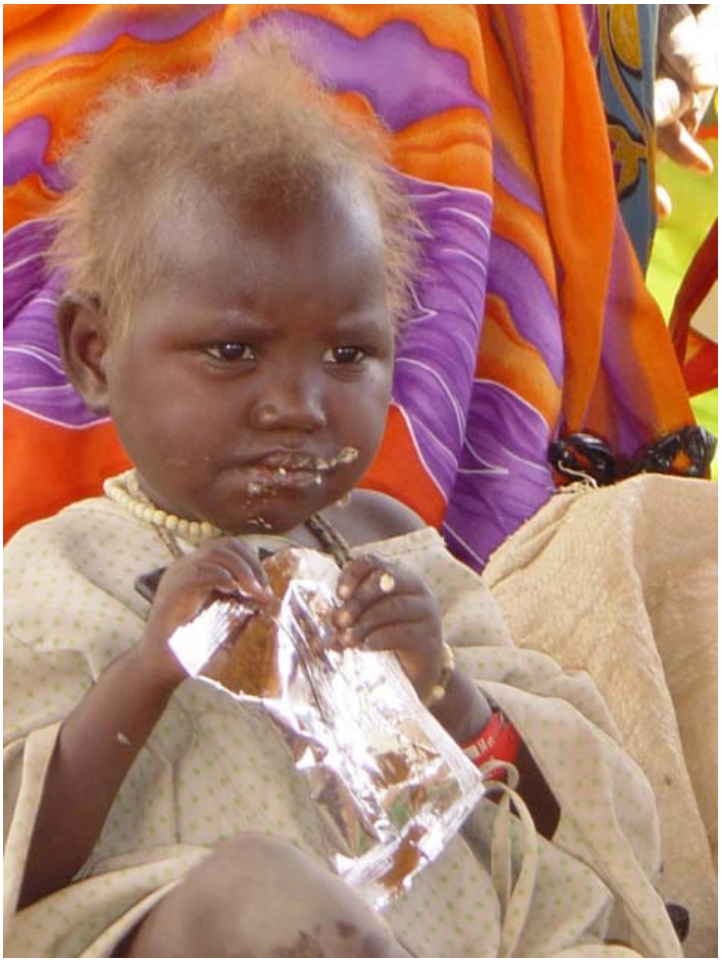
# Community-based Therapeutic Care:

## treating severe acute malnutrition in sub-Saharan Africa.



**Thesis submitted to University College London in part fulfilment of the degree of Ph.D.**

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**Declaration**

I, Kate Sadler, confirm that the work presented in this thesis is my own and has not been previously submitted for any other degree. Where there has been contribution from anyone other than myself or information has been derived from other sources, I confirm that this has been indicated in the thesis.

# 1 Acknowledgements

Thanks are due to many people. My friends and colleagues at Valid International; particularly Tanya Khara, Anne Walsh, Nicky Dent, Saul Guerrero, Paluku Bahwere, Marko Kerac, Al Hallam and Judy Walters; have all been an unfailing support and I consider this piece of work as much theirs as mine. A very special thanks must go to Valid's Director Steve Collins, both friend and mentor, whose passion and dedication to the plight of the world's malnourished people has provided the inspiration behind this work and to me as a public nutritionist working in this field. My supervisors Andrew Seal and Andrew Tomkins, who have guided me through the minefield of academia, and provided countless comments on drafts and redrafts of this thesis.

I'd like to acknowledge the contribution of all the Ministry of Health and NGO staff that have worked on CTC programmes across the world; without their effort and commitment none of these programmes would ever be possible.

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Last, but by no means least, I'd like to thank my family; Mum, Dad, Em and Tom who have given me the grounding, support and constant encouragement to fulfil my potential – to you a million thanks.

# 2 Abstract

Severe acute malnutrition (SAM) affects approximately 13 million children under-five and is associated with over 1.5 million preventable child deaths each year. Case fatality rates in hospitals treating SAM remain at 20-30%, and coverage of those affected remains low. Training and support to improve centre-based management can reduce case fatality rates. However, an exclusive inpatient approach does not consider the many barriers to accessing treatment that exist for poor people in the developing world. Community-based therapeutic care (CTC) is a new approach for the management of SAM that uses Ready-to-Use Therapeutic Foods (RUTF) and triage to refer cases without complications to outpatient care and those with complications to inpatient treatment.

This thesis aims to test the hypotheses that a CTC strategy can treat children with SAM effectively and can achieve better population treatment coverage than a centre-based approach. Five studies, using primary data, are presented. The first 3 studies evaluate the clinical effectiveness of CTC through examination of individual outcome data from research programmes in Ethiopia and Malawi. The fourth study examines the coverage of a CTC programme for SAM in Malawi and compares this with coverage of a centre-based programme. The final study is a multi-country evaluation of 17 CTC programmes implemented across Africa.

Results from all studies that use the CTC treatment model show that outcomes can meet the international Sphere standard indicators of < 10% mortality and > 50% coverage. Coverage of a CTC programme in Malawi was three times that of a centre-based programme in the same region (73.64% (95% C.I. 66.0%, 81.3%) vs. 24.5% (95% C.I. 17.8%, 31.4%). A number of factors were vital to achieving low mortality and high coverage in these programmes. These included decentralisation of outpatient treatment services and community mobilisation techniques to encourage early presentation, and the use of appropriate triage criteria, to identify children suffering from SAM with no complications that could be treated safely as outpatients. The use of triage did not appear to increase mortality (OR 0.51 95% CI 0.28, 0.94). This thesis suggests that CTC does not increase case fatality rates associated with SAM and could reduce them, and that it could increase the number of children receiving treatment.

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# 3 Glossary of Terms and Acronyms

| | |
|---|---|
| ARV | Antiretroviral (treatment for HIV) |
| CFR | Case Fatality Rate |
| CHW | Community Health Worker |
| CI | Confidence Interval |
| CMAM | Community-based Management of Acute Malnutrition (the term recently adopted by the 'International Community' for CTC-like programmes) |
| CSAS | Centric Systematic Area Sampling |
| CSB | Corn Soy Blend |
| CTC | Community-based Therapeutic Care (encompassing SC, OTP, SFP, RUTF and community mobilisation) |
| EPI | Expanded Programme on Immunisation |
| F75 | Formula 75 therapeutic milk used in phase 1 of inpatient treatment for SAM |
| F100 | Formula 100 therapeutic milk used in phase 2 of inpatient treatment for SAM |
| FGD | Focus Group Discussion |
| GAM | Global Acute Malnutrition (WFH <-2 Z scores or <80% of the reference median and /or bilateral oedema) |
| GMP | Growth Monitoring Programme |
| GMV | Growth Monitoring Volunteer |
| HSA | Health Surveillance Assistant |
| HT (HBT) | Home treatment (home based treatment) (encompassing use of outpatient treatment with RUTF) |
| IDA | Institutional Drug Administration |
| IMCI | Integrated Management of Childhood Illness |
| IQ | Interquartile Range |
| LOS | Length of Stay |

| | |
|---|---|
| MAM | Moderate Acute Malnutrition (WFH >-3 <-2 Z scores and or > 70 <80% of the reference median) |
| MDG | Millennium Development Goal |
| MoH | Ministry of Health |
| MSF | Médecins sans Frontières |
| MUAC | Mid-Upper Arm Circumference |
| NCHS | National Centre for Health Statistics |
| NGO | Non Governmental Organisation |
| NRC | Nutrition Rehabilitation Centre |
| NRU | Nutritional Rehabilitation Unit |
| OTP | Outpatient Therapeutic Programme (treatment at home with weekly follow up)<br>*Direct OTP*: encompassing only outpatient treatment with RUTF<br>*Indirect OTP*: encompassing phase 1 inpatient treatment followed by outpatient treatment with RUTF |
| PEM | Protein energy malnutrition |
| Phase 1 | The first phase of inpatient treatment for children with severe acute malnutrition |
| Phase 2 | The rehabilitation phase of inpatient treatment for children with severe acute malnutrition. |
| PPS | Probability Proportional to Size |
| RCT | Randomised control trial |
| RR | Relative Risk |
| RUTF | Ready to Use Therapeutic Food |
| SAM | Severe Acute Malnutrition (WFH <-3 Z scores or <70% of the reference median and /or bilateral oedema and/or MUAC < 11cm) |
| SAU | Severe acute undernutrition, defined as SAM, term used to differentiate from overnutrition |
| SC | Stabilisation Centre |
| SFP | Supplementary Feeding Programme |

| | |
|---|---|
| TA | Traditional Authority (in Malawi) |
| TFC | Therapeutic Feeding Centre |
| UNICEF | United Nations Children's Fund |
| WFH | Weight for Height |
| WHM | Weight for Height % of the median |
| WHZ | Weight for Height z score |
| WHO | World Health Organisation |

# 4 Glossary of Definitions

| | |
|---|---|
| Acute malnutrition | WFH <-2 Z scores or < 80% of the reference median and/or bilateral oedema |
| Categories of SAM | Severe Acute Malnutrition (WFH <-3 Z scores or <70% of the reference median and /or bilateral oedema and/or MUAC < 11cm)<br>***Marasmus:***<br>WFH <-3 Z scores or <70% of the reference median<br>***Kwashiorkor:***<br>The presence of any bilateral pitting oedema<br>***Marasmic kwashiorkor:***<br>WFH <-3 Z scores or <70% of the reference median and bilateral pitting oedema<br>***MUAC:***<br>MUAC < 11cm (children > 75cm only) |
| GAM | Global Acute Malnutrition (WFH <-2 Z scores or <80% of the reference median and /or bilateral oedema) |
| MAM | Moderate Acute Malnutrition (WFH >-3 <-2 Z scores and or > 70 <80% of the reference median) |

# 5 Hypothesis and Objective

The hypotheses investigated in this thesis are:

1. A community-based therapeutic care (CTC) strategy can treat children with severe acute malnutrition effectively as defined by international quality indicators.
2. In areas with similar demographic and socio economic profile, a CTC strategy can achieve better population treatment coverage than a centre-based approach.

The research objective of this work is to evaluate the adequacy of CTC programmes using standard therapeutic feeding programme quality indicators and to compare coverage with that of an exclusively centre-based approach.

# 6 Introduction and Literature Review

## 6.1 Background

I (the author) graduated as a public health nutritionist in 1997 and first started working in the field of emergency nutrition early in 1998. I was sent to Burundi, by the Irish agency Concern Worldwide, where people were beginning to return to their homes after years of displacement. Here, my learning curve was steep. I experienced the frustration of trying to provide care for large numbers of severely malnourished people in centres that were too small to accommodate them. I heard stories from the people that we were treating of the distances that they'd had to travel to reach us and the home, fields and family that they'd had to leave behind. I saw children start to recover from malnutrition only to be struck down by malaria, which was at epidemic levels in the lowlands where our centres were based, or infections contracted from others in the overcrowded centres. I remember a visiting nutrition advisor asking many of the severely malnourished adults in our centres where they would prefer to be receiving treatment. The majority stated a strong preference to receive take home rations and were subsequently discharged in to a programme that enabled this, despite it meaning that they received only the care and food normally given to those less malnourished.

In Ethiopia, in 2000, I came across Valid International. The Director, Dr Steve Collins, was discussing the potential of a new ready-to-use-therapeutic-food to deliver treatment for severely malnourished people in their homes. With Concern, I was setting up programmes to respond to high levels of severe acute malnutrition against a backdrop of strong governmental opposition to the set up of new centres and a highly dispersed population. A programme that might enable us to treat the malnourished at home seemed to hold the answers to these problems. The resulting programme, implemented during September to December 2000, was the first implemented under the community-based therapeutic care (CTC) research programme. This research programme supported the set up and evaluation of CTC programmes in North and South Sudan, North and South Ethiopia and Central and Southern Malawi between September 2000 and June 2005. I joined Valid International as a research nutritionist in August 2001 and in December of the same year registered on a PhD programme to study the impact of CTC. The work described here forms part of a wider examination of CTC by Valid International in Africa.

## 6.2 Malnutrition

Malnutrition is defined by the standard medical dictionaries as "any disorder resulting from a deficiency or excess of one or more essential nutrients" (1). In the developing world this is generally characterised as under-nutrition or protein energy malnutrition (PEM) whereby there exists varying degrees of deficiencies in essential nutrients. A child's body responds to PEM in two ways that can be measured by anthropometry: a deceleration or cessation of growth, which in the long term results in low height for age or stunting; and body-wasting and/or nutritional oedema, which are short term responses to inadequate nutritional intakes that often occur in combination with infection. Wasting is commonly assessed by weight relative to height (2) and nutritional oedema by the presence of bi-pedal pitting oedema (3). The indicators height for age and weight for height thus discriminate between different biological processes and result in different clinical, bio-chemical and functional characteristics. Under weight or low weight for age is a composite indicator that conflates stunting and wasting and is used as an official indicator of progress towards achieving the first Millennium Development Goal (MDG): eradication of extreme poverty and hunger (4). The most recent UN Standing Committee for Nutrition's 5th report on the World Nutrition Situation estimates that the Latin America and Caribbean region is on track to meet this MDG, Asia is close to meeting it, but in Africa, the gulf between projected rates and the MDG is widening (5). It is estimated that 26.5% of children under 5 years of age in developing countries are stunted or chronically undernourished with the highest levels occurring in sub Saharan Africa, where on average 34.5% of children are affected. In their State of the World's Children Report 2007, UNICEF estimates that wasting affected 10% of children under 5 in developing countries between 1996 and 2005, and whilst it is Asia that has the highest prevalence, Africa is the only region where wasting continues to rise (6).

It is not, of course, the numbers in themselves that give rise to concern but the effects that malnutrition has on host populations. Starting with Pelletier's work in the 90s, many studies now estimate that malnutrition is an underlying factor in over 50% of the 10-11 million children under 5 years who die each year of preventable causes (see Figure 1) (7-12).

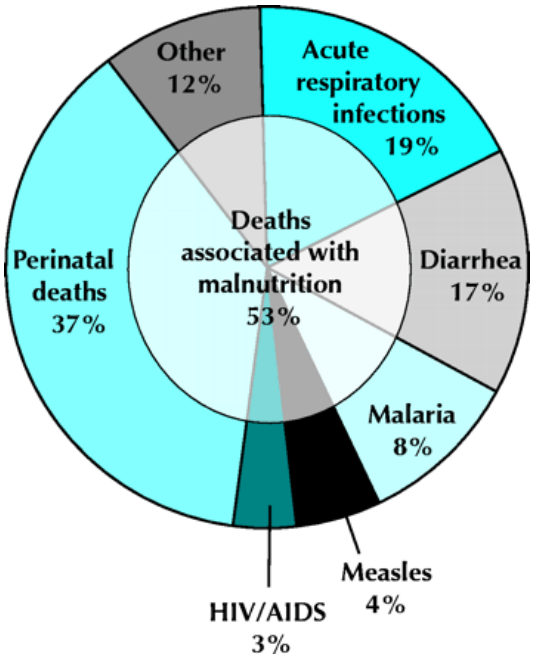



**Figure 1: Causes of death among children under 5 years of age, 2000–2003, worldwide.**

Adapted from Muller *et al*, 2005. (12)

This malnutrition encompasses stunting, wasting, intra-uterine growth retardation (or low birth weight) and deficiencies of essential vitamins and minerals (collectively referred to as micronutrients). It is important to note that the risk of death increases with descending Z scores for all categories of malnutrition: underweight, stunting, or wasting; as well as for infants born with low birth weight. Although this thesis focuses on 'severe acute malnutrition' (those children that are severely wasted) the numbers of young children that are stunted or born low birth weight are of great relevance to the discussion presented here; not only are they present in much greater numbers across the world, but children that suffer from these conditions are much more likely to develop severe wasting than those of normal birth weight and normal height for age (13).

The link between malnutrition and child mortality is brought about by compromised immunity. Malnutrition and infection are intertwined in a synergistic vicious cycle (14). Malnutrition reduces immunity and raises the risk of mortality by increasing the likelihood that the illness will be prolonged or become severe. A more prolonged or severe illness is more likely to cause and/or aggravate malnutrition by causing appetite loss, malabsorption, metabolic changes and behavioural changes which affect feeding

practices and thus deplete body nutrient stores (5). This relationship results in a potentiating effect on child mortality (15). The WHO discussion paper entitled "Turning the tide of malnutrition. Responding to the challenge of the 21st century"(16) summarises the effects of malnutrition worldwide:

- Malnutrition kills, maims, cripples and blinds on a massive scale worldwide.
- Malnutrition affects one in every three people worldwide, afflicting all age groups and populations, especially the poor and vulnerable.
- Malnutrition plays a major role in half of the 10.4 million annual child deaths in the developing world; it continues to be a cause and consequence of disease and disability in the children who survive.
- Malnutrition is not only medical; it is also a social disorder rooted in poverty and discrimination.
- Malnutrition has economic ripple effects that can jeopardize development

### 6.2.1 Causes of malnutrition

The concept of malnutrition as having multivariate causes has been discussed for many decades and a number of models have been developed in an attempt to explain them. Currently, the most widely used of these was first published by UNICEF in 1990, and is entitled "The Causes of Malnutrition" (see Figure 2). This framework was incorporated within the original Sphere Project's minimum standards for humanitarian response as the conceptual basis for all nutrition-related assessment and analysis in humanitarian response (17). It therefore remains the basis of a public nutrition approach to assessment and analysis within nutritionally vulnerable populations (18). It encompasses the concepts of the primary causes of malnutrition; the synergistic relationship between inadequate food intake and infectious disease discussed in 6.2 above, which in turn, result from a combination of three main secondary causes that relate to the nutrition, social and health environment of the child.

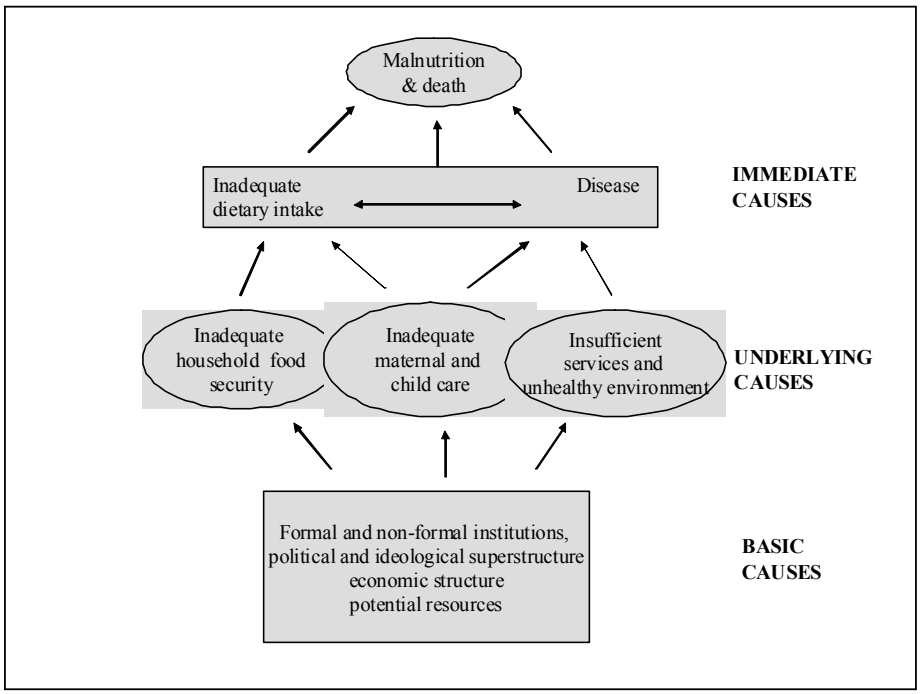



**Figure 2: Causes of severe malnutrition adapted from UNICEF 1990.(19)**

## *6.3 Severe acute malnutrition*

### 6.3.1 A note on history and the nature of the nutritional deficiency

In 1932, Cecily Williams reported her findings about a disease found in very young children in the Gold Coast (20;21). At about the same time Trowell reported similar cases from Uganda (21). By the late 1940s, scientists had agreed that the two syndromes were the same and called it 'Kwashiorkor' (literally meaning 'the disease of the deposed baby when the next one is born'). At this time the attention of nutritional scientists was largely concentrated on the vitamins and it was thought that nutritional oedema might be a manifestation of vitamin B deficiencies. William's work however showed that kwashiorkor developed in children weaned on starchy paps and that milk could cure it. So emerged the 'protein deficiency' theory of severe malnutrition and in 1963 Williams said explicitly:

*'kwashiorkor is a disease primarily due to protein deficiency'* (3)

Quite quickly however, dietary studies began to show that children with both marasmus and kwashiorkor had inadequate intakes of energy as well as protein. This led to the concept of a spectrum of combined deficiency called '*protein energy malnutrition*' (PEM), with protein being most limiting at the kwashiorkor end and energy at the

marasmus end (3;22). In the 70s, work in Jamaica demonstrated that children with kwashiorkor fed a low protein diet improved more rapidly than those fed higher protein diets and that the rate of loss of oedema was entirely independent of the protein content of the diet. With this work the early argument that kwashiorkor was the result of protein deficiency was judged to be fallacious (23) and nutrition scientists began the search for alternative explanations of the different syndromes seen in malnutrition. Work started by Waterlow in Jamaica in the 50s and 60s and later developed by Golden in the 80s suggested that kwashiorkor might be caused by antioxidant depletion as a result of an imbalance between the production of free radicals and their safe disposal (24). Linked to this, Golden classified nutrients into those that cause specific clinical signs (type I) and those that cause growth failure (type II).

**Table 1 Classification of nutrients according to whether the response to a deficiency is a reduced concentration in the tissues (type I) or a reduced growth rate (type II)**

| ***Type I*** | ***Type II*** |
|---|---|
| Selenium | Nitrogen |
| Iodine | Sulphur |
| Iron | Essential amino acids |
| Copper | Potassium |
| Calcium | Sodium |
| Manganese | Magnesium |
| Thiamine | Zinc |
| Riboflavin | Phosphorus |
| Ascorbic acid | Water |
| Retinol | |
| Tocopherol | |
| Calciferol | |
| Folic acid | |
| Cobalamin | |

Adapted from Golden *et al*. Oxford Text Book of Medicine (25)

He hypothesised that wasting is caused by a severe deficiency of type II nutrients that result in tissue catabolism in association with anorexia. Kwashiorkor on the other hand, according to the free radical theory, occurs when patients lacking type I nutrients suffer from tissue damage and free radical production. A recent randomised controlled trial in Malawi that provided antioxidant supplementation to prevent kwashiorkor has cast some doubt however on the free radical hypothesis (26). It found that antioxidant depletion may be a consequence rather than a cause of the condition and suggested, as an alternative hypothesis, that variant isozymes or variations in concentrations of enzymes

in the metabolic pathways might permit the development of kwashiorkor in some children with poor diets. Alternative theories propose that the toxic effects of aflatoxins, directed primarily toward the liver, could account for many of the clinical features of kwashiorkor (27). However, later papers have discredited this theory (28). Thus, the explanation of the pathogenesis of kwashiorkor continues to evade us.

### 6.3.2 Classification and epidemiology

Today, the syndrome protein energy malnutrition described by Williams and others is commonly described as severe acute malnutrition (SAM) in order to differentiate it from more chronic conditions. It is this term that I have adopted throughout this thesis. Severe acute undernutrition (SAU), synonymous with the term SAM, is in the process of being adopted by the United Nations as a more appropriate term to differentiate wasting and oedema from obesity, a form of malnutrition most common in the developed world. The causes of SAM are an extension of those discussed above whereby the environment that has supported the development of malnutrition has been particularly acute or prolonged in nature. There is an especially high risk of the development of SAM when "disaster events", such as acute severe food deprivation and/or infections, occur in an already chronically malnourished population or individual. The WHO manual for the treatment of severe acute malnutrition reflects this understanding of causes being multivariate in nature and refers, in its introductory chapter, to severe malnutrition as being "both a medical and social disorder" and states that "…the medical problems of the child result, in part, from the social problems of the home in which the child lives" (29).

SAM is characterised by severe body wasting (marasmus) and/or nutritional oedema (kwashiorkor). In 1956, Federico Gomez described the clinical profile and the apparent cause of death of a group of malnourished children admitted to the Nutrition Department of the children's hospital in Mexico City (30). Using these data, he described an indicator (weight-for-age) to classify varying degrees of malnutrition linked to prognosis, or risk of death. With time, the so-called ''Gomez classification'' (using a reference population and different cut-off points, i.e., 80%, 70% and 60% of median weight for age) was used widely to classify individual children for clinical referral as suffering from severe malnutrition or marasmus (< 60% of the reference weight for age), moderate malnutrition, or mild malnutrition. Subsequently however, the indicator weight-for-age was shown to be a poor discriminator between children that were severely stunted (with short stature) and those that were severely wasted (with recent weight loss) and several

authors identified low weight-for-height (as a measure of recent weight loss) as the indicator of choice for screening severely malnourished children who are at increased risk of dying (31),(32). Bern reported that 3 indicators; visible severe wasting, a low weight for height score and bipedal oedema, were all associated with a significantly increased mortality risk. These findings, in combination with the threshold effect, first reported by Chen *et al* in 1980 (33), whereby mortality increased with worsening nutritional status when malnutrition was severe, are now used in international protocols for the identification of children who require special therapeutic attention. The most recent guidelines from WHO on the management of severe malnutrition (34;35) uses the following definitions to define the level of severe acute malnutrition that requires intensive treatment, and it is these definitions therefore, that I have adopted for defining SAM in this thesis:

- Severe wasting or Marasmus: weight for height less than -3 SD (or z scores) or less than 70% of the median National Centre for Health Statistics (NCHS) reference values (36).
- Oedematous malnutrition or Kwashiorkor: symmetrical oedema involving at least the feet

Many organisations also diagnose SAM when the Middle Upper Arm Circumference (MUAC) of a child is less than 110mm (37;38). A recent review suggests that MUAC is a precise, accurate, sensitive and specific indicator for the identification of severe acute malnutrition and that it is also simple, cheap and acceptable (39). Recently, an informal scientific committee convened by the WHO concluded that MUAC < 110 mm could be used as an independent criterion for admission to therapeutic feeding programmes for children aged 6-59 months (40).

Approximately 2%, which is equivalent to 13 million children living in developing countries suffer from SAM (41). A recent review paper, on which the author contributed (see 14.1.1: Appendix 1), estimates that SAM contributes to 1.7 million child deaths per year. This estimate used the UNICEF global database and applied the epidemiological approach of Pelletier (42). However other more recent publications have attributed fewer; 449 000 child deaths, to severe wasting (13). When taken together with the fact that these figures do not include children who die of oedematous malnutrition, a form of SAM that in some countries is more common, it is clear that SAM is an important health

problem worldwide. This is made all to clear with a visit to almost any hospital in a developing country where it is likely that severely malnourished children comprise a significant proportion of paediatric deaths (43).

**Table 2: Analysis of the worldwide burden of acute malnutrition**

| Regions† | Under-5 population 2000 (×1000) | Wasting prevalence (%) | | Wasting numbers (×1000) | | Annual mortality numbers | | |
|---|---|---|---|---|---|---|---|---|
| | | Moderate and severe | Severe | ≥2 Z scores below WFH | ≥3 Z scores below WFH | 2–3 Z scores below WFH* | >3 Z scores WFH† | Total |
| Sub-Saharan Africa | 106 394 | 10 | 3 | 10 639 | 3192 | 565 768 | 421 767 | 987 535 |
| Middle East and north Africa | 44 478 | 7 | 2 | 3114 | 890 | 168 942 | 117 547 | 286 489 |
| South Asia | 166 566 | 15 | 2 | 24 985 | 3331 | 1 644 950 | 440 201 | 2 085 151 |
| East Asia and Pacific | 159 454 | 4 | - | 6378 | - | 484 528 | - | 484 528 |
| Latin America and Caribbean | 54 809 | 2 | 0 | 1096 | - | 83 273 | - | 83 273 |
| CEE-CIS and Baltic states | 30 020 | 4 | 1 | 1201 | 300 | 68 416 | 39 668 | 108 084 |
| Industrialised countries | 50 655 | - | - | | | - | - | - |
| Developing countries | 546 471 | 9 | 2 | 49 182 | 10 929 | 2 905 951 | 1 444 214 | 4 350 164 |
| Least developed countries | 110 458 | 10 | 2 | 11 046 | 2209 | 671 290 | 291 918 | 963 209 |
| Total | 707 584 | | | 60 228 | 13 139 | 3 577 241 | 1 736 132 | 5 313 373 |

Population and prevalence of wasting from UNICEF global database on child malnutrition 2001.[24] CEE-CIS=Central and Eastern Europe and Commonwealth of Independent States. WFH=weight-for-height index. *Moderate mortality rate=76/1000/year (average of nine studies range 30–148 for children with <80% weight for height or −2 Z scores).[29] †Severe mortality rate=132/1000/year (average of five studies, range 73–187 children with mid-upper-arm circumference <110 mm).[29]

*Table:* **Worldwide burden of acute malnutrition in children aged less than 5 years**

Adapted from Collins *et al*. Lancet 2006 (42)

Despite these huge numbers and the high risk of mortality and morbidity that goes with them, severe acute malnutrition is seldom mentioned in standard child survival interventions and publications. It is other indicators of malnutrition (low weight for age) that are used in mortality surveillance data (44) and for the identification of malnutrition in Growth Monitoring or Integrated Management of Child Illness (IMCI) interventions across the world (45;46). This means that acute malnutrition in many countries remains partially hidden and untreated. There is now ongoing discussion of the need for international agencies such as WHO to differentiate clearly between chronic malnutrition and acute malnutrition and to prioritise the identification and treatment of SAM within the child survival agenda (42;47).

## *6.4 The treatment of severe acute malnutrition during emergencies*

The vast majority of cases of SAM can be prevented by economic development and public health measures designed to increase dietary quantity and quality alone, with no need for clinical inputs. However, as malnutrition becomes more severe, normal

physiological mechanisms designed to adapt the organism to differences in food intake become more pronounced (48-51). These "reductive adaptations" affect every physiological function in the body mobilising energy and nutrient reserves and decreasing energy and nutrient demands (3). Initially they are beneficial and allow the organism to maintain homeostasis. However, as the severity of nutritional insult increases, adaptations such as those to conserve energy and slow protein turnover become increasingly damaging (52;53). The organism becomes poikilothermic (49); loses its ability to produce an acute phase response (54); becomes progressively more immunosuppressed and loses control of water and electrolyte balance (3). As these changes progress, treatment must become increasingly intensive and costly if it is to succeed and units treating SAM are frequently confronted by extremely ill patients who require intensive medical and nursing care.

### 6.4.1 Modern management protocols

A structured approach to the clinical care of SAM involving ten steps in two phases (stabilisation and rehabilitation) and taking into account the profound physiological changes that exist in severe acute malnutrition is now generally accepted as a robust and effective treatment model (55;56). The current clinical protocols were developed as a result of a long history of clinical research in the 20th century, particularly prompted by the spectre of mass starvation associated with each of the world wars (3). International protocols were first published as a Pan American Health Organisation manual in 1974 and later with minor changes, as the first WHO manual in 1981 (57). This manual included many of the treatment elements recommended today, such as cautious initial re-feeding; cautious, predominantly oral, treatment of dehydration with low sodium high potassium rehydration solutions; enhanced micronutrient content of rehabilitation diets, and highly energy dense diets to enable catch-up growth. By the end of the 1970s, such protocols were producing dramatic reductions in case fatality rates in well run, well resourced units. For example, the children's nutrition unit in Dhaka Bangladesh, reduced mortality rates from 20% in 1976 to between 4-7% in 1979 (58). Even in emergency situations such as Ethiopia and Biafra, the implementation of similar dietary protocols without the use of systematic antibiotics for all admissions, achieved mortality rates of < 15% (59-61). In 1999, the WHO manual was revised to take into account further advances in the understanding of the pathophysiology of SAM (29). Changes were made to reflect new ideas over the role of protein (62-64), the importance of free radicals and

antioxidants in the pathogenesis of SAM (65) and the development of the concept of type 1 and type 2 nutrients (25). A growing realisation of the importance of immunosuppression (14;66) also resulted in the addition of systematic antibiotics for all cases of SAM. This basic protocol with minor adaptations forms the core of all major guidelines in use today (34;35;37;67;68) and, with the WHO guidelines for the management of severe malnutrition in first referral facilities (45), forms part of the WHO/UNICEF initiative of Integrated Management of Childhood Illness (IMCI) (46).

The essential elements of these guidelines are:

- Prevention or treatment of hypoglycaemia, hypothermia, dehydration and correction of electrolyte imbalances right at the start of treatment. Rehydrate more slowly than usual using a rehydration fluid with a lower sodium and higher potassium content. Use low osmolarity feeds during the initial stages of treatment to reduce incidence of refeeding diarrhoea.
- Treatment of infection by giving all patients broad-spectrum antibiotics on admission, paying particular attention to gram negative cover. Treat any patient suffering from complications with parenteral antibiotics.
- Correction of micronutrient imbalances. Withhold iron supplementation until the recovery phase of treatment.
- Cautious initial re-feeding, carefully controlling intake to provide just enough energy and protein to meet basic needs (80-100 kcal $kg^{-1}day^{-1}$ and 1-1.5g protein $kg^{-1}day^{-1}$) in the first phase of treatment.
- Provision of formula diets enhanced with a range of micronutrients to correct micronutrient imbalance. This method uses a dietary approach to supplementation, wherein the ratio of all the different nutrients, including energy, is fixed, as opposed to a medical approach, where supplements are provided as a dose per kg body weight.
- Transfer to a rehabilitation phase on the stabilisation of vital signs such as appetite. This indicates that infections are coming under control, the liver is able to metabolize the diet, and other metabolic abnormalities are improving.
- Provision of 150-220 kcal $kg^{-1}day^{-1}$ and 4-5 g $kg^{-1}day^{-1}$ protein in highly energy dense feeds provided 8 times a day to allow for the metabolic costs of catch-up growth during the rehabilitation phase of treatment.
- Provision of psycho-social stimulation during rehabilitation.

- Provision of education to carers and a structured follow-up after discharge.

### 6.4.2 Delivery of treatment

During nutritional emergencies when organisations are faced with large numbers of severely malnourished individuals it is the inpatient therapeutic feeding centre (TFC) or the paediatric ward that usually provides most of the treatment required (67;69;70). These centres are often set up and/or supported by external international agencies; provide high quality individual patient care, and appropriate diets and medical treatments based on the WHO inpatient management protocols described above and elsewhere (37;38;71). The widely accepted standards that many organisations use to measure the quality of care delivered have been developed by the Sphere Project's Humanitarian Charter and Minimum Standards in Disaster Response and now, as well as purely clinical indicators, include others that are more community and socio-economic orientated (72) (Figure 3).

- Proportion of exits from a therapeutic feeding programme who have died is < 10%
- Proportion of exits from a therapeutic feeding programme who have recovered is > 75%
- Proportion of exits from a therapeutic feeding programme who have defaulted is < 15%
- Minimum mean rate of weight gain (g $kg^{-1}$ $person^{-1}$ $day^{-1}$) is >8g
- Nutritional and medical care is provided to people who are severely malnourished according to clinically proven therapeutic care protocols.
- Discharge criteria include non-anthropometric indices such as: good appetite; no diarrhoea, fever, parasitic infestation or other untreated illness; and no micronutrient deficiencies.
- Nutrition worker to patient ratio is at least 1:10
- All carers of severely malnourished individuals are able to feed and care for them.

In 2003 the following indicators were added to the second edition of the Sphere Standards:

- Coverage is > 50% in rural areas and >70% in urban areas. In a camp situation coverage is > 90%.
- Breastfeeding and psycho social support are given equal attention as clinical care

**Figure 3: Sphere indicators for Therapeutic Feeding Programmes**

### 6.4.3 Therapeutic Foods

As our understanding of severe acute malnutrition and its treatment has advanced so to have the foods with which we provide treatment become more sophisticated. In TFCs severely malnourished children are fed a milk based diet that has been developed to meet their specific requirements for protein, energy and micronutrients (73). Formula 75 (F 75), so called because it contains 75 kcal per 100 ml of product, is used during the first phase of treatment. It is low in protein and is fed to the patient at maintenance energy levels in order that the intestine, liver and other organs are not overloaded. Formula 100 (F 100), so called because it contains 100 kcal per 100 ml of product, is used during the second and third phases of treatment. It is a more nutrient dense product, containing iron and more protein than F 75 and is provided in quantities that promote rapid weight gain.

Blended foods are often used as a dietary supplement for those in the last phase of treatment for severe acute malnutrition or for those receiving treatment for malnutrition at home (71). These foods most commonly contain a mixture of corn and soy flours and micronutrients. They are given, sometimes with oil and sugar, as a dry take-home ration and are used to make porridge or bread to supplement household food intake. The same 'corn soy blend' (CSB) flour is now produced to WFP standards by many countries under different names including Lukini phala in Malawi and Famix in Ethiopia.

#### 6.4.3.1 Ready-to-Use Therapeutic Food

Because powdered milk, such as F100, is an excellent medium for bacteria, it has to be prepared before each meal and used by experienced staff. F100 resembles infant formula and its distribution by nutrition health workers might undermine efforts to discourage formula feeding and promote breastfeeding. Non milk-based diets could be used to avoid these problems, but these diets have been described as less effective in the rehabilitation of children suffering from severe acute malnutrition (74). Until recently this has limited treatment of SAM to inpatient health facilities which is seen to hold problems of acceptability and coverage as described above. Therefore, during the past few years, researchers have developed a new Ready-to-Use Therapeutic Food (RUTF), that is made from peanuts, dried milk, oil, sugar and micronutrients. It is designed to be nutritionally equivalent to, but more energy dense than, F100 and can be used easily and stored safely

for several months in a simple pot (75;76). These foods have been vital to the feasibility and success of the studies described in this thesis.

RUTF is a paste that patients can eat directly from the packet. It has an energy density that is > 5 times that of F100 (543 kcal/100 g), but a similar ratio of nutrients to energy (see Table 3). It is produced by replacing part of the dried skim milk used in the F100 formula with peanut butter. Studies have shown that it is at least as well accepted by children as is F100; that it is effective for rehabilitating severely malnourished children, and that it promotes faster weight gain than F100. In a study reported by Diop, this was thought to be because children consumed higher daily amounts of energy during the same number of meals on a diet of RUTF, than on a diet of F100 (77).

**Table 3: Comparison of the nutritional composition of F100 and RUTF**

Comparison of the nutritional composition of the 2 diets[1]

| | Per 100 g | | Per MJ | |
|---|---|---|---|---|
| | F100 | RTUF | F100 | RTUF |
| Macronutrients | | | | |
| Energy (kJ) | 414 | 2281 | — | — |
| Protein (g) | 2.5 | 13.6 | 6.0 | 6.0 |
| Lipid (g) | 5 | 35.7 | 12.2 | 15.8 |
| Minerals | | | | |
| Potassium (mg) | 212 | 1111 | 513.6 | 487.3 |
| Calcium (mg) | 58 | 320 | 140.9 | 140.9 |
| Phosphorus (mg) | 58 | 349 | 140.9 | 152.9 |
| Magnesium (mg) | 15 | 92 | 38.2 | 40.6 |
| Zinc (mg) | 2.1 | 14 | 5.0 | 6.2 |
| Copper (mg) | 0.3 | 1.8 | 0.7 | 0.7 |
| Iodine (μg) | 14 | 110 | 33.4 | 47.8 |
| Selenium (μg) | 4 | 30 | 9.6 | 14.3 |
| Iron (mg) | 0.4 | 11.5 | 1.0 | 5.0 |
| Vitamins | | | | |
| Thiamine (mg) | 0.1 | 0.6 | 0.2 | 0.2 |
| Riboflavin (mg) | 0.3 | 1.8 | 0.7 | 0.7 |
| Vitamin B-6 (mg) | 0.1 | 0.6 | 0.2 | 0.2 |
| Vitamin B-12 (μg) | 0.3 | 1.8 | 0.7 | 0.7 |
| Vitamin C (mg) | 9.7 | 53 | 23.4 | 23.2 |
| Folic acid (μg) | 39 | 210 | 93.2 | 93.2 |
| Niacin (mg) | 1 | 5.3 | 2.4 | 2.4 |
| Biotin (μg) | 12 | 65 | 28.7 | 28.7 |
| Pantothenic acid (mg) | 0.6 | 3.1 | 1.4 | 1.4 |
| Retinol (μg) | 154 | 910 | 372.7 | 398.9 |
| Vitamin D (μg) | 2.9 | 16 | 6.9 | 6.9 |
| Vitamin K (μg) | 2.9 | 21 | 6.9 | 9.3 |
| Vitamin E (mg) | 3.9 | 20 | 9.3 | 8.8 |

[1] F100, liquid, milk-based diet; RTUF, solid ready-to-use food.

Reproduced from Diop *et al*, 2003 (77)

Because RUTF does not require any mixing or cooking before use, and as it contains almost no water, it is highly resistant to bacterial contamination, and therefore is safer than powdered milk to send home with mothers.

However, as RUTF was developed as an equivalent to F100, i.e. with amounts of both macro and micro nutrients suitable for children entering phase II of treatment, its use for children that had not been through phase I feeds with F75, for children with nutritional oedema and for particularly small children (> 6months < 4kg) was of concern to many (76;78).

## 6.5 The impact of programmes to treat severe acute malnutrition

Impact measurement of programmes to treat SAM has historically focussed on clinical outcomes such as cure and case fatality rates. This emphasis was underlined by the first edition of The Sphere Project's Humanitarian Charter and Minimum Standards in Disaster Response that gave a number of indicators for monitoring programme quality that were exclusively centre orientated (17). This focus on improving effectiveness of interventions and case management at an individual level, rather than a population level, has not been unusual in child survival interventions and was highlighted in 2003 by the Bellagio Child Survival group who in their second paper in the series discussed the poor global coverage of child survival interventions and suggested that " the child survival effort had lost its focus" (79). There is now renewed focus on the wider impact of interventions and, specifically, the effectiveness of interventions to reduce morbidity and mortality at a population level.

For the purpose of this thesis I will consider impact to include both individual and population level indicators, these include recovery and case fatality at the individual level and coverage of interventions at the population level. "Adequacy" of these outcomes will be measured primarily against the Sphere Standards.

### 6.5.1 Recovery and case fatality rates

Although there is good evidence that the implementation of modern management protocols for the treatment of SAM combined with attention to the quality of care can substantially decrease CFRs (58;78;80-84) there are many treatment units that continue to struggle to keep mortality low and recovery high. In humanitarian emergencies across the world performance of TFCs is varied. Many international agencies often report a case fatality rate that meets Sphere's indicator for mortality. Rossi *et al* recently evaluated the impact and appropriateness of programmes for the management and treatment of severe malnutrition in Burundi. They reported average mortality and recovery rates across 20 TFCs in 2004 that exceeded Sphere standards (85). Unfortunately the performance of the majority of humanitarian nutrition programmes is rarely published, making a thorough review difficult here. Grellety in her doctoral thesis in 2000, details the largest study of TFC outcomes to date. This contains data from 11,287 patients (8,484 children) admitted to 20 TFCs run by a specialised TFC agency between 1993 and 1998. These TFCs achieved an average mortality of 12% and an average recovery rate of 65% (78), which, although better than that seen before implementation of standardised protocols, remain outside the Sphere standard of < 10% for mortality and > 75% for recovery. Other TFC programmes implemented in nutritional crisis such as that reported by Pecoul *et al* in Niger in 1988 report similar outcomes, a recovery rate of 46.2% and mortality of 14.4%, to Grellety's (86).

High default rates in emergency therapeutic feeding programmes are often a cause of low recovery rates, and reduced recovery considerably in the Grellety (default rate of 18%) and Pecoul (default rate of 18%) studies reported above. The problem of default is an important one that reduces recovery overall and may, unbeknown to programme managers, be increasing mortality.

Outside of nutritional emergencies, modern management protocols have not resulted in a widespread decrease in CFRs in most hospitals in the developing world, many of which continue to see mortality rates of above 20% (87-90). The persistence of high CFRs is often attributed to inappropriate case management as a result of poor knowledge and inadequate training (56;91-93). Although there is good evidence that adequate training of health staff in the management of SAM is essential if the implementation of the WHO guidelines is to be effective, the evidence base supporting the view that the wider

implementation of the WHO guidelines alone is the key to reducing CFRs, is debated (42;47;56;89;90;94;95). There have been no published controlled trials looking at the impact of the use of the WHO protocol in operational settings. Instead, the evidence for the positive impacts of the WHO protocols comes from observational studies performed in selected hospitals or well resourced NGO humanitarian operations and there has been some discussion over the extent to which most of these studies are representative of the majority of first line rural hospitals or clinics in developing countries (42;88).

Sustained reductions in CFRs to less than 10% have been obtained in large, specialised, well financed institutions in Dhaka, Bangladesh (58;96). One was the ICCDR-B, an internationally acclaimed research institution, the other, the Children's Nutrition Unit in central Dhaka, Bangladesh, a unit of 60 inpatient beds and 40 day care places, staffed by seven doctors and twelve nurses. Other positive reports showing the impact of implementing the WHO guidelines come from South Africa and Brazil (81;97;98), countries where health staff to population ratios are lower than those in Bangladesh but considerably higher than those reported in the twenty African countries most affected by SAM (99). These reports underline the importance of appropriate protocols in effective management, but indicate that even in these relatively affluent countries, the availability of resources is also a vital determinant of CFRs. The use of similar protocols and the addition of a complex mineral vitamin mix in Nutrition Rehabilitation Units (NRUs) in Malawi have had little impact on CFRs in nutritional rehabilitation units, only reducing them from 25 to 20% (100). This is likely to be as a result of a combination of factors including a high prevalence of HIV among the severely malnourished, but also as a result of these resource constraints (see Study 2, section 9.3.6).

The recent WHO informal consultation reviewing current literature on severe malnutrition quotes two examples that purport to show the WHO guidelines are feasible and sustainable even in small district hospitals with limited resources (56). The first, reports CFRs falling from 46% to 21% and 25% to 18% at two hospitals in South Africa following the introduction of WHO guidelines. In this study, implementation of the guidelines required a number of changes in nursing, medical and administrative systems and additional day to day support. Despite this and the presence of researchers, mortality rates never fell below 18% and in one of the two hospitals returned to 38% after the intervention period (92). The other study cited by the consultation assessed the impact of

the introduction of the guidelines in a district general hospital in South Africa and a mission hospital in Ghana. These were the only two hospitals out of sixteen that the researchers considered suitable for conducting such a study. The introduction of the protocol was combined with two weeks of specialist paediatric input and the no-cost provision of a commercial vitamin and mineral complex. The selection criteria for the hospitals included agreement to provide administrative support for food supply, presence of essential drugs, provision of free treatment with no cost recovery schemes in place, the absence of bed space limitations and the presence of staff interested and committed to improving the management of severe acute malnutrition. These criteria ruled out fourteen of the sixteen hospitals approached for the study and would rule out the majority of rural hospitals and clinics in Africa. Staffing levels in both the hospitals were high, with approximately one nurse to ten paediatric beds in each. Despite this, the impact on mortality rates was equivocal. In one, the CFR appeared to drop from 35 to 18%; however, concurrent changes to entry criteria resulted in a 400% increase in admissions and confounded interpretation. In the other hospital, CFRs only dropped from 21 to 18% (84).

Lastly it is important to note that the severity of illness at presentation for treatment is a major determinant of CFRs (25;90). A study in Malawi compared CFRs in 1,625 cases of kwashiorkor treated at central hospitals, district hospitals or rural clinics. Mortality rates were 30.5%, 25.8% and 7.5% respectively, despite the fact that quality of care was far superior in the central hospital and worst in the rural clinic (89). In many other hospitals in Africa, the high prevalence of HIV and tuberculosis, and socio-economic changes resulting in an increasing severity of illness at presentation, are given as the main determinants of persistently high CFRs (101-103).

#### 6.5.1.1 Impact of HIV and tuberculosis on mortality

An estimated 38.6 million (33.4 million–46.0 million) people worldwide were living with HIV at the end of 2005. An estimated 4.1 million (3.4 million–6.2 million) became newly infected with HIV and an estimated 2.8 million (2.4 million–3.3 million) lost their lives to AIDS (104). Africa remains the global epicenter of this pandemic, where, in countries like Malawi, HIV/AIDS defining illness can account for as many as three-quarters of adult medical hospital admissions (105) and among malnourished children, the HIV prevalence can be as high as 40-45% (106). HIV/AIDS (or wasting syndrome as

it is colloquially know) and acute malnutrition are closely linked in the developing world, with each increasing an individual's vulnerabilities to the other. It is now widely recognised that making the link between HIV and nutrition is critical to achieving progress in prevention and treatment programmes (107). It follows that, by increasing both the numbers of children admitted to inpatient units with severe acute malnutrition and by increasing the complexity of the condition at presentation, HIV is making SAM much harder to treat successfully (101). This is important to consider when examining the impact of SAM treatment programmes. Without doubt, HIV is making it harder for many units to achieve international standards even where treatment is provided according to WHO protocols (103). In addition, widely used models to standardize mortality in therapeutic feeding programmes such as the Prudhon Index (see 8.4.7.4) have not considered HIV status as a prognostic indicator. Where HIV is highly prevalent, this is likely to considerably increase the estimation of 'excess' mortality using such models (108).

### 6.5.2 Coverage

Coverage of basic child survival interventions has long been a key indicator for measuring the health and nutrition status of the world's children. The State of the World's Children Reports produced annually by UNICEF include coverage indicators for exclusive breast feeding, vitamin A supplementation, use of iodized salt, immunization and use of treated bed nets (6). It is a vital determinant of the impact of any health or nutrition intervention and is recently attracting considerable attention as such (79;109;110). Figure 4 demonstrates the importance of coverage as an indicator of impact or met need. High coverage but low cure-rate programs will meet a higher proportion of need in a population than those with low coverage but high cure rate (111). In order to maximise impact, programmes must have both high coverage and high cure rates.

Despite this, the measurement of coverage of programmes that treat severe malnutrition has, historically, not been standard practice (see 6.5 above) and the importance of coverage has only recently been acknowledged for emergency selective feeding interventions with the addition of coverage indicators into the second edition of Sphere (72). One contributor to the paucity of data on therapeutic feeding programme coverage has been the absence of a feasible and accurate means of measurement (112).

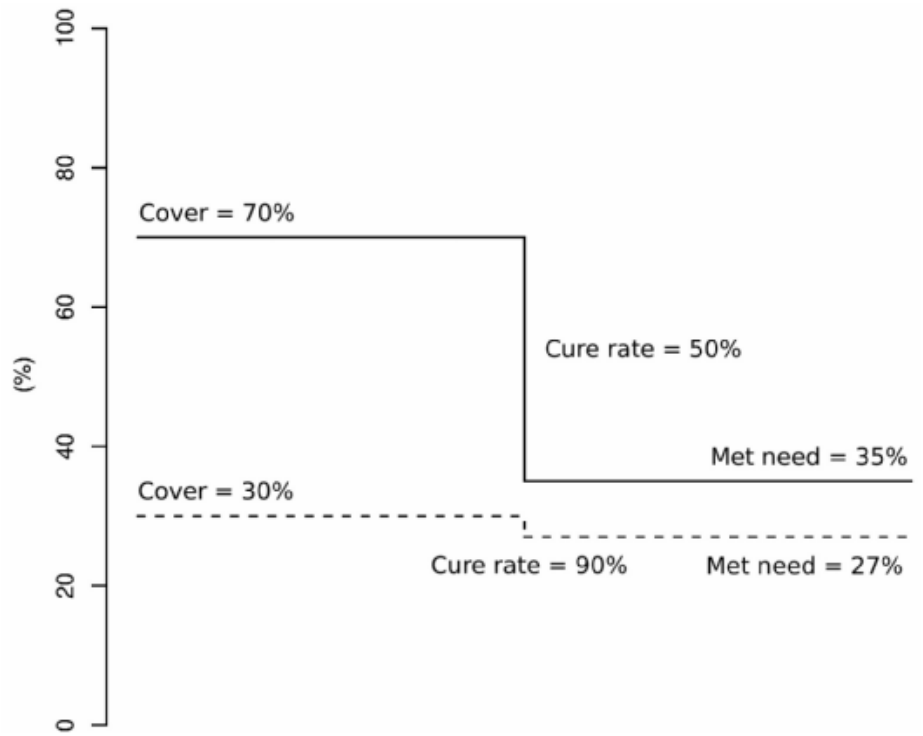



**Figure 4: The relationship between coverage, cure rate and met need (impact) in the treatment of SAM**

Shengelia *et al* 2005 presents a useful conceptual framework that refers to 'met need', as presented above, as 'effective coverage' and argues that effective coverage is only achieved with a combination of quality (cure rate as we describe it above), utilisation and actual need (as opposed to perceived need). Utilisation results from a number of factors that decide access and demand for a service; these include perceived need, distance, price, opportunity costs of seeking care, cultural acceptability, perceived quality and economic status (113).

Little coverage data exists from the past 20 years of inpatient programmes that treat SAM, and there have been few specific studies of coverage. In one of the few published studies looking at TFC coverage in humanitarian crises, Van Damme estimated coverage rates for TFC programmes treating severely malnourished refugees in Guinea to be less than 4% (114). Jha, during a health intervention cost-effectiveness evaluation also in Guinea estimated the coverage of treatment services for severe malnutrition at 5% (115). Other data suggest that such low levels of TFC coverage are not unusual. Table 4 presents coverage data from the national Nutritional Rehabilitation Unit (NRU)

programme in Malawi. These data, obtained ten months after the start of the emergency intervention in 2002, show low coverage rates for all the NRUs. The average NRU coverage of cases of severe acute malnutrition was approximately 18.7% (13.8% rural and 38.6% urban) with none of the NRUs meeting current Sphere standards for coverage.

**Table 4: Reported coverage rates in the national NRU programme in Malawi, April 2003, ten months after the start of emergency interventions.**

| ***District*** | ***Target nos. (SAM), nutritional surveys, April 2003*** | ***No. in NRUs (April 2003)*** | ***% Coverage*** |
|---|---|---|---|
| Lilongwe Rural | 1,459 | 178 | 12.2% |
| Ntchisi | 270 | 23 | 8.5% |
| Kasungu | 516 | 107 | 20.7% |
| Rumphi | 46 | 8 | 17.4% |
| *Rural totals and average coverage* | *2,291* | *316* | *13.8%* |
| Lilongwe Urban | 315 | 62 | 19.7% |
| Blantyre | 270 | 164 | 60.7% |
| *Urban total and average coverage* | *585* | *226* | *38.6%* |
| **Total and average coverage** | **2,561** | **480** | **18.7%** |

## *6.6 The need for a change in the way we address SAM*

There is no doubt that the intensive care provided by inpatient units for SAM is essential for the initial phase of treatment of patients with complicated malnutrition associated with anorexia, septicaemia, hypothermia, hypoglycaemia, or severe dehydration (69), and, as reviewed in section 6.4.1 above, clinical protocols for the management of these patients are now capable of reducing case fatality rates to below 5%. However, most of these units are in the poorest parts of the poorest countries in the world, have severe resource and staff constraints and are usually centralised, with long distances between them and many of the malnourished people they need to treat. In addition, the carers of the malnourished children almost always come from the poorest families and have great demands on their time in order to maintain their fragile existence. In order to achieve good impact at a population level, clinical management protocols must take these geographic and socioeconomic realities into account. This involves balancing the potentially conflicting demands and ethics of clinical medicine and public health. The

clinician's duty to provide the best possible care must be reconciled with the public health imperative to provide the greatest possible benefit to the largest number of people. Bryce *et al* of the Bellagio Child Survival Group brought new focus to this issue in 2003 stating that the distinction between interventions *(to improve case management)* and delivery strategies *(to reach all that need treatment)* is essential for reducing child mortality (110).

Concerns over the limited capacity to treat and limited impact of the hospital treatment of SAM are not new. Since the 1960s, the high cost and poor success rates of hospital inpatient treatment has prompted continued debate over whether hospitals are the best place to treat such patients (116-119). In 1971 Cook asked the question "Is hospital the place for the treatment of malnourished children?" (116). His review of published literature highlighted a number of problems with hospital treatment that are very relevant to TFC care today.

Firstly, he identified a problem of coverage, where the number of children who qualified for admission far exceeded the capacity of the hospital. During nutritional emergencies humanitarian agencies are often faced with numbers of severely malnourished that run in to the thousands. To provide timely treatment to high numbers of people according to international Sphere standards for TFC care most often proves impossible. To do so would require high numbers of centres that quickly become operational and that have a huge requirement for skilled local and expatriate staff. In many countries this mismatch of high numbers requiring care to low levels of resources continues well after the emergency has ended (92;93).

Secondly, Cook discussed problems associated with separating mother from child. Although in the majority of centre-based programmes today the mother remains with the child for the duration of treatment this is likely to bring about problems of its own. The centralised nature of many TFC programmes means that the primary caretaker must leave home for a considerable length of time. Nobody has studied the effects of this factor, but given a mother's importance to household food security and food supply and the well known clustering effect of malnutrition within families (120), it is likely that the negative effects are substantial and that the opportunity costs involved of complying with

treatment might delay presentation. The absence of a mother could be particularly damaging for younger siblings, many of whom might also be moderately malnourished.

Thirdly, Cook and others have highlighted the danger of cross infection (121). Congregation of severely malnourished patients inside centres promotes centre-acquired infection, a major problem in many TFCs today. Also, as De Waal noted in his book "Famine that kills" the congregation of communities around feeding centres promotes breakdowns in public health, an important cause of mortality and morbidity during famine (122).

To the above issues we can now add others. Collins has discussed the undermining of local health infrastructures and the process of disempowerment of communities that takes place during emergencies (69). Often, TFCs are managed by international agencies in isolation from any local health capacity that does exist, with the only overlap between the two taking place in the form of skilled staff moving from local structures to better paid jobs in humanitarian aid. TFC programmes tend to ignore the socio-economic factors associated with severe malnutrition. This means that at the least they miss opportunities to build self-reliance for the treatment and prevention of malnutrition in the future, and at most can create problems for beneficiary families that impact on family nutritional status.

Finally there is the issue of cost effectiveness. TFCs with their large parallel structures, long intensive treatment protocol and very high staff:patient ratio are a costly intervention per child treated. Add to this the problem of chronic cyclical emergencies, where the need for a treatment facility for severe malnutrition becomes long-term, and difficult questions arise for aid agencies and international donors regarding the reality of prolonged costly interventions. Figure 5 attempts to summarise the main concerns with centre-based TFC care for SAM.

- TFCs, when set up in parallel to local heath services, are heavily dependent on external support and are apt to disrupt and damage local health infrastructures.
- They require substantial infrastructure and skilled and experienced staff that are dedicated to a relatively small proportion of the population as a whole. This makes them an expensive intervention, relative to others forms of nutritional support, per patient treated.
- TFCs are usually centralised and, in rural environments, people must often travel long distances to reach them. They must then stay in inpatient care for an average of 30 days. This imposes high opportunity costs on patients and their carers, undermining family life, food production and the care of other children.
- The internal environment of TFCs must be tightly controlled, and treatment is carried out via protocols over which patients have little influence. This can be disempowering for carers
- After admission to a TFC, large numbers of highly susceptible patients are put in close proximity to one another, increasing the risks of cross-infection.
- Given the risks and opportunity costs associated with them, TFCs can be unpopular with the target population. This encourages people to present for treatment late, often once complications have occurred, and to leave before treatment is successfully completed.

**Figure 5: The potential problems of TFC care.**

Adapted from Community-based therapeutic care a new paradigm for selective feeding in nutritional crises (123).

## *6.7 Treatment at home and in the community*

Back in the 1970s, the problems discussed above prompted moves to de-medicalise the treatment of SAM. This involved moving the locus of treatment away from hospitals towards the community, either into simpler Nutrition Rehabilitation Centres (NRC), existing Primary Health Care Clinics or into the homes of those affected. These programmes either treated early discharges from hospitals or admitted children directly from the community, aiming to increase the likelihood of successful long-term rehabilitation by providing care that was more appropriate and understandable to the

community i.e. treating malnutrition with foods that were recognisable to local people (116). In the 70s and 80s, NRCs were usually simple treatment centres staffed by an auxiliary nurse who provided only basic oral medication, ingredients for nutritious meals and nutrition and health and hygiene education. Children ate on site and the responsibility for care remained with the mothers who prepared the food using local ingredients, according to special recipes (124). Many of these programmes provided support and education to mothers to facilitate them to treat their children at home.

The results from these early outpatient treatment programmes were variable. Some NRCs achieved low mortality and positive impacts on growth while children were attending the centres, but usually these benefits were not maintained after discharge (125;126). In other programmes, mortality and relapse rates both during treatment and post discharge have been high, and rates of weight gain very low (127-129). Daily attendance at these centres by caregivers was often unpopular and poor effectiveness was a result of this spasmodic attendance as well as low nutrient dense meals. In addition there was often limited opportunity for weight gain as many children were not wasted at admission; being admitted with low weight for age rather than low weight for height or MUAC (130).

Ashworth made two thorough reviews of published programmes that implemented community-based rehabilitation (i.e. outside the inpatient hospital unit) of severely malnourished children within *routine health systems* in *non emergency settings* (130;131). She used two indicators of effectiveness: a CFR of < 5% and an average weight gain of >5g/kg/day. In the first review, six (22%) out of the twenty seven studies reviewed achieved effectiveness by these standards; in the second the success rate had gone up to 33% (eleven studies out of thirty three) and of the 13 published within the last 10 years 62% (8 studies) were effective. The most common shortcoming was an inadequate appreciation of the specific nutritional needs of malnourished children, in particular the need to provide regular, energy and nutrient dense food during rehabilitation to allow for catch-up growth and recovery. Few of the day care and residential units provided appropriate nutritional support and several attempted to rehabilitate severely malnourished children with advice and education alone. Even those that did provide some nutritional support usually reported few details about foods or quantities. Other studies achieved low weight gain and low recovery rates despite

providing high energy supplements. In some of the programmes, the use of Gomez weight for age entry criteria probably contributed to low weight gains, as weight for age overestimates the severity of acute malnutrition in stunted children, thereby decreasing the potential for rapid catch-up growth. Many of the day care and residential studies were unpopular with caregivers because of the high opportunity costs of attending treatment.

Of the eleven programmes that did meet Ashworth's effectiveness criteria in her second review, two were delivered through well resourced (relative to many centres in Africa) day care centres in Bangladesh and South Africa, two through health clinics and seven were home-based. Of the home-based programmes two provided no food at all, but relied on education and support to mothers for the nutritional care of their children. These studies took place in Bangladesh where it was feasible for carers to access the kind of foods required for the rehabilitation of their severely malnourished child. This would not have been feasible in many of the Africa-based studies. The remaining five home-based programmes provided RUTF (see section 6.7.1 below). Rates of weight gain in these programmes varied considerably (12 g/kg/day in Sierra Leone vs. 3-5 in some of the Malawi studies). Ashworth attributes this variable weight gain to 'careful training of caregivers and an effective stabilisation phase' in Sierra Leone, but there is no mention of the level of wasting at baseline; the Sierra Leone children were possibly more wasted at admission (WFH < 70% of the median no oedema) than the Malawi children (mean WFH z scores -1.9 to -3.4 considerable oedema).

The successful programmes discussed in these reviews tended to share several features:

- All of them aimed to provide, either through the promotion of appropriate local foods or through the provision of RUTF, a high energy, nutrient dense food that allowed for good catch up growth and minimal relapse (See Table 3 for composition of RUTF).
- Those that provided inpatient care did so for less than 4 weeks.
- All programmes considered at least some of the wider social, economic, and health issues that face poor families.
- Staff were motivated and carefully trained.
- All programmes received some kind of external support, be it staff and technical assistance in Bangladesh and South Africa or RUTF in Malawi.

### 6.7.1 Recent introduction of RUTF into outpatient care for SAM.

The recent development of Ready to Use Therapeutic Food (RUTF) (see section 6.4.3) has greatly eased the difficulties associated with providing a suitable high energy, nutrient dense food that is safe to use in outpatient programmes. In a clinical trial in severely malnourished children undertaken in a therapeutic feeding centre in Senegal, energy intakes (193 vs. 137 kcal/kg/day $P < 0.001$), rates of weight gain (15.6 vs. 10.1 g/kg/day $P < 0.001$) and time to recovery (13.4 vs. 17.3 days $P < 0.001$) were all significantly better in those receiving RUTF from phase 2 than in those receiving F100 (77).

#### 6.7.1.1 Evaluation of the efficacy of RUTF for rehabilitating children with SAM from phase two of treatment

Of the seven successful home-based studies that did meet Ashworth's effectiveness criteria above, five of them provided RUTF as the nutritional treatment. These included trials in Malawi which have successfully used RUTF as a take-home ration for children in the recovery phase of the treatment of SAM. In one, an RUTF take home ration of 175 Kcal/kg/day successfully rehabilitated HIV negative severely malnourished children, after early discharge from an NRU providing phase one care according to WHO protocols. Rates of weight gain (5.2 vs. 3.1 g/kg/day) and the proportion of children recovering to 100% weight for height (95% v 78%, RR 1.2, 95% CI 1.1 to 1.3) were significantly better in the RUTF groups when compared to groups receiving a larger amount of energy from corn/soya blend flour supplied by the World Food Programme (132). In the same trial, 56% of the HIV positive children treated with RUTF also achieved 100% weight for height (133). In another trial implemented in rural NRUs, 175 Kcal/kg/day of locally made RUTF given during the rehabilitation phase of treatment, produced significantly better rates of weight gain (3.5 vs. 2.0 g/kg/day), recovery (79% vs. 46% RR 2.8 95% CI 2.5 to 3.1) and mortality (3.0 vs. 5.4% OR 0.5 95% CI: 0.3, 0.7) than the standard inpatient treatment using F100, followed by outpatient supplementation with a large one off ration (50kg) of corn/soya blend flour (134). A study in Sierra Leone also used RUTF to successfully rehabilitate children with SAM in an outpatient setting (135).

#### 6.7.1.2 Evaluation of the efficacy of RUTF for rehabilitating children with SAM from phase one of treatment

In addition, studies not included in the Ashworth review, in Niger (136) and again in Malawi (100) have both used RUTF successfully for the rehabilitation of severely malnourished children from phase one (i.e. no inpatient care with therapeutic milks provided) of treatment in an outpatient setting, although the Malawi study did not produce weight gains of > 5g/kg/day. However, it is important to note for this thesis that both of these studies have made a number of exclusions that make it difficult to evaluate the potential effect of outpatient care and RUTF at a programmatic level, particularly as a treatment from phase one of care. These include: recruiting for the study only after all the sickest children (Malawi) had been through phase 1 in inpatient treatment that used therapeutic milks; and in Niger excluding oedematous children and children below 1 year of age from direct outpatient treatment (i.e. using RUTF from phase one of treatment).

It is also important to note that none of the studies discussed above mentioned or measured coverage of the affected population, although the programme in Niger has since been extended to many more decentralised sites, is admitting a higher proportion directly to outpatient treatment and is reporting low default rates which is a good indication of high acceptability and probably better coverage (personal communication: Milton Tectonidis, Nutrition and Health Coordinator, MSF France)

Ashworth's second review described above lists a number of advantages and disadvantages of treatment at home with RUTF, some of which are only relevant to the non-emergency setting (130):

Relevant to all settings:

Advantages:

- Independent of home resources
- Needs no cooking
- Liked by caregivers and children; few defaulters
- Responsive to fluctuating numbers
- RUTF contains electrolytes and micronutrients

- Free supplies may provide inducement for clinic attendance

Disadvantages:

- High institutional cost
- Requires clinic nearby or community health workers for monitoring progress, treating illnesses, and distributing RUTF
- Requires efficient transport and distribution networks
- Requires quality control measures if RUTF is to be locally made

Particularly relevant to the non emergency setting:

Advantages:

- Avoids need for formative research as to which home foods to promote
- Avoids need for intensive teaching of caregivers about what foods to give

Disadvantages:

- Little opportunity to learn about good child-feeding practices and malnutrition prevention
- Risk of dependency

# 7 Nomenclature, Principles & Conceptual Basis of the CTC Approach

The community-based therapeutic care (CTC) model was designed as an integrated public health response to acute malnutrition, aiming to treat the majority of cases of SAM solely as outpatients and integrating this treatment with a variety of other interventions designed to reduce the incidence of acute malnutrition and improve public health and food security (69). This put the treatment of SAM firmly within the realm of public nutrition, a concept first used by Mason *et al* in 1996, to refer to those programmes that aim to solve nutrition problems in populations rather than those laboratory and clinical activities aimed at elucidating basic mechanisms for the provision of individual treatment (137). CTC programme design attempted to take into account the socio-economic factors, particularly poverty, high workloads for women and the relative exclusion from health services, that contribute to the late presentation of cases of acute malnutrition and other conditions (138). Programmes are therefore highly decentralised to minimise geographical barriers to access and include intensive community consultation and mobilisation to maximise understanding and participation. This design aimed to minimise the costs and maximise access for families and individuals requiring treatment (42).

The CTC approach was thus designed around four core operating principles:

- Maximising coverage and access: to achieve the greatest possible coverage and make services accessible for the highest possible proportion of a population in need.
- Timeliness: to start case-finding and treatment before the prevalence of malnutrition escalates and to catch the majority of cases of acute malnutrition before serious medical complications occur.
- Appropriate care: to provide simple, effective outpatient care for those who can be treated at home and inpatient treatment for those who require more intensive care in order to survive.
- Care for as long as it is needed: by improving access, to ensure that children can stay in the programme until they have recovered, and by integrating in to existing health service where possible, to ensure treatment continues to be available for as long as acute malnutrition is present in the population.

The most important conceptual basis of these principals is that the serious physiological consequences of acute malnutrition appear late in the evolution of the condition (see section 6.4 above). If programmes can focus on finding and addressing acute malnutrition early in the progression of the condition, before its metabolic and immunological aspects become marked, then outpatient treatment could be a feasible and effective strategy for a large proportion of children. This required that children be separated in to 2 groups, those with medical complications that need inpatient treatment and those without medical complications that might be treated directly in outpatient care. This was discussed in detail by Collins and Yates in a letter to the Lancet in 2003 (139). To support the earliest identification of acutely malnourished children, programmes need to be designed to minimise physical, logistical and socio cultural barriers to access. Understanding of these premises is developed throughout the studies presented in this thesis.

The iterative nature of this research and programme development has meant that terms and acronyms attached to CTC programmes in different countries have varied and have evolved over time. The most important of these however are:

- SC (stabilisation centre) or NRU (nutritional rehabilitation unit)
- OTP (outpatient therapeutic programme)
- SFP (supplementary feeding programme)
- CTC (community-based therapeutic care)

*1. Inpatient Treatment*

The stabilisation phase takes place in an inpatient unit called a stabilisation centre (SC) or nutritional rehabilitation unit (NRU) and is the initial phase of treatment for severe acute malnutrition with complications. Here life-threatening problems are identified and treated; specific deficiencies are corrected; metabolic abnormalities are reversed and feeding begins with Formula 75 milk. This treatment follows the phase 1 protocols laid out by WHO with minor adaptations that replace F100 milk with RUTF at the end of phase 1 (29).

*2. Outpatient Treatment*

The outpatient therapeutic feeding programme (OTP) requires programme beneficiaries to make weekly or fortnightly visits to outpatient treatment centres. It includes two groups of admissions:

*i. Directly admitted into OTP (direct OTP)*

Children with severe acute malnutrition with no complications are admitted directly into OTP with no stabilisation phase

*ii. Indirectly admitted into OTP (indirect OTP)*

Children who previously suffered from severe acute malnutrition with complications and have first received inpatient treatment in a stabilisation center.

In the OTP beneficiaries receive a take home ration of RUTF and systematic medical treatment according to WHO protocols for the treatment of severe acute malnutrition.

*3. Supplementary Feeding*

The supplementary feeding programme (SFP) provides a dry take home supplementary ration and basic health care for children discharged from the OTP. Where feasible it ensures that all those that have been severely malnourished receive at least two months follow up after they have been discharged from the OTP.

*4. Community Mobilisation*

A community-based therapeutic care (CTC) programme includes all of the above components with the addition of measures to mobilise the community in order to encourage early presentation and compliance.

All four of these programme components have developed and evolved over the course of the studies presented in this thesis and are discussed in detail below.

# 8 Background to the Studies and Core Methods

## 8.1 Background

Since 2001, debate within the international nutrition community regarding the potential merits and disadvantages of treating severe acute malnutrition during emergencies at home has been animated (70;140;141). Letters included in appendix 2 section 14.2 describe one exchange that highlighted differing opinion about the numbers of children that could be successfully treated at home and about the programme design needed to do this. On the one hand there is a need to provide services that meet all medical and metabolic requirements for different age groups and severities of malnutrition. On the other, it is essential from a public health perspective, to set up a level of services that within resource poor settings, can reach the majority of those who need treatment. Here lie some difficult choices. How do Health Ministries and International Agencies working in developing countries match the specialised needs of the severely malnourished with the high numbers and wide spread of those who need treatment? There has been some scepticism during this debate that a community based therapeutic care approach to treating severe acute malnutrition can obtain good coverage of the needy population whilst providing the quality of care required to keep programme mortality rates low. For this reason, this research was designed to take place in phases, with results from initial research projects defining the parameters essential for subsequent phases of the research programme.

## 8.2 Introduction to the studies

This thesis presents the main findings from several studies that made up the first phase of the CTC research and development programme. Chapter 8 presents an in depth analysis of 3 studies that examined the clinical effectiveness of using RUTF to treat cases of SAM on an outpatient basis. The first of these studies (study 1), a retrospective cohort study, was a small study in Southern Ethiopia that used RUTF, delivered through health centres, to provide outpatient treatment to all children suffering from SAM. There was no inpatient care available during this study. The second study (study 2), introduced RUTF to discharge children early from an inpatient nutrition unit (an NRU) in a busy hospital in Southern Malawi. There were no health centres admitting or treating children as outpatients in this study. The last prospective cohort study in this chapter (study 3)

followed a prospective cohort in central Malawi and introduced a number of anthropometric and clinical triage criteria to refer children suffering from SAM either to inpatient care or directly to outpatient treatment delivered through health centres.

Chapter 9 examines the issue of coverage of CTC programmes and presents one study (study 4) that describes a new survey tool for measuring coverage of selective feeding programmes and, using this tool, compares coverage of the CTC programme in central Malawi and of a TFC programme in a neighbouring district. Chapter 10 presents study 5 that describes monitoring data from 17 programmes that have used the CTC model of treatment across Africa and reflects on factors that have impacted on both the clinical effectiveness and the coverage of these programmes. Chapter 11 draws together the lessons learnt from preceding studies and goes on to discuss how the results from these programmes have started to change international thinking on treatment approaches for severe acute malnutrition during emergencies. This chapter also discusses the way forward for future work.

## *8.3 Research and implementing partners*

### 8.3.1 Valid International

For the duration of the work described in this thesis, the author was either working with (as an employee of Concern Worldwide) or for (as an employee) Valid International. Valid International is a research and consultancy company that was formed in 1999 with a goal of improving the impact of humanitarian action, through action-orientated research. In 2001, Valid International established a partnership with Concern Worldwide to develop and test the CTC model of treatment for SAM. This partnership extended throughout the period covered by this thesis. The work described here forms part of a wider examination of CTC by Valid International and Concern in Africa.

### 8.3.2 Concern Worldwide

Concern Worldwide was an implementing partner for a large proportion of the field research (detailed in chapters 8, 9 and 10) for this thesis. During the fieldwork in Ethiopia, the author was employed as a nutrition programme manager by Concern Worldwide. By 2002, the author was an employee of Valid International but worked closely with Concern Worldwide on study design, implementation and documentation. Concern is a non-governmental, not-for-profit organisation, based in Dublin Ireland.

Emerging out of church relief programmes during the Biafran war in 1967, Concern has expanded and secularised and now engages in a variety of developmental and relief work. Their organisational aim is "..to help people living in extreme poverty achieve major improvements in their lives, which last and spread without ongoing support from Concern" (142). At the time of writing, they worked in approximately 28 countries. Historically, Concern have relied on a strong volunteer ethos. However, with the launch of the Sphere Project in 1999 and subsequent efforts across the international community to improve the quality of humanitarian assistance, the organisation has prioritised an operational research agenda that aims to improve the effectiveness of their programming. It was within this context in 2001 that the partnership with Valid, to develop and test the CTC model in a number of countries across Africa, was established.

### 8.3.3 Other partners

Queen Elizabeth Central Hospital (QECH) and the College of Medicine in Blantyre, Malawi were the main implementing partners for study 3 presented in chapter 8 of this thesis. The College currently has strong links with the Liverpool School of Tropical Medicine and St Andrew's university in the UK. QECH houses, among others, a paediatric ward and a nutritional rehabilitation unit for the inpatient treatment of severe acute malnutrition which has long been one of the busiest in the country.

In all the countries of work described in this thesis the MoH has been an extremely important operational partner. Wherever it has been possible, the work described here has supported the implementation of CTC programmes through existing health structures and this has meant considerable involvement at both national and sub national levels of MoH staff to manage, supervise and implement programme activities.

Valid partnered with several NGOs to implement the CTC programmes discussed in chapter 10 (Going to scale with CTC). These included Save the Children UK, Save the Children US, Tearfund and World Vision.

## *8.4 Core Research Methods*

To avoid repetition in subsequent chapters this section presents some of the core research methods used in the cohort studies 1, 2, 3 and 5 that examine the outcomes and clinical

effectiveness of CTC research programmes. Specifically, which methods were adopted for each study is indicated in the sections below.

### 8.4.1 Subjects

All subjects were either inpatients or outpatients of CTC programmes that were supported by the implementing partners described in section 8.3 above.

The admission criteria for each study are reported in the methods section of each study (see sections 9.2.3.2; 9.4.4.1.5; 9.3.4.1.2; and 11.2.2.1). These admission criteria varied slightly according to the national protocol in the country of implementation. The existence and quality of alternative medical care also played an important role in patient selection, sometimes forcing the programmes to admit some patients who were not severely malnourished. Their data were excluded from analysis in studies 1, 2 and 3. In general, only children with a weight for height of < 70% of the NCHS median, a MUAC < 11cm or those with nutritional oedema were included in the analysis of each of the cohort studies. Less severely malnourished children were referred to supplementary feeding programmes. There were some groups of children that were severely malnourished with a primarily medical cause, these included children of < 6 months and those with severe disabilities. These children were also excluded from the main analysis in studies 1, 2 and 3. The potential inclusion of some primarily medical patients in the analyses is of most relevance in studies 2 and 3 where the impact of HIV infection on outcomes of children being treated for severe acute malnutrition is discussed in some detail.

### 8.4.2 Measurements, equipment and precision

All studies were implemented within operational programmes that were not primarily research sites. Conditions therefore were sometimes disorganised and with high rates of mortality and morbidity either present or expected, there was some urgency to get programmes operational quickly. Often at the start of programmes, there were few trained staff to cope with high levels of admissions. Workloads were therefore high and time available for supervision low. These conditions will have promoted errors in precision and accuracy in the assessment of height, weight, MUAC and clinical data. They also precluded any formalised assessment of inter and intra staff variability in measurement precision and accuracy. Therefore, for this thesis, some internal validity was sacrificed in order to maximise external validity (143).

However, several attempts were made to reduce and to quantify measurement errors. In all sites the staff responsible for weighing, measuring and assessing clinical indicators were literate and were trained before and during the studies. The details of training at each study site are discussed below and under the relevant studies (see sections 9.2.3.5; 9.4.4.1.1; and 9.3.4.2.2). Random error in data collection (i.e. randomly distributed) causing systematic bias was minimised with large sample sizes and by the statistical methods used i.e. the use of standard deviations and confidence intervals around the mean. Any systematic errors (or bias) arising during data collection were potentially far more serious and several steps were taken to avoid introducing systematic errors into the data. These are described below:

All health staff were trained to collect anthropometric measurements according to WHO guidelines (144;145).

The hanging Salter scales (25kg max weight) were used to take the weight of each child, in minimal clothing, and measurements were recorded to the nearest 0.1 kg. The reading was taken by 1 health worker and recorded immediately. For every study the scales were regularly adjusted to zero and in studies 2 and 3 in Malawi the scales were calibrated before and after the study using a known 1 kg weight. Scale calibration in Malawi revealed no systematic errors in accuracy.

Height measurements were taken using calibrated height/length wooden boards with a close fitting head/foot piece and measurements were recorded to the nearest 0.1 cm. 2 health staff worked together to measure height and check that readings were accurate. Children less than 24 months of age (<85cm) were measured lying down and children over 24 months of age (>=85cm) measured standing up. The reading was recorded immediately.

Mid-upper arm circumference (MUAC) was measured on the left arm, at the mid point between the shoulder and elbow. It was expressed in cm to the nearest 0.1cm and recorded immediately after measurement.

Bilateral oedema was diagnosed by placing the thumbs on the upper side of each foot and/or shin and applying medium pressure for three seconds. Oedema was classified as present if a skin depression remained after the pressure was released.

Age of the study children was determined from health or growth monitoring cards or directly from mother's recall. It was recorded in months.

### 8.4.3 Data collection and programme monitoring

For studies implemented after study 1 (the study in Ethiopia) several tools were developed to assist the standardised collection of study data and for the monitoring of individual and programme performance.

#### 8.4.3.1 Individual monitoring & data collection

Key elements for the data collection and monitoring for each admission were:

1. The routine collection of medical, nutritional and follow-up data, recorded on individual monitoring cards.
2. A clear numbering system.

##### *8.4.3.1.1 Monitoring card*

On admission to each programme component (i.e. inpatient and outpatient) every patient was issued with a monitoring card. These cards were used by trained health workers for the recording of a unique patient identification number (see below), basic anthropometric and clinical data over time, all medical and nutritional treatment and of final exit outcome. Appendix 3: The monitoring card used in the OTP, Dowa, Malawi, gives an example of the monitoring card used for the outpatient component in study 3, section 9.4. Where children went through inpatient care clinicians also used medical notes for recording of diagnosis and treatment prescription. It was these detailed individual data on cards that was used for the analyses in studies 2 and 3.

##### *8.4.3.1.2 Numbering*

In all studies subsequent to study 1 a unique registration number was given to each child on admission to outpatient or inpatient care. Each registration number was made up of several parts, for example, for the registration number:

NAM / 003 /OTP

- NAM refers to the name of the programme site where outpatient or inpatient treatment was received
- 003 is the sequential number allocated to the child
- OTP refers to the programme component where the child entered the programme.

The full number allocated to a child on admission was retained as s/he moved through each level of treatment (i.e. inpatient and outpatient) to discharge. This unique number was recorded on all records concerning the child, i.e. on individual monitoring cards, registration books, ration cards, transfer slips (for transfer between programme components) and identity bracelets. Returning defaulters (i.e. those children that had absconded from treatment before attainment of cure and subsequently returned, several weeks later, to complete treatment) retained the same number that they were given on admission and their treatment continued on the same monitoring card. Readmissions after relapse (i.e. those children that had attained cure in the programme and subsequently, several weeks later, were readmitted to the programme as malnourished again) were given a new number and a new card.

#### 8.4.3.2 Programme monitoring

For all studies subsequent to study 1, inpatient treatment units and outpatient treatment sites completed basic reports every week that tallied the number and type of programme admissions and exits (see section 14.4 Appendix 4: OTP weekly report, Dowa Malawi). The data from these reports were entered (usually weekly) in to a designed database (146), which enabled the analysis of:

- total admissions, exits and the number of children in the programme;
- the number of admissions by category and
- the number of exits by category.

This allowed continuous monitoring of admission, exit and outcome trends overall and by treatment site. These monitoring data were regularly compared to the standard indicators of quality for therapeutic feeding interventions laid out by Sphere (72). It was these data that were used for the analysis presented in study 5 and in some of the discussion in studies 2 and 3. See section 14.5 Appendix 5: Example of database for data input and a programme monitoring report, Dowa Malawi.

Additional description of data collection and monitoring can be found under each study.

### 8.4.4 Data coding

Data from the individual monitoring records were used for analysis in study 1 and studies 2 and 3. This section describes the core methods for coding these data.

Oedema was coded as present if there was any mention of oedema on the admission card. Grade of pitting oedema was coded using the classification of Beattie *et al*. (147), (0 = absent, 1 = minimal oedema on the foot or ankle that was demonstrable but not visible, 2 = visible on foot and lower leg, 3 = generalised, including both feet, legs, hands and face). Pitting oedema, recorded as present but unquantified, was not graded.

| Localisation | Degree of severity | Classification |
|---|---|---|
| Both feet/ankles | Mild: pitting barely detectable | + (1) |
| Both feet plus lower legs | Moderate: pitting in between mild and severe | ++ (2) |
| Generalised, including both feet plus legs, hands, arms and face | Severe: skin very tense, pitting deep | +++ (3) |

**Figure 6: Classification of oedema**

Admission criteria is coded according to the following classification:

- Kwashiorkor: the presence of any bilateral pitting oedema
- Marasmus: weight for height ≤ -3 z scores or ≤ 70% of the median NCHS reference weight-for-height
- Marasmus kwashiorkor: weight for height ≤ -3 z scores or ≤ 70% of the median NCHS reference weight-for-height and bilateral pitting oedema
- MUAC: none of the above and mid-upper arm circumference ≤ 11cm (children > 75cm)

Appetite was coded as present when a child was willing and able to eat RUTF or absent (anorexic) if not.

Fever was coded as present where temperature was >39$^{o}$C and hypothermia as present where temperature was < 35$^{o}$C. This was measured with a standard thermometer. Hypothermia was defined where the mercury level was read at 35 or below.

Acute lower respiratory infection was coded as present when respiration rate was:

- > 60 respirations/minute for under 2 months.
- > 50 respirations/minute from 2 to 12 months.
- > 40 respirations/minute from 1 to 5 year-olds.
- > 30 respirations/minute for over 5 year-olds.

Severe anaemia was coded as present when the child had very pale conjunctiva and severe palmer pallor and difficulty breathing and/or a haemoglobin count of <7g/100ml.

Severe superficial infection was coded as present where the child presented with ear discharge or skin that was ulcerating, raw or peeling or with any infection that required intra muscular treatment.

Severe dehydration was coded as present if the child presented with a recent history of diarrhoea, vomiting, fever or sweating and with recent appearance of clinical signs of dehydration including sunken eyes or weak pulse or low urine output.

Outcome data are coded as either recovered, died, default, transfer or non responder. The definitions of outcomes vary slightly for each study and therefore are given in the relevant study sections.

Missing data values are coded as missing.

Additional description of data coding can be found under each study (see sections 9.2.3.5; 9.4.4.2.3; and 9.3.4.2.3)

### 8.4.5 Data entry and verification

All data for studies 1, 2 and 3 were transferred from the patient record cards into Epiinfo version 6.04 (148) using the Epidata data entry programme (149). The Epidata programme contained a number of checks that helped to ensure the validity of the data during the data entry process. A check file was created for data entry related to studies 1, 2 and 3 and included some or all of the following examples:

Limiting entry of numbers or dates to a specific range:

- Date of admission and discharge limited to the years covered by study for example 2002-2003
- Age limited to 1-120 months
- Weight limited to 2-40 kg
- Height limited to 50-150 cm
- MUAC limited to 80-180 mm

Forcing an entry to be made in a field

- Registration number

Help messages to the person entering data included labelling key for all coded fields set to appear in 'pop up' boxes, for example:

- Admission criteria: 1 Marasmus
  2 Kwash-Maras
  3 Kwashiorkor
  4 Other
- Oedema grade: 0 NA
  1 +
  2 ++
  3 +++

The author spent considerable time cleaning all data after data entry. All missing data were verified missing against original card data. If the data were present on the card they

were entered in to the database. All quantitative data were examined with range checks. The following range was defined for each variable as 'normal', any data that fell outside this range were verified against original card data:

- Age: 0-60 months
- Height: 50-120 cm
- Weight: 2-20 kg
- MUAC: 100-170 mm

The frequency distribution of all quantitative data, including age, height, weight, MUAC, admission and discharge dates, weight gain and length of stay was closely examined for outliers. Any data that fell outside +/- 3 standard deviations of the mean were verified against original card data.

### 8.4.6 Data manipulation and creating new variables

Specific procedures were written in EpiInfo to transform the data. In their original form individual child data for admission and each week of treatment thereafter were stored in sequential rows in EpiInfo against ID number. To enable analysis of outcomes, this week by week data needed to be put in to the same row for each child. The core programmes to do this were written by Dr Steve Collins, originally for his own doctorate, but required significant adaptation by the author for her own data. Additional programmes to create new variables and to produce the required analyses were written by the author.

The anthropometric variables weight for height z scores and percentage of the median were created by EpiNut, part of the EpiInfo version 6.04 software, which uses the NCHS standard growth curves as the reference population (36).

Programmes were written in EpiInfo to calculate programme length of stay and weight gain variables.

Individual weight gains are expressed in g $kg^{-1}$ $day^{-1}$. In marasmic patients these are calculated using the formula:

> ((discharge weight – admission weight) / admission weight) / number of days stay in programme

For those admitted with oedema, rates of weight gain after oedema had disappeared are used. The lowest weight achieved during the study is taken as synonymous with the weight of the child at disappearance of oedema:

> ((discharge weight - lowest weight achieved during the study) / lowest weight achieved during the study) / number of days between lowest weight and discharge.

### 8.4.7 Data Analysis

Unless otherwise stated all data analysis was completed using EpiInfo v6.04 (148) and SPSS v14.0 (150) and graphics were developed using Microsoft Excel V11 2003 (146).

#### 8.4.7.1 The use of means and medians

In describing and comparing data such as age, weight-for-height z scores and % median, length of stay and weight gain a combination of means and medians are used. If the data distributions approximated to a 'normal distribution', population means are quoted and if the distributions were skewed, population median values were used. Skewness for all relevant variables was examined in SPSS and a skewness value greater than 1 was used to signify a significant difference from a normal, symmetric distribution.

#### 8.4.7.2 Use of Pearson and Yate's corrected chi square test and the Fisher exact test

The Chi square and Fisher Exact tests were used to test for associations between variables in 2x2 tables. These were used, for example, to test for associations between different outcomes (i.e. death, recovery etc) and categories of malnutrition (i.e. kwashiorkor, marasmus etc) at admission.

#### 8.4.7.3 Use of survival curves

Kaplan-Meier survival curves were used to show the timing of discharges, deaths, defaults and transfers during study implementation.

#### 8.4.7.4 Use of the Prudhon Index

A short programme in Excel was developed to calculate the likelihood of death or 'expected mortality' of the patients (a prognostic index) in study 3 according to the equations published by Prudhon *et al* (151). This equation is based on the weight, height and oedema status of patients and was calculated only for children that recovered or died and that were aged 6-59 months as this was the population from which the prognostic index was derived. The expected mortality was compared with the observed mortality

using the Fisher's exact test to assess for significance. (see section 9.4.4.2.4 for more detail)

#### 8.4.7.5 Use of relative risk

Relative risk is used to quantify any significant increased or decreased risk of, for example, death in one group of malnourished children compared to another. It is also used to quantify the difference in risk of mortality between that calculated by the Prudhon index (see above) and that observed in the studies.

Additional description of data analysis techniques used for specific studies can be found under sections 9.4.4.2.4; 9.3.4.2.3; and 10.2.3.7.

### 8.4.8 Ethical approval

All of the work presented in this thesis was approved by the Great Ormond Street Hospital for Children NHS Trust / Institute of Child Health Research Ethics Committee in London, UK. In addition, the individual studies 2, 3 and 4 were formally approved by the Ministry of Health and Population in Lilongwe, Malawi.

# 9 Can CTC Achieve Clinical Effectiveness?

## *9.1 Introduction*

This chapter presents a series of three studies that aimed to test the clinical effectiveness of the CTC model of care i.e. one that includes inpatient care for children suffering from SAM with complications, outpatient care for children suffering from SAM with no complications and community mobilisation to encourage early presentation and compliance (See Chapter 7). This series of studies were iterative in nature with results from the first two studies defining the study and programme protocols for the final study.

The first of these studies took place in Southern Ethiopia in 2000 and was a 'natural experiment'. Government policy at the time forced a 'non-standard', suboptimal approach that meant that there was no inpatient care available during this study. All children suffering from SAM were treated as outpatients with RUTF from health centres. During study implementation, the author was employed by Concern Worldwide in Ethiopia and led all data collection and compilation; she went on to play a significant role in the analysis and publication of these data.

To build on and strengthen results found in the first study, the second study was designed prospectively and used RUTF to discharge children early from a nutrition unit in a busy hospital in Southern Malawi. It examines the impact of this on programme mortality and recovery. There were no health centres admitting or treating children as outpatients in this study. For this study the author led study design in Malawi, supported data collection through monitoring visits and led data analysis and write up for publication.

The last study in this chapter took place in central Malawi and was the first to implement the full CTC model of care which used triage to refer children suffering from SAM with complications to a stabilisation centre and those suffering from SAM with no complications directly to outpatient treatment delivered through health centres. It examined the effectiveness of this treatment strategy for a large group of children over the first year and a half of the 2002 Southern Africa emergency and disaggregates response to treatment by age group and category and level of malnutrition. For this study the author lived in Malawi for the first 12 months of study implementation where she led

study design and supported data collection through site monitoring visits. The author subsequently completed all data analysis and write up for this study.

## *9.2 Study 1, Ethiopia 2000: Can an outpatient model using RUTF for the treatment of SAM meet Sphere standards?*

See Appendix 1, section 14.1.2 for published paper (152)

### 9.2.1 Background

During the field work for this programme, the author was employed as the nutrition field officer by Concern in Ethiopia and was responsible for nutrition programme design, set up and monitoring. The programme took place in Bedawacho Woreda (district), in the Southern Nations Nationalities and Peoples Regional Government (SNNPR) of Ethiopia, 350km south of Addis Ababa.

In July 2000, Bedawacho had experienced three consecutive years of drought and failed harvests, leading to generalised poor food security. In August 2000, Concern started a dry Supplementary Feeding Programme (SFP), distributing 3.5 kg of a blended food (maize, soya, sugar and mineral/vitamins) every fortnight, to each child identified as having a weight for height less than 80% of the reference weight-for-height (WFH). This ration provided each child with 918 kcal day-1.

During the first few weeks of the SFP, many of the children that presented to the feeding centres were identified as suffering from severe acute malnutrition. These children were dispersed across the Woreda and, due to the difficult topography and poor communications, many were inaccessible. At the time there was considerable opposition from the regional Government to the setting up of new TFCs and therefore in patient care was not available. Consequently all children suffering from SAM were treated solely as outpatients with weekly attendance at clinics or distribution sites.

The resulting programme data was analysed as a retrospective cohort study.

**Figure 7: Bedawacho Woreda, SNNPR Ethiopia**

## 9.2.2 Objective

To examine the effectiveness, compared with international standards, of outpatient treatment for severe acute malnutrition during an emergency relief programme in Southern Ethiopia.

## 9.2.3 Method

### 9.2.3.1 Subjects

This study analysed data from 170 patients aged between 6 and 120 months old, admitted to the Concern outpatient therapeutic programme, Bedawacho, Ethiopia, between 16th October 2000 and 31st January 2001. Criteria for inclusion in the study were a weight for height (WFH) percentage of less than or equal to 70% of the NCHS (36) reference, and/or bilateral pitting oedema. There were no exclusion criteria.

### 9.2.3.2 Admission and Discharge Criteria

The severely malnourished were identified at any of the ten SFP distribution points using anthropometry and an examination for pedal oedema. After identification, they were registered into the outpatient therapeutic feeding programme (OTP) and underwent a

rapid medical screen. Joint SFP and OTP distributions took place once every two weeks at each of the ten distribution sites, all of which were located at government primary health clinics or health centres . Once in the programme, each child attended their nearest distribution site every week where they were medically examined and received a ration of RUTF and blended food. In between visits, Concern community nutrition workers followed up patients in their houses once or twice a week. At these visits they checked the progress of the child and referred any who were ill to the clinic. Patients were discharged from the OTP to the SFP once the field staff assessed that their WFH was > 75% of the reference median weight-for-height on two consecutive weeks and that they were free from infective disease. After discharge into the SFP, outreach workers continued to follow up patients until they were discharged from that programme when their WFH was > 85% of the reference median weight-for-height on two consecutive weeks.

#### 9.2.3.3 Dietary Treatment

At admission and each visit thereafter, each child received 14 sachets (92g) of RUTF (total 1.28 kg) regardless of their weight and 7.5 kg of blended food for 1 week together with medication according to a protocol. This ration provided 1000 kcal of energy and 24.3 g of protein $day^{-1}$ (protein-energy ratio = 10%). In addition, all patients in the OTP received 7.5 kg of blended food, providing 1967 kcal of energy and 79 g of protein $day^{-1}$ (protein-energy ratio = 16%).

#### 9.2.3.4 Medical Treatment

At admission, all patients received medication according to a protocol, using drugs provided by Concern Worldwide. This protocol consisted of a single oral dose of Vitamin A (100,000 I.U. <12 months age and 200,000 I.U. for all other age groups); a single oral dose of mebendazole (250mg for children aged between 12 and 24 months and 500 mg for all other age groups); and a single oral dose of Folic acid (5 mg). All patients also received a five day course of the broad-spectrum antibiotic cotrimoxazole (25mg of Sulfamethoxazole + 5mg of Trimethoprim per kg orally every 12 hours). If considered to be dehydrated by the admitting staff, they were orally rehydrated using ReSoMal, an oral rehydration solution specifically designed for the treatment of severe acute malnutrition.

#### 9.2.3.5 Data Collection

The study was implemented as part of the day to day operations of an emergency feeding operation. The situation was difficult with high rates of mortality and morbidity and

insecurity that on one occasion resulted in a machine gun attack on a Concern Worldwide car. The difficulties of implementing a programme in these circumstances and the pressures of the work meant that some of the data collection was incomplete. Admission WFH data was collected for 167 and follow up weight change data for 169 of the 170 admissions.

On presentation to the SFP, patients were weighed, had their height measured by trained local enumerators and were assessed for the presence of bilateral pitting pedal oedema. On registration for the OTP, the clinic nurse performed a rapid clinical screen, assessing degree of pitting oedema and hydration, and the presence or absence of dysentery, diarrhoea, anaemia and signs of chest infection. At each follow-up visit to the clinic or SFP, a nurse recorded follow-up weight, extent of pitting oedema and clinical condition. Follow up weights, clinical complications, grade of pitting oedema according to the classification given in chapter 7 (see Figure 6) and all drugs prescribed, were recorded on the patient's individual treatment card. Outcome (death in the programme, discharge alive, default or transfer) was also recorded on the patient's card and in the programme's registers.

#### 9.2.3.6 Data Coding

Discharge outcomes were defined as:

***Death***

Death whilst registered on the programme (within two weeks of failing to attend the OTP).

***Recovered***

For two consecutive weeks:

- a weight-for-height of more than or equal to 75% of the median NCHS reference and;
- absence of bilateral pitting oedema;

***Default***

Failure to attend treatment on two consecutive occasions

***Transfer***

Transferred out of the programme to hospital

## 9.2.4 Results

### 9.2.4.1 Mortality, recovery and default

Table 5 presents outcome data. One hundred and forty four patients (85%) recovered, seven patients (4.1%) died and eight patients (4.7%) defaulted. Table 6 compares recovery, mortality and default rates with the Sphere standard indicators for therapeutic feeding. Recovery, mortality and default rates were all within the Sphere indicators. Case fatality rates were 4.7% for marasmic, 14.3% for marasmic-kwashiorkor and 0.0% for admissions with kwashiorkor (Table 5).

**Table 5: Outcome data for children treated in study 1**

| | | total | | marasmus | | marasmic kwashiorkor | | kwashiorkor | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | (%) | n | median (range) | n | median (range) | n | median (range) |
| outcome | overall | 170 | | 106 | | 14 | | 50 | |
| | recovered | 144 | 85 | 86 | | 10 | | 48 | |
| | died | 7 | 4.1 | 5 | | 2 | | 0 | |
| | defaulted | 8 | 4.7 | 6 | | 0 | | 2 | |
| | transferred | 11 | 6.5 | 9 | | 2 | | 0 | |
| | case fatality rate (%) | | 4.1 | 4.7% | | 14.3% | | 0.0% | |
| length of stay (days) | overall | 170 | 42 (28 - 56) | 106 | 42 (28 - 56) | 14 | 56 (35 - 70) | 50 | 42 (28 - 42) |
| | recovered | 144 | 42 (28 - 56) | 86 | 42 (28 - 56) | 10 | 56 (42 - 70) | 48 | 42 (28 - 45) |
| | died | 7 | 19.2 | 5 | 14 (14 - 26) | 2 | 13 (4 - 21) | | |
| | defaulted | 8 | 18.0 | 6 | 10.5 (7 - 35) | | | 2 | 18 (14 - 21) |
| | transferred | 11 | 77.8 | 9 | 70 (42 - 105) | 2 | 67 (63 - 70) | | |
| weight gain ($g\ kg^{-1}\ day^{-1}$) | overall | 169 | 2.9 (1.8 - 5.1) | 106 | 3.6 (2.1 - 6.0) | 14 | 2.6 (2.2 - 5.5) | 49 | 2.1 (0.9 - 3.2) |
| | recovered | 143 | 3.4 (2.2 - 5.5) | 86 | 4.4 (2.6 - 7.2) | 10 | 3.9 (2.3 - 6.6) | 47 | 2.2 (1.0 - 3.2) |
| | died | 7 | 0.0 (0.0 - 0.7) | 5 | 0.0 (0.0 - 0.0) | 2 | 0.3 (0.0 - 0.7) | | |
| | defaulted | 8 | 0.0 (-1.3 - +1.5) | 6 | 0.0 (0.0 - 3.1) | | | 2 | -2.5 (-3.9 - -1.1) |
| | transferred | 11 | 1.6 (0.8 - 2.2) | 9 | 1.6 (1.1 - 2.0) | 2 | 1.1 (-0.2 - +2.4) | | |

* Range = Interquartile range

**Table 6: A comparison between the Sphere (2000) indicators for therapeutic feeding programmes and the study results**

| Key indicator | International standard | Study result |
|---|---|---|
| Proportion of exits from a therapeutic feeding programme who have died is | < 10% | 4.1 |
| Proportion of exits from a therapeutic feeding programme who have recovered is | > 75% | 85 |
| Proportion of exits from a therapeutic feeding programme who have defaulted is | < 15% | 4.7 |
| Minimum mean rate of weight gain (g $kg^{-1}$ $person^{-1}$ $day^{-1}$) | > 8g | 2.86 |

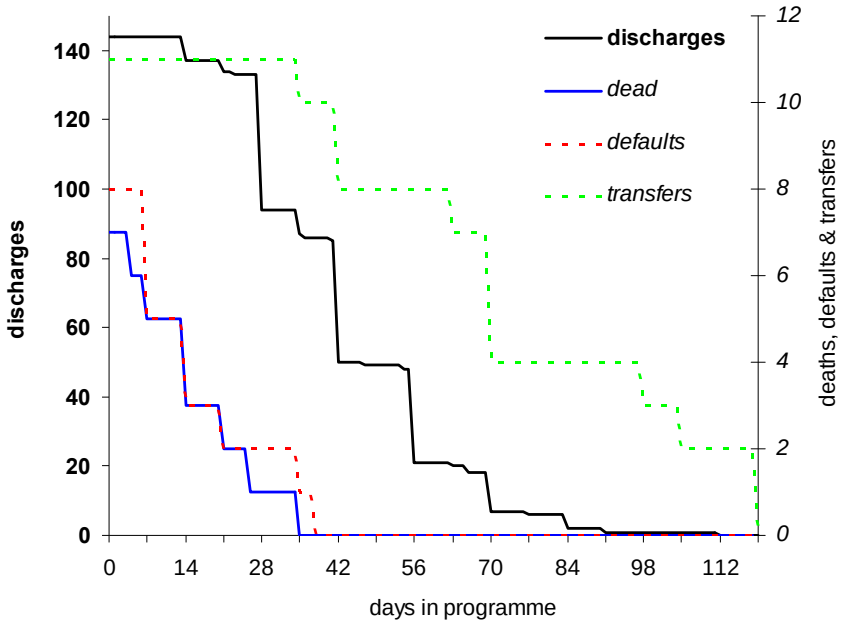



**Figure 8: Kaplan-Meier survival curves showing the timing of discharges, deaths, defaults and transfers in study 1**

### 9.2.4.2 Length of stay and weight gain

Median [IQ range] time to recovery was 42 [28 - 56] days, median time to death 14 [7 - 26] days and median stay in the programme was 14 [7 - 28] days. Median [IQ range] time to clinical resolution of oedema was 28 [21 – 35] days, 28 [24.5 – 38.5] for

marasmic-kwashiorkor and 27 [21 – 35] for kwashiorkor patients. Overall, the median [IQ range] rate of weight gain amongst all admissions was 3.2 [1.9 – 5.6] g $kg^{-1}$ $day^{-1}$. Among patients that recovered the median rates of weight gain were 4.8 [2.9 – 8.1] g $kg^{-1}$ $day^{-1}$ for marasmic children, 4.0 [2.7 – 4.3] g $kg^{-1}$ $day^{-1}$ for marasmic-kwashiorkor children, and 2.7 [0.0 – 4.8] g $kg^{-1}$ $day^{-1}$ for those with kwashiorkor. Two deaths occurred during the first two weeks of treatment (Figure 8).

## 9.2.5 Discussion

### 9.2.5.1 Mortality, recovery and default

The mortality, recovery and default rates in this programme appeared better than internationally accepted minimum standards for TFCs. This suggested that in this context, severe acute malnutrition could be treated effectively on an outpatient basis and that outpatient treatment was acceptable to participants.

### 9.2.5.2 Appropriateness of dietary regime

However, not all patient groups in this study did equally well. Two out of the fourteen patients with marasmic-kwashiorkor died. One potential cause of their increased mortality is that the dietary regime was inappropriate for these patients. Patients with marasmic-kwashiorkor suffer from profound metabolic dys-adaptation, are invariably infected, often anorexic and have a high risk of death and complications (3). It is for this group of patients especially that the intensive care and cautious re-feeding regimens available during phase 1 of TFC treatment is important for the attainment of low case fatality rates. The dietary regimes provided here may not have been appropriate for these patients. Conventional treatment guidelines call for an intake of between 80–100 kcal $kg^{-1}$ $day^{-1}$, a protein to energy ratio of about 5%, less than 8mg/kg body weight of sodium and no iron during the initial phase of treatment; and greater than 200 kcal $kg^{-1}$ $day^{-1}$ during the recovery phase of treatment (34). The outpatient treatment regime in this study provided approximately 43.9mg /kg body weight of sodium, 2.7mg/kg of iron and an average of 400 kcal $kg^{-1}$ $day^{-1}$ right from the start of treatment. In addition, oedematous patients lost oedema more slowly than is normal during TFC based treatment using F75, and it is possible that a sub-optimal dietary composition that was too high in protein contributed to their delayed recovery. This has been seen elsewhere (153).

This study provided a large amount of calories to try to ensure that even if the rations were shared with other family members, the patient still received sufficient food to enable adequate catch-up growth. If during the first few days of treatment a severely malnourished child consumed their entire ration, there was a risk of serious metabolic imbalance. We felt that such overfeeding was unlikely as previous research into the supplementary feeding of moderately malnourished children has shown that take home rations are usually shared with other family members (154). In addition, metabolic dysfunction sufficient to produce life threatening metabolic imbalance from overfeeding, is usually associated with anorexia that tends to limit spontaneous intake. Figure 8 shows that only two of the seven deaths (29%) occurred during the first two weeks of treatment, the period usually associated with mortality from overfeeding (30), suggesting that overprovision of calories was not a major contributor to mortality in this study.

#### 9.2.5.3 Length of stay and weight gain

Length of stay was longer and rate of weight gain lower than would be expected in a well run TFC programme (72). This study did not investigate factors influencing the rates of response. However, in a TFC, where children are given 200 kcal $kg^{-1}$ $day^{-1}$ during the recovery phase of treatment, weight gain would be expected to be in the region of 10g $kg^{-1}$ $day^{-1}$ (29). The low mortality rate seen in this study suggests that children were not sicker than those that present to many TFC programmes. It is likely therefore that the low range of weight gain observed was due to sharing of both the RUTF and the blended food rations. It may also be that the children treated in this study were less wasted than many seen in TFC programmes. This will also have reduced proportional weight gain. In a conventional TFC, it is important that patients recover and are discharged as soon as possible. Severely malnourished patients are immunocompromised and when in a TFC, are exposed to many foreign pathogens. The risk of nosocomial infection is therefore high. In an outpatient programme, the severely malnourished are not removed from their home environments and are not congregated together. The danger of nosocomial infection is therefore much lower (77). Although it is still preferable that patients recover quickly, the safer surroundings remove the imperative for patients to recover as fast as possible. More than 25% of marasmic patients gained weight at greater than 8 g $kg^{-1}$ $day^{-1}$. Presumably this was due to a combination of the patient receiving a greater proportion of the RUTF and supplementary food as well as positive feeding and caring

practices. Subsequent studies in this thesis have examined the possibility of using mechanisms such as follow up at home by CHWs and community group support networks, for improving home-based support to encourage faster recovery.

#### 9.2.5.4 Population level impact

Finally, this study did not collect data on programme coverage (the proportion of the severely malnourished population that were admitted into the programme), and this was a serious omission.

## *9.3 Study 2, Southern Malawi: the impact of introducing RUTF into a central hospital with a high HIV caseload.*

See Appendix 1, section 14.1.3 for published paper (155)

### 9.3.1 Introduction and aims

The study in Ethiopia demonstrated that outpatient care using RUTF could, in certain circumstances, attain international standards for recovery mortality and default rates. However, this study was retrospective in nature, programme data were generated from a less than ideal research environment and the study was not able to examine the use of RUTF in an ideal programme setting due to the absence of inpatient care. There remained therefore many unanswered questions around the clinical effectiveness of using RUTF for children suffering from SAM in an outpatient setting and around how best to deliver treatment.

In Malawi in 2002, levels of overcrowding and of mortality related to severe malnutrition in many centrally located NRUs remained unacceptably high (see Figure 19 below). Therefore it became important to examine alternative, feasible approaches that could be introduced with relatively little impact on existing resources and protocols, which could reduce the pressure on inpatient units and that might reduce mortality. This provided an opportunity to take one step back, and more cautiously and rigorously examine the effectiveness of using RUTF from phase two of treatment in a more controlled research setting.

Therefore, this study aimed to prospectively examine an approach that would, within current resources and structures, decongest a central NRU in Blantyre, Southern Malawi by discharging children suffering from SAM immediately after phase one treatment to outpatient care with RUTF.

### 9.3.2 Objective

To assess the operational outcomes of implementing a combined approach to the treatment of severe acute malnutrition using:

1. an initial inpatient stabilisation phase, based on WHO guidelines,
2. a subsequent outpatient recovery phase with ready-to-use therapeutic food.

### 9.3.3 Background

Moyo House NRU is situated within Queen Elizabeth Central Hospital (QECH), Blantyre. Blantyre District is 2012 $km^2$ and has a population of 809,397 of whom 502,053 live in urban and semi-urban township areas and the remainder in rural areas (156). The estimated prevalence of HIV among people aged between 15 and 49 years in Blantyre District is 22.3%, the highest in the country (157). Moyo is Malawi's biggest and busiest NRU, regularly admitting over 1200 children each year (unpublished data: 'Action Against Hunger' attendance records 2002-4). The mortality rate of children being treated for severe acute malnutrition in the unit has been high, between 20% and 40%, for many years (89). Many of the children from rural areas have to travel long distances (up to 40km), often by foot, to reach the unit.

Prior to Malawi's 2002/3 food emergency, studies implemented from QECH assessed the use of home based treatment for SAM with RUTF. These studies demonstrated good weight gains and cure rates of 86% and 75% respectively for HIV negative and positive children (132;133). However, these encouraging results were recorded in children recruited after phase 1 treatment and did not address the ongoing high inpatient mortality. In addition, these studies were able to remunerate travel costs to help sustain outpatient clinic attendance through to recovery.

In an HIV prevalence study undertaken in the paediatric wards of QECH 40% of the malnourished children tested positive and HIV infection contributed to over 40% of all paediatric deaths (106). A further study in Moyo House nutrition unit assessed the impact of HIV infection on the clinical presentation and case fatality of SAM (101). HIV sero-prevalence among malnourished children was reported as 34.4% and overall inpatient mortality was 28%. The same unit had earlier reported a case fatality rate of 30.5% for children with kwashiorkor (89). These last two studies discussed the difficulties in maintaining food supply lines, accessing suitable training and maintaining staff motivation. In resource limited settings such as these, improved case management of both SAM, and especially HIV-related SAM is urgently needed.

In September 2002, as a result of the Food Emergency, an international NGO started support to the nutrition unit team in Moyo House. Staff were retrained according to latest

WHO guidelines, locally produced milk feeds were replaced by pre-packed F75 and F100 formulae milks (Nutriset, France) and supply lines of drugs, blankets and bed nets were established. Despite these efforts an audit over the 3 month period December 02-March 03 showed that the case fatality rate had remained unchanged at 29%, with HIV/AIDS infection contributing to 32% of deaths, and average inpatient stays were 14 days. Cure rates were 45%. (Geenan, ACF unpublished data 2003). The Ministry of Health and Population shared concern about the poor outcomes and agreed that a new treatment approach could be evaluated.

At the time of the study the NRU was staffed by a trained paediatrician, 1-2 paediatricians in training and a rotating intern. There were 6 full time nurses, 2 health assistants and 2 patient attendants. Just prior to the study, staff received training from WHO trainers on the inpatient management of SAM followed by training on the use of RUTF outpatient protocols.

## 9.3.4 Methods

### 9.3.4.1 Programme methods

This study ran from May 2003, when RUTF was introduced to the unit as a second phase treatment. The study phase stopped 1 year later, although treatment with RUTF continued beyond this date.

#### *9.3.4.1.1 Procedures*

All children that presented at Moyo House were either referred from the paediatric ward or were self-referred from the community. There was no active community screening for malnutrition nor any decentralised admission sites. At the NRU children were screened for severe malnutrition using anthropometry and a brief examination for pedal oedema. After identification, they underwent a medical screening and started to receive standard inpatient phase 1 treatment according to WHO (34) and Malawi National protocols. The child's medical and nutritional status and food intake was monitored closely throughout the duration of their inpatient stay. When appetite improved children were transferred to the recovery phase during which nutrient density of feeds was gradually increased. When these feeds were well tolerated, appetite was good and infections under control, milk feeds were replaced with RUTF.

HIV testing was intermittently available, dependent on available resources and ongoing studies at the time. When it was available it was offered after counselling of carers by an independent team. Results were recorded. HIV treatment programmes for children were not well established at the time of the study.

After discharge from the NRU each child returned to Moyo House once every two weeks to attend the outpatient clinic. Later in the study, in October 2003, a second outpatient clinic was established in Lirangwe, a rural health centre 25 km away from QECH. Any child living closer to this clinic was referred here to continue their outpatient treatment. At each visit to an outpatient clinic the child was seen by a doctor and/or nurse, underwent follow up nutritional and medical examinations and received a 2 week ration of RUTF and of a locally produced blended flour of maize and soya. The RUTF was prescribed as a 'medicine' for the recovering child and the blended flour was given as a family ration to try and prevent excessive sharing of the RUTF. In between clinic visits outreach workers followed up children at home that had defaulted from treatment. At these visits they checked the nutritional progress of the child and referred any who were ill or still malnourished back to the clinic.

#### *9.3.4.1.2 Admission and discharge criteria*

Children were admitted to the programme according to national protocol; if weight for height was less than or equal to 70% of the median NCHS reference weight-for-height and/or they presented with bilateral pitting oedema and/or their age was > 6 months and weight < 4kg. All children completed phase 1 treatment in the NRU. Once the child was seen to finish a test dose of RUTF s/he was discharged to the outpatient care programme

Children were discharged from the programme once the clinic nurse assessed that their weight for height was ≥ 85% of the reference weight-for-height on two consecutive clinic visits and that they were free from oedema and treatable infection.

#### *9.3.4.1.3 Dietary treatment*

In the NRU inpatient dietary treatment included an initial phase of feeding with Formula 75 at 100 kcal $kg^{-1}$ $day^{-1}$ followed by a transitional phase of feeding with Formula 100 at 125 kcal $kg^{-1}$ $day^{-1}$. RUTF was gradually introduced at the end of inpatient treatment. The child was discharged to outpatient care when s/he was eating 175-200 kcal $kg^{-1}$ $day^{-1}$ of RUTF. At each outpatient clinic each child received enough RUTF to provide them with 200-250 kcal $kg^{-1}$ $day^{-1}$ until their next clinic visit. In addition, all children in

outpatient care received a family ration of 2 kg of blended flour that provided 542 kcal $day^{-1}$.

#### *9.3.4.1.4 Medical treatment*

On admission to the NRU, all patients received medication according to the standard WHO and Malawi protocol for the treatment of severe malnutrition. This protocol consisted of a single oral dose of Vitamin A (100,000 I.U. <12 months age and 200,000 I.U. for all other age groups); a single oral dose of mebendazole (250mg for children aged between 12 and 24 months and 500 mg for all other age groups); and a single oral dose of Folic acid (5 mg). All patients also routinely received a broad-spectrum antibiotic. For most children this was amoxicillin 250mg three times daily . Dehydrated children were treated with ReSoMal, an oral rehydration solution specifically designed for the treatment of severe malnutrition. At each outpatient clinic children were reassessed and treated according to clinical findings.

### 9.3.4.2 Research methods

#### *9.3.4.2.1 Subjects*

This study analysed data from 1270 children admitted for treatment to Moyo House nutritional rehabilitation unit. Criteria for inclusion in analysis were:

1. Severe acute malnutrition according to WHO and national protocol classification (=weight for height less than or equal to 70% or -3 z scores of the NCHS reference and/or bilateral pitting oedema and/or age>6 months and weight<4kg)
2. Age more than 5 months.
3. Absence of any severe disability.

193 children admitted on to the programme fell outside these criteria for inclusion, leaving 1077 for the analysis.

#### *9.3.4.2.2 Data Collection*

This study was implemented as part of the day to day operation of an emergency feeding programme. The difficulties of implementing a programme in these circumstances and the pressures of the work meant that some of the data collection was incomplete.

On presentation to the NRU, patients were weighed, had their height measured by trained local nurses and were assessed for the presence of bilateral pitting pedal oedema. Those

with a WFH less than or equal to 70% of the reference weight-for-height and/or with bilateral pitting oedema, an age > 5 months and absence of any severe disability were admitted to the study. Other children that fell outside these criteria but were still considered sick enough to warrant treatment were provided with the full treatment described above but excluded from study analysis.

On admission to the NRU, a doctor performed a rapid clinical screen, assessing degree of pitting oedema, hydration, dysentery, diarrhoea, anaemia and signs of chest infection and filled out a patient monitoring card very similar to that used in Dowa, Malawi. At each follow-up visit to the outpatient clinic, a nurse recorded follow-up weight, extent of pitting oedema and clinical condition. Outcome (death in the programme, discharge alive, and default) was recorded on individual monitoring cards and in the programme's registers. An outcome and/or clinical condition for those defaulters that were followed up and found at home were also recorded on the patient's cards.

An independent consumer satisfaction survey was led by an MSc student of the Liverpool School of Tropical Medicine, UK. Data were collected through several interviews and focus group discussions (FGDs) with mothers of children admitted to the programme. Respondents were chosen randomly by drawing individual programme monitoring cards from the file. The interviews were conducted privately, using a structured questionnaire and lasted for between 20-30 minutes. Notes were made by a local research assistant who attended each interview. Each FGD included 5-6 mothers, lasted between 45-60 minutes and was taped on to cassette.

#### *9.3.4.2.3 Data coding*

HIV status was coded as positive if the test returned a positive result and negative if the test returned a negative result. Outcome data was coded as 'recovered', 'died', or 'defaulted'. Any child that was transferred to another paediatric ward in QECH was followed up and allocated to one of these three outcomes above.

Discharge outcomes were defined as:

***Death***

Death whilst registered on the programme (within two weeks of failing to attend the OTP).

***Recovered***

For two consecutive weeks:

- a weight-for-height of more than or equal to 85% of the median NCHS reference;
- and a MUAC of > 11cm (children > 75cm);
- and absence of bilateral pitting oedema;
- and absence of treatable infection

***Default***

Failure to attend treatment on two consecutive occasions

All defaulters were coded as either seen well, seen unwell or lost to follow up.

Missing data values were coded as missing.

Both the interview notes and the discussions on cassette were translated from Chichewa to English by the local research assistant and then summarised.

For additional research methods that describe measurements, equipment and precision; data collection; data coding and data analysis techniques see core methods section 8.4.

### 9.3.5 Results

Admission WFH data was recorded for 1044 and follow up weight change data for 791 of the 1077 admissions analysed in this study.

Table 7 presents patient admission profile. The sex distribution was similar ($p>0.05$), with 53.7% males and 46.3% females. 843 children (78.3%) suffered from oedematous malnutrition, (732 [68.0%] kwashiorkor and 111 [10.3%] marasmic-kwashiorkor), and 228 (21.2%) from marasmus.

**Table 7: Admission characteristics of children treated in study 2**

| Variable | | total | | marasmus | | marasmic kwashiorkor | | kwashiorkor | | > 6month < 4kg | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | median (IQ range) | n | median (IQ range) | n | median (IQ range) | n | median (IQ range) | n | median (IQ range) |
| age (months) | overall | 1077 | 24 (17-33) | 228 | 19 (13-25) | 111 | 20 (15-26) | 731 | 25 (19-36) | 6 | 9 (6-13) |
| | recovered | 626 | 24 (18-36) | 76 | 19 (14-26) | 42 | 19 (15-27) | 506 | 25 (19-37) | 2 | 11 (8-13) |
| | died | 276 | 21 (14-28) | 108 | 20 (13-27) | 47 | 18 (15-28) | 117 | 24 (16-32) | 4 | 8 (6-12) |
| | defaulted | 174 | 23 (16-28) | 44 | 18 (12-24) | 22 | 23 (15-25) | 108 | 24 (18-36) | 0 | |
| | | | mean (SD) | | mean (SD) | | mean (SD) | | mean (SD) | | mean (SD) |
| admission weight for height (z-scores) | overall | 1044 | -2.3 (1.3) | 226 | -3.7 (0.6) | 111 | -3.8 (0.6) | 705 | -1.7 (1.1) | 2 | -2.9 (0.1) |
| | recovered | 614 | -2.0 (1.2) | 76 | -3.5 (0.5) | 42 | -3.7 (0.6) | 495 | -1.6 (1.0) | 1 | -2.8 |
| | died | 260 | -3.1 (1.2) | 107 | -3.8 (0.7) | 47 | -3.9 (0.6) | 105 | -2.1 (1.0) | 1 | -3.0 |
| | defaulted | 170 | -2.5 (1.3) | 43 | -3.7 (0.5) | 22 | -3.7 (0.4) | 105 | -1.8 (1.1) | 0 | |

### 9.3.5.1 Overall outcomes by HIV status

Table 8 and Figure 9, the trial profile, presents outcome data stratified by HIV status.

**Table 8: Outcome by HIV status**

| | | total | | HIV + | | HIV - | | unknown | |
|---|---|---|---|---|---|---|---|---|---|
| | | n | (%) | n | (%) | n | (%) | n | (%) |
| outcome | overall | 1077 | | 186 | | 73 | | 818 | |
| | recovered | 626 | 58.1 | 64 | 34.4 | 50 | 68.5 | 512 | 62.6 |
| | died | 277 | 25.7 | 92 | 49.5 | 11 | 15.1 | 174 | 21.3 |
| | defaulted | 174 | 16.2 | 30 | 16.1 | 12 | 16.4 | 132 | 16.1 |
| | | | median (IQ range) | | median (IQ range) | | median (IQ range) | | median (IQ range) |
| length of stay (days) | overall | 1059 | 38 (17-62) | 185 | 41 (13-85) | 73 | 49 (27-82) | 801 | 37 (17-55) |
| | recovered | 626 | 49 (36-70) | 64 | 69 (50-109) | 50 | 63 (41-84) | 512 | 47 (36-64) |
| | died | 260 | 7 (3-18) | 91 | 15 (7-49) | 11 | 10 (7-23) | 158 | 5 (2-11) |
| | defaulted | 173 | 24 (13-50) | 30 | 36 (24-100) | 12 | 31 (20-83) | 131 | 21 (10-41) |
| weight gain (g/kg/day) | overall | 791 | 5.0 (2.7-7.6) | 110 | 3.2 (1.1-5.9) | 63 | 6.2 (3.2-8.4) | 618 | 5.0 (3.0-7.7) |
| | recovered | 585 | 5.2 (3.4-7.5) | 56 | 5.0 (3.2-7.0) | 45 | 6.9 (4.4-8.4) | 484 | 5.2 (3.3-7.5) |
| | died | 69 | 1.2 (0-5.1) | 38 | 1.1 (0-2.2) | 7 | 3.6 (0-9.3) | 24 | 3.4 (0-13.5) |
| | defaulted | 137 | 3.1 (0.8-8.6) | 16 | 2.4 (0.3-5.2) | 11 | 2.5 (0.2-7.9) | 110 | 3.9 (1.0-9.3) |

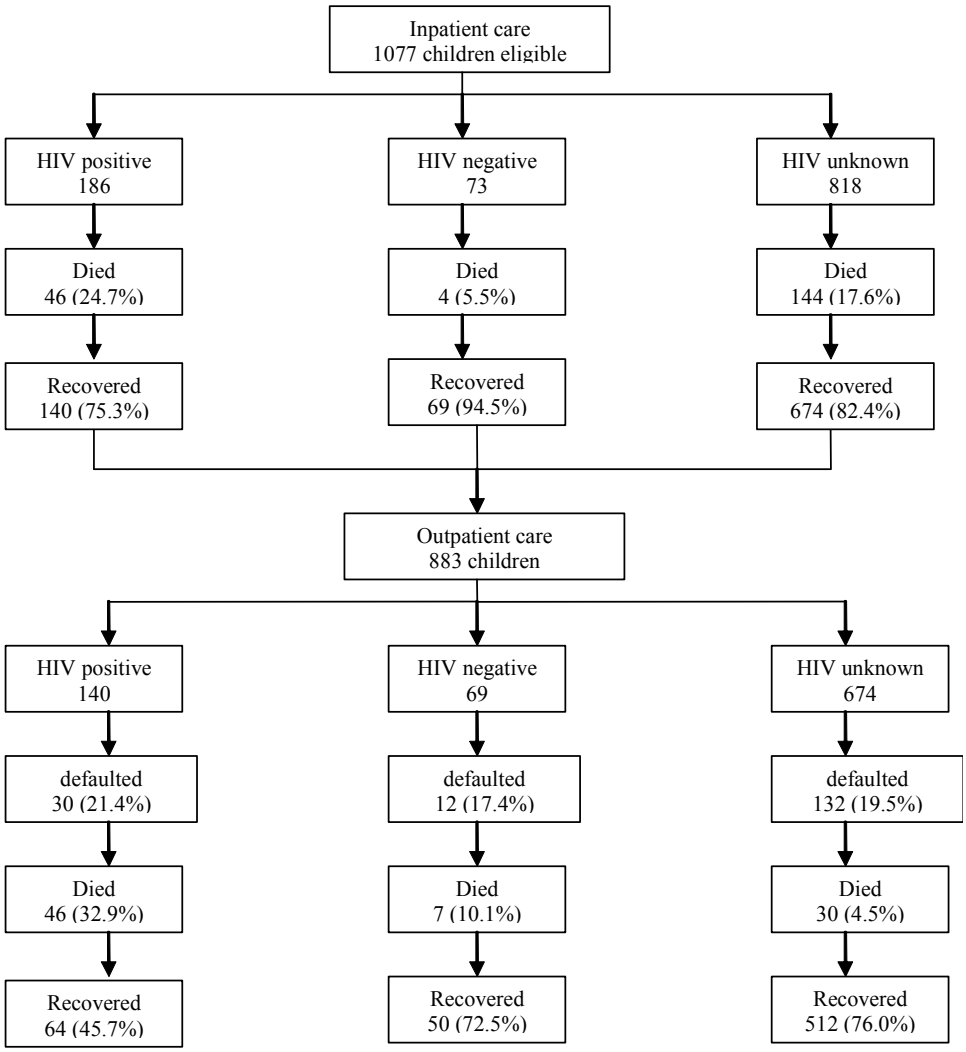



**Figure 9: The trial profile**

Overall recovery rate was 58.1%; case fatality rate 25.7%; and default rate 16.2%.

186 children (17.3%) were confirmed HIV seropositive. Confirmed HIV was significantly higher ($p<0.0001$) in marasmic children (90/228, 39.5%) than in those suffering from oedematous malnutrition (94/842, 11.2%).

HIV had significant impact on mortality. Of the total known HIV seropositive children, 92/186(49.5%) died vs. 11/73(15.1%) of known seronegative children ($p <0.001$). Of outpatient deaths 46/83(55.4%) were confirmed HIV positive.

#### 9.3.5.2 Outcomes by level of treatment

The overall case fatality rate was 25.7%, of whom 194/1077(18.0%) died whilst inpatients and 83/883(9.4%) died as outpatients.

103 (53.1%) of the inpatient deaths occurred within the first 4 days of admission (Figure 10).

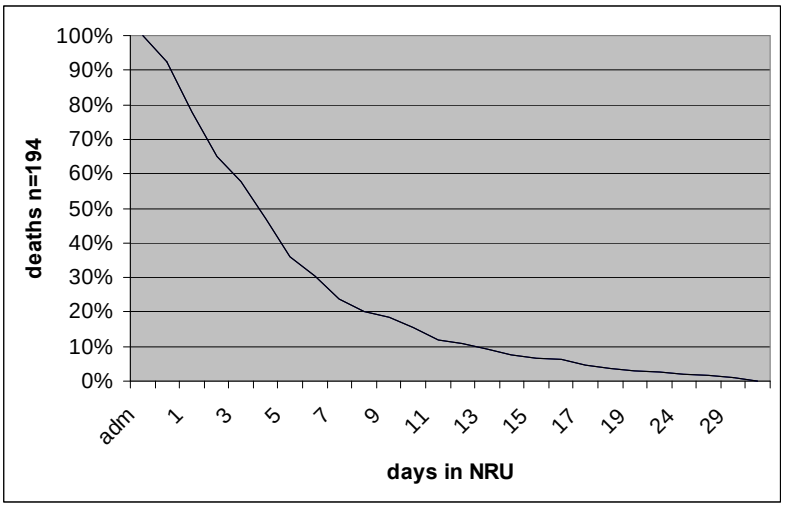



**Figure 10: Kaplan-Meier survival curve showing the timing of deaths in the NRU**

#### 9.3.5.3 Default

Of the 174 defaulters 84 (48.3%) were traced and a final outcome identified (See Figure 11). 90 (8.4%) of the children admitted on to the study were lost to follow up. The recovery rate rose to 63% when defaulted children who had nutritionally recovered by follow up were recoded as recovered.

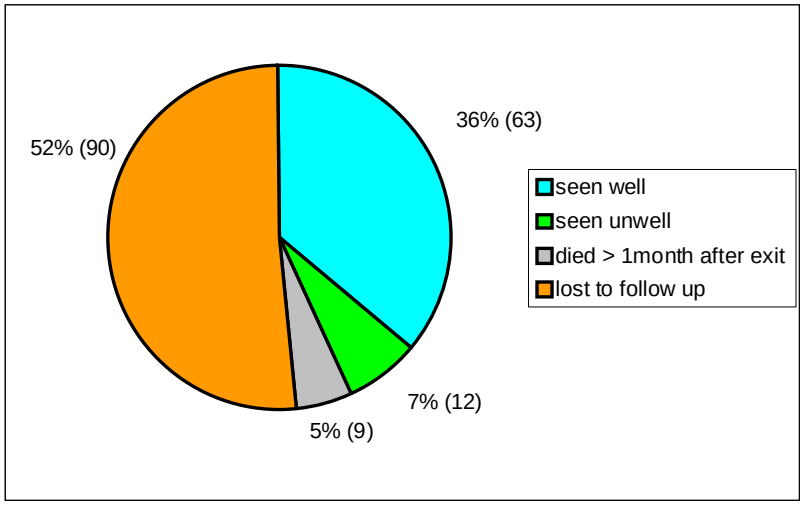



**Figure 11: Defaulter outcomes**

#### 9.3.5.4 Length of stay and weight gain

Overall, median [IQ range] length of stay in the programme for those children that recovered was 49 days [36-70]. Length of stay was longer for confirmed HIV sero-positive children (69 days [50-109]) than for HIV sero-negative children (63 days [41-84]) but not significantly so (Table 8). The median inpatient stay was 9 days [7-13] and outpatient stay was 36 days [28-59]. Overall, the median [IQ range] weight gain in the programme for children who recovered was 5.2 g kg-1 day-1 [3.4-7.5].

#### 9.3.5.5 Acceptability of care to programme participants

RUTF was widely accepted by children, including those with advanced HIV disease, and was more acceptable than milk based therapeutic feeds. In focus group discussion carers valued the short hospital stay and ongoing outpatient follow up. Transport costs and distance to the NRU were however prohibitive for some families.

### 9.3.6 Discussion

Overall programme mortality during this intervention remained high at 25.7% and did not meet the international standard of less than 10% for therapeutic care.

#### 9.3.6.1 Contributing factors to mortality

There are several factors that are likely to have contributed to this persistently high mortality rate. The high prevalence of HIV among malnourished children admitted to QECH and its association with mortality is well documented (101;106). In this study, 46% of inpatient deaths occurred in patients who were known to be HIV positive. However, as this study did not test for HIV routinely it is likely that at least some of the mortality in the group with unknown HIV status was also HIV related. Of the children who died in outpatient care 55.4% were confirmed HIV sero-positive. The programme mortality rate for confirmed HIV sero-negative children (15.1%) is lower but does not meet the Sphere international standard of less than 10%. This mortality is complicated however by the fact that they were particularly sick children that i.e. they had shown signs of infection that warranted an HIV test.

53.1% of inpatient deaths occurred within the first 4 days of admission (Figure 10). This suggests that children were very sick on arrival at the unit. Moyo House is a centralized nutritional rehabilitation unit that covers a large target area. Distance and high opportunity costs of travelling to and staying at the unit are likely to have delayed presentation. Qualitative data collected by FGD and interview from mothers of malnourished children receiving treatment showed a strong preference for more decentralised treatment to reduce the opportunity costs associated with care. The high default rates during this study also suggest some problems with acceptability by study participants. In addition, the study NRU location within a tertiary level referral hospital meant that a proportion of the unit's referrals came from the main emergency paediatric ward where malnutrition was secondary to other serious illness. This is likely to have resulted in a higher proportion of sicker children presenting here than at a more rural NRU. In the paediatric unit children did not receive any specialised nutritional treatment and this is likely to have further increased the time between onset of acute malnutrition and receiving appropriate treatment. Very sick children require complicated treatment regimes that increase staff workloads and require significant inputs. Although Queen Elizabeth Hospital is relatively well resourced compared to other hospitals in Malawi (89), staffing and resource levels were insufficient to implement certain aspects of the protocols, such as close 24 hour monitoring, that the WHO require for such children. Although the unit did decongest in comparison to previous years, early discharge and shorter inpatient stays did not completely solve the problem of overcrowding, and over night and at weekends there was often only one patient attendant for 90 children. This

finding reflects similar experience elsewhere in Africa where lack of human resources, in particular skilled staff, has been identified as a major limitation to reducing case fatality rates (87;92;158). In summary, the combination of high HIV prevalence, complex and late case presentation and staffing levels insufficient to meet high workloads are probably the main factors behind the persistently high mortality rate in this unit.

#### 9.3.6.2 Comparison of study outcomes with previous years

Several factors complicated comparison of our outcome data with previous years. Some monitoring data exists from the NRU programme that ran up to the introduction of RUTF but as there was no concrete definition of 'cure', children were discharged when they were 'clinically well' rather than at 80 or 85% weight for height and they were not followed up in the community. This study, through the outpatient component of the programme, put substantial resources in to following children up until discharge at 85%. Therefore, the author feels that in order to compare like with like, any comparison of these study data with previous monitoring data can only be made, tentatively, by comparing inpatient programme statistics from each period. In September 2002 an international NGO providing some technical support to the NRU undertook an audit of deaths in the unit, employing additional resources to ensure accurate recording of mortality data. Comparison of these data with data from the same season during our study, show a fall in mortality from 29% to 18% during our study, a rise in cure rate from 45% to 63% and a reduced average inpatient length of stay by 5 days. Although data were not available to control for the level of malnutrition between the two groups, this fall in mortality might be attributed to a number of plausible factors. During the period of the death audit in 2002-2003 there was a diarrhoeal epidemic that resulted in the deaths of 11 children over a 5 day period. During this study there was no outbreak of any infection recorded. Reduced nosocomial infection therefore, because of less ward overcrowding, could be one reason for the reduction in mortality. Less inpatients and decreased workload may also have helped health staff improve quality of care through better implementation of the WHO protocols on which they were trained. Staff morale was certainly seen to improve during this study with nursing staff requesting transfer to the unit at the annual staff rotation meetings: a phenomenon unheard of previously.

#### 9.3.6.3 Addressing mortality in the future

Although the introduction of ARVs should reduce mortality rates, it is unlikely that the unit will meet the international standard unless steps are taken to encourage earlier presentation. The outpatient treatment protocols used differed from those proposed by the full CTC model where access to services should be decentralised and a proportion of cases of SAM with no complications treated solely as outpatients. By contrast, the treatment in this study remained centralised and all cases of SAM were initially admitted as inpatients. This placed high demands on families accessing care and may have delayed presentation and increased default rates. Admitting all cases into inpatient care for phase 1 is also likely to be a contributing factor to overcrowding and cross infection and probably decreased the degree to which scarce medical and nutritional resources could be focused on the sickest patients.

In an effort to address some of these problems a rural outpatient clinic in Lirangwe, 25 kms north of QECH was set up 5 months in to the study. Although this did not address the problem of the high opportunity cost of initial access to treatment and overcrowding in the inpatient unit, it did reduce the opportunity costs for many mothers of attending follow up outpatient care. This appears to be reflected in a lower default rate in Lirangwe (4/44 9.1%) compared to that found overall (16.2%), although numbers are too small to demonstrate significance (9.1% 95% CI 0.6%, 17.6%). Recovery and mortality rates here were also much better than that found overall although this may be a reflection of the lower HIV prevalence rates in rural areas than one of any difference in presentation time.

Promoting earlier presentation and decreasing NRU congestion in Moyo House will need a change of treatment focus. Instead of designing the programme from the perspective of the health care provider and simply extending services out from the hospital into the community, the programme needs to start by building the understanding and participation of communities. Allowing families to access care in local clinics would reduce their opportunity costs, and in doing so may encourage earlier presentation and reduce the proportion who present with medical complications. The use of RUTF as an outpatient treatment in this study was relatively effective. If children survived inpatient treatment and were not HIV positive mortality was low: 5.0% (37/743). This suggests that such a change of treatment focus could be successful. This would subsequently allow the programme to have a stronger focus on coverage, an aspect of programme

impact that was not considered in this study. Treating a smaller proportion of cases as inpatients would allow scarce hospital inpatient resources to be reserved for the sickest children who require the intensive treatment provided by the WHO phase 1 protocol in order to survive. Any decentralised nutrition intervention in a high HIV prevalence area such as this would need to ensure access to HIV and other diagnostic and treatment facilities using well defined referral criteria. However, reducing the opportunity costs of programme attendance is especially important in the context of the HIV epidemic in Malawi. HIV positive children took, on average, 20 days longer to recover than HIV negative children in this programme. Spending large amounts of time attending treatment programmes can have a particularly negative impact on the food and economic security of this group.

## *9.4 Study 3, Central Malawi: the impact of combining decentralised outpatient treatment with inpatient care and triage on clinical outcomes.*

### 9.4.1 Introduction and aims

The results of study two suggest that, HIV disease aside, effectiveness as measured by recovery and mortality rates might be improved by a change in programme design. Study three therefore went on to test this hypothesis by implementing the full CTC model i.e. one that included inpatient phase one care *only* for those suffering from SAM with complications; a system of triage to identify these complicated cases and decentralisation and social mobilisation techniques to encourage early presentation and compliance. This study took place in central Malawi, an area known to have much lower rates of HIV than those seen in the south.

It aimed to answer questions around the clinical effectiveness of the CTC model for different groups of children, how best to deliver treatment, the acceptability of the treatment approach to participants and communities and to examine how utilisation and programme coverage could be maximised.

This study (Study 3) focuses particularly on the clinical effectiveness of treatment provided, whilst Chapter 9 Study 4, an output of the same programme as that presented here, begins to develop understanding of the issues around maximising coverage and programme utilisation.

### 9.4.2 Objective

To examine the clinical effectiveness of the CTC model of treatment for different age groups, degree of malnutrition and by type (direct outpatient or combined inpatient/outpatient) of treatment.

### 9.4.3 Background

Malawi is one of the poorest countries in the world and has seen a fall in the gross national income per capita for several years (159).

The country has long had a problem with food insecurity and malnutrition. In a "normal" year, approximately 5% of children under 5 years of age, equivalent to about 117,000, are acutely malnourished at any point in time (6). Historically, growth monitoring programmes using weight for age have been the main approach for identification of malnutrition at community level. Any children identified as suffering from severe acute malnutrition were referred to nutritional rehabilitation units (NRUs) for inpatient treatment. These units were regularly very overcrowded and understaffed, commonly used outdated protocols, and, where data were available, regularly showed high (> 20%) mortality rates. It was against this background of chronic poverty and poor quality under resourced health care that in February 2002, the Malawi government declared a national nutritional emergency and the UN launched an international appeal for emergency assistance.

In response to the crisis the national Ministry of Health and Population (MoHP) and the humanitarian community began to develop strategies for the treatment of the large numbers of children suffering from SAM that were predicted. Nationally, a strategy of upgrading the 115 NRUs across the country was adopted, with the aim of each NRU being able to provide centre-based therapeutic treatment according to WHO protocol by the end of the year. UNICEF and several non-governmental organisations (NGOs) provided therapeutic products, training and support for this strategy. At the same time, Valid International presented the community-based therapeutic care approach to the MoHP as a strategy that could potentially be set up quickly through existing NRUs and health centres to achieve coverage of the dispersed rural population that existed in Malawi. As a result, the MoHP gave Concern and Valid permission to pilot CTC in two districts in the central Region. The author supported design and set up during 2002 from Sudan and arrived in Malawi as the research nutritionist at the beginning of 2003 to oversee implementation and data collection. It was agreed that the main focus of the operational research should be in one of the two Districts, Dowa, and that a process of programme monitoring and lesson learning in Dowa would be applied directly to the CTC programme in neighbouring Nkhotakota District.

#### 9.4.3.1 Dowa District

Dowa district is 50km to the north east of Lilongwe in the central region of Malawi. It covers an area of 2,770 sq km, has a population of around 500,000 people, including an

estimated 100,000 children under five years of age, and a population density of 135 persons per $km^2$. There are some good tarmaced roads that run east-west and north-south and many dirt tracks connect most villages that are easily traversed but frequently become impassable during the height of the rainy season.

The population is almost entirely subsistence farmers cultivating mainly maize, with some additional cassava, sweet potato, beans and vegetables. HIV/AIDS is an increasing problem in the District, although it remains more obvious in the few urban and more densely populated areas. Cholera and Falciparum malaria are also seasonally common with malaria being the most frequent cause of death at most health facilities.

The district has a weak medical and nutritional referral infrastructure with one 140-bed district general hospital, 3 small mission hospitals, thirteen health centres and two dispensaries. Before the CTC programme, facilities for inpatient nutritional rehabilitation, as in the rest of Malawi, were of poor quality. Nutrition Rehabilitation Units (NRUs) were rudimentary with only one or two staff members who had no training in modern techniques of screening and treating severe malnutrition. They had no beds, little or no equipment; no system of supervision and inappropriate food commodities.

By contrast, community outreach capacity for health was good. In Dowa there were 100 health posts each with two to four Health Surveillance Assistants (HSAs), several growth monitoring volunteers and substantial numbers of community level hygiene assistants. In the villages most children had a "health passport" that demonstrated systematic vitamin A distribution and good vaccination coverage providing evidence of the functionality of this system. This infrastructure represents an important resource around which this programme was designed.

## 9.4.4 Methods

### 9.4.4.1 Programme Methods

The programme started in August 2002. All outpatient and inpatient treatment was delivered through the existing MoH District Hospital, health centres and NRUs in Dowa.

#### *9.4.4.1.1 Staffing*

For the first 18 months of implementation the programme was supported by one Concern doctor, one nutritionist and 10 health workers, recruited and trained by the Valid research staff before programme set up. These workers split in to teams and rotated around the NRUs and health centres in the District to support Ministry of Health staff to register all admissions and to deliver inpatient and outpatient treatment. After 18 months the number of supporting Concern staff and the frequency of their support visits to health facilities began to reduce. The MoH programme implementing staff included:

- Health assistants, 1 in most health centres, managed health facilities and carried out many of the outpatient consultations, particularly for the more serious complicated cases. They were medically trained for 4 years to 1 level below doctor.
- Nurses, 1 in most health centres and 1-3 in most NRUs, assisted with management of health facilities, carried out outpatient and inpatient consultations, patient monitoring in NRUs and ran clinics such as growth monitoring. They were medically trained for 3 years to 1 level below health assistant.
- Health surveillance assistant (HSA), 2-4 based at most health facilities, were responsible for assisting with clinics such as growth monitoring and any community-based work such as vaccination, tuberculosis surveillance, cholera prevention and health promotion. Typically they had been through at least 3 months training.
- Home craft workers, 1-3 based at each NRU, were responsible for making up feeds, supervising meal times and assisting nurses with patient monitoring. They had typically had some training although this had been irregular.
- Other community-based workers such as growth monitoring volunteers (GMVs) and hygiene assistants were voluntary workers that assisted the HSAs with their community-based work. They had typically had some training although this had been irregular.

At the beginning of this programme, all government workers received two days training on the treatment of severe malnutrition from Concern and Valid staff and were supervised on site thereafter.

At programme start, 25 paid outreach workers were trained by Concern Worldwide staff to work at community level and use MUAC to screen and refer children to their nearest health centre or NRU. Gradually, many of the HSAs and other community workers (eg growth monitoring volunteers) in the District were also trained in the use of MUAC and this job was handed over to them. By 6 months in to the programme, 110 HSAs and community workers had been trained and were using MUAC to screen children as part of their community-based activities.

#### *9.4.4.1.2 Community Mobilisation*

About 4 months in to programme implementation, after input from a social anthropology team, meetings were set up with traditional authority leaders and community health workers to explain the programme approach and target groups. A message sheet in the local language (Chichewa) was also produced and was used by traditional leaders to explain the programme and the signs of severe acute malnutrition to be aware of (recent weight loss and/or swelling) to their village leaders. This enabled these key individuals at community level to get involved with referral of children that they considered to be at risk.

#### *9.4.4.1.3 Procedures*

(Appendix 6, section 14.6 gives examples of the most important programme procedures developed for staff implementing CTC in Dowa)

The programme in Dowa supported four referral NRUs (1 located within the District Hospital) to provide stabilisation centre (SC) protocols according to WHO and Malawi inpatient phase 1 national protocols (29) and 17 health centres to provide outpatient therapeutic care according to CTC protocol. Figure 12 shows the location of NRUs that provided inpatient stabilisation and of health centres that provided outpatient care. For the first 5 months (1st August-31st December 2002) whilst numbers allowed, all children admitted to the programme received phase 1 treatment in the hospital or one of the supported NRUs, followed by outpatient care in the OTP. From 1st January 2003, triage criteria were introduced that allowed children suffering from severe acute malnutrition with no complications to be treated directly in the OTP.

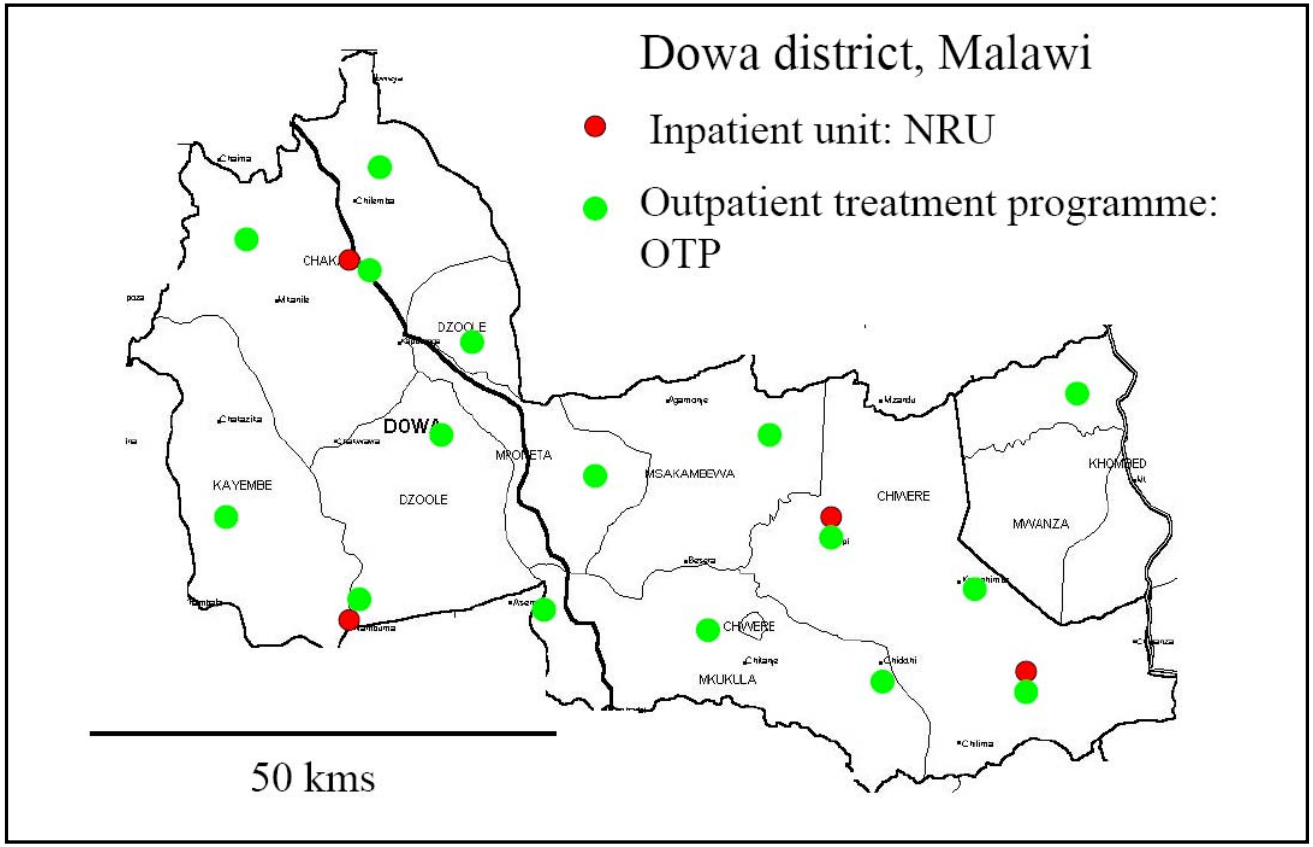



**Figure 12: Map of Dowa District showing location of NRUs and OTP sites used in study 3**

Children were screened and referred by paid outreach workers or HSAs using MUAC or by village/community leaders who referred children on the basis of visible wasting and swelling. When children arrived at an NRU or health centre a health worker, usually a trained HSA, measured their weight, height, and MUAC and examined for pedal oedema. A nurse did a medical examination and if severe acute malnutrition was confirmed registered the child on to the programme. All registered children received a unique identification number and a monitoring card (see section 8.4.3). At health centres it was the attending HSAs that performed and recorded the majority of the anthropometric measurements and gave out the food, and the nursing/health assistant staff that medically examined the children, administered any treatment and completed the monitoring card. At the stabilisation centres it was the attending home craft workers that performed and recorded the majority of the anthropometric measurements and gave out the food, and the nursing staff that medically examined the children, administered treatment and filled out the monitoring card.

#### *9.4.4.1.4 Screening criteria*

Where MUAC was used for screening in villages, any child > 1 year old with a MUAC < 13cm was referred to their nearest health centre for assessment. Referral of children < 1 year was made based on clinical signs of malnutrition. Later in the programme, as community leaders became more involved in the identification process, children were also referred on the basis of recent acute weight loss or visible swelling (oedema).

#### *9.4.4.1.5 Admission and Discharge Criteria*

Admission and discharge criteria followed the Malawi national protocol for the treatment of SAM as closely as possible. Children more than or equal to 6 months old were admitted to the programme if:

- their weight for height was less than or equal to 70% of the median NCHS reference weight-for-height;
- and/or their MUAC was less than or equal to 11cm (children > 75cm)
- and/or they presented with bilateral pitting oedema.

Discharge from the outpatient therapeutic programme (OTP) in to the supplementary feeding programme (SFP) took place when the child demonstrated all of the following for two consecutive weeks:

- a weight-for-height of more than or equal to 85% of the median NCHS reference;

- and a MUAC of > 11cm (children > 75cm);
- and absence of bilateral pitting oedema;
- and free from serious infective illness.

#### *9.4.4.1.6 Triage and Referral Criteria*

During the first 5 months of the programme, all children were referred first to one of the NRUs for phase 1 inpatient treatment. Discharge from the NRU to the OTP occurred when:

- the child appeared well;
- was eating required amount of RUTF according to OTP protocol or suckling at mother's breast with a good appetite;
- oedema was decreasing and only on feet;
- weight was stable or increasing;
- general medical problems such as fever and serious infection were under control.

Triage was introduced from January 2003. This allowed children suffering from SAM with no complications to be referred directly to OTP treatment and those suffering from SAM with complications to be referred first to an inpatient unit for stabilisation. Table 9 shows these criteria and means of measurement for each sign that health workers used to decide the level of treatment that each child required. These criteria were primarily based on the WHO criteria for moving from the phase 1 diet of F75 in inpatient care to the rehabilitation diet of F100. The WHO criteria uses the return of appetite as the most important sign "*that infections are coming under control, the liver is able to metabolize the diet, and other metabolic abnormalities are improving*" (34). We therefore adopted the use of appetite as the most important sign that a child's clinical condition was sufficiently stable for treatment in outpatient care with a food of nutritional equivalence to F100 and the absence of appetite (or anorexia) as the most important sign that a child required urgent referral to hospital. We also added all of the vital signs (apart from those referring specifically to the presence of severe acute malnutrition) from the IMCI guidelines used to indicate the need for immediate referral to a hospital (45;160), these include: convulsions; unconsciousness or lethargy; and dehydration due to vomiting or diarrhoea (together referred to as 'general danger signs' by IMCI); difficulty breathing (assessed by respiration rate); fever or hypothermia; and ear discharge (together referred to as 'main symptoms' by IMCI); and severe anaemia. The presence of any one of these signs was sufficient for referral to an NRU.

**Table 9 Signs and criteria used to triage children to different levels of treatment in Dowa, Malawi**

| SIGN | REFERAL to NRU | REFERRAL TO OTP |
|---|---|---|
| OEDEMA | **grade +++ or ++** | **No oedema or grade +** |
| AGE | **<6 months** | **> 5 months** |
| APPETITE/ANOREXIA | **No appetite *or* unable to eat** | **Tries RUTF and asks for more** |
| AXILLIARY TEMPERATURE | **Fever: >= 39$^{o}$C**<br>**Hypothermia: <= 35$^{o}$C** | **> 35$^{o}$C <39$^{o}$C** |
| RESPIRATION RATE | **≥ 60 respirations/minute for under 2-months**<br>**≥ 50 respirations/minute from 2 to 12 months**<br>**≥ 40 respirations/minute from 1 to 5 years**<br>**≥ 30 respirations/minute for over 5 year-olds** | **Normal range** |
| HYDRATION STATUS | **As reported by carer: recent history of acute diarrhoea &/or vomiting &/or fever; *and* no urine output; *and* no tears; *and* mouth dry; *and* eyes recently sunken**<br>***Or* Fontanelle depressed** | **Absence of signs of severe dehydration** |
| ANAEMIA | **< 7 g/100ml *Or***<br>**Severe palmar pallor *and* difficulty breathing** | **≥ 7g/100ml *Or***<br>**Good nail *and* good eye colour** |
| SUPERFICIAL INFECTION | **Discharges from ears; *or* extensive absesses; *or* extensive sores** | **No serious infection** |
| ALERTNESS | **Very weak; *or* apathetic; *or* unconscious**<br>**Fitting/convulsions** | **Alert *and* conscious** |

Criteria for discharge from the NRU to the OTP remained the same.

#### *9.4.4.1.7 Dietary Treatment*

In the 4 stabilisation centres dietary treatment was provided according to WHO protocol (29) This included phase 1, 24 hour feeding with Formula 75 at 100 kcal $kg^{-1}$ $day^{-1}$ using 8 feeds per day. RUTF was introduced when the following conditions were satisfied:

- been on f-75 for 3 days
- good appetite
- oedema reducing
- no serious medical problems i.e. respiratory distress, vomiting, dehydration

Later in the programme the '3 day rule' i.e. only introducing RUTF after 3 days of F75 was stopped, and health workers relied on the clinical signs listed above. RUTF was introduced in a transitional phase whereby F75 feeds were continued and the RUTF given cautiously to ensure acceptability. Once a child was eating the required amount of RUTF according to OTP protocol F75 feeds were stopped.

RUTF was provided in proportion to a child's weight (rather then the set quantity delivered during study 1). The ration size was read from a chart by the health worker and was calculated to deliver 175-200 kcal $kg^{-1}$ $day^{-1}$ and 4-5g protein $kg^{-1}$ $day^{-1}$ as recommended by WHO for the second phase of therapeutic treatment (see 14.7 Appendix 7: RUTF ration chart for the OTP, Dowa). Children also received a 3.75kg ration of blended flour (corn soya blend) to reduce the risk of sharing of the RUTF. This provided an additional 984 kcal $day^{-1}$ of energy.

Any severely malnourished infant less than 6 months old was treated according to WHO and Malawi national protocol. This included Formula 75 at 100 kcal $kg^{-1}$ $day^{-1}$ using 8-10 feeds per day in phase 1 and Formula 100 in phase 2. Every effort was made to re-establish breastfeeding where this was possible. No infant in this age group was given RUTF.

Formula 100 was used for any child that did not tolerate the RUTF. This was given according to WHO protocol (34).

#### *9.4.4.1.8 Medical Treatment*

All medical treatment followed protocols as specified in the WHO and the Malawi national protocol for the treatment of SAM (see 14.8 Appendix 8: Medical protocol for the CTC programme, Dowa). This consisted of a single oral dose of Vitamin A (100,000 I.U. <12 months age and 200,000 I.U. for all other age groups, a single oral dose of Folic acid (5 mg) and a single oral dose of Fansidar. All patients also routinely received a broad-spectrum antibiotic. For most children this was amoxycillin 60 mg $kg^{-1}$ $day^{-1}$ 3 times daily. Dehydrated children were treated with ReSoMal, an oral rehydration solution specifically designed for the treatment of severe acute malnutrition. A single oral dose of albendazole (200mg for children aged between 12 and 24 months and 400

mg for children > 2 years) was given to each child on discharge to outpatient care or, for those children admitted directly to outpatient care, on admission. All medication was administered by either NRU or OTP nursing staff with the exception of the antibiotic which, for those children that were admitted directly in to the OTP, was administered by the carer. The OTP nurse instructed each carer on when and how to give the drug. Either a calibrated spoon or an empty syringe body was provided to each mother to facilitate dose measurement, i.e. staff marked on the syringe body how much antibiotic needed to be given each day and demonstrated pulling up the correct amount and administering this in to the child's mouth.

#### *9.4.4.1.9 Follow up in the OTP*

At each return visit to the OTP the child was seen by a nurse, underwent follow up nutritional and medical examinations and received a 1 week ration of RUTF and of the corn soya blend mix. OTP staff used the 'Action Protocol' described in Appendix 9 (see section 14.9) to either:

- continue with OTP treatment where the child was responding well;
- to refer back to inpatient treatment for further assessment where the child was not responding to treatment;
- or to arrange a home visit where closer monitoring seemed necessary.

Trained HSAs or community volunteers/growth monitors followed up children at home if they defaulted from treatment. At home visits the community worker checked the nutritional progress of the child and referred any who were ill or still malnourished back to the nearest OTP treatment site.

#### *9.4.4.1.10 Education*

There were a number of basic education messages used to promote the recovery of the child. These messages were discussed with the mother at each OTP visit, usually during the medical assessment by the OTP nurse or by an attending HSA. At the core of this education was the importance of prioritising the RUTF for sick children over the blended flour and other local foods, and the importance of continuation of breastfeeding where appropriate. (see 14.10 Appendix 10: Education message sheet for OTP, Dowa)

#### 9.4.4.2 Research Methods

##### *9.4.4.2.1 Subjects*

The study population came from 1672 children admitted for treatment to the Dowa CTC programme between 1st August 2002 and the 31st December 2003. Criteria for inclusion in analysis were:

- Severe acute malnutrition according to WHO and Malawi national guideline (WFH less than or equal to 70% or -3 z scores of the NCHS reference and/or bilateral pitting oedema and/or MUAC < 11cm for children aged > 1 year and/or age > 6months, weight < 4kg)
- Age more than 5 months.
- Absence of any severe disability

100 children admitted on to the programme fell outside these criteria for inclusion leaving 1572 for the study analysis.

##### *9.4.4.2.2 Data Collection*

This study was implemented as part of the day to day operation of an emergency feeding programme. The difficulties of implementing a programme in these circumstances and the pressures of the work meant that some of the data collection was incomplete.

On presentation to a NRU or to the OTP site, patients were weighed, had their height measured by trained health staff and were assessed for the presence of bilateral pitting pedal oedema. Those that fulfilled the admission criteria were admitted in to the study. Other children that fell outside these criteria but were still considered sick enough to warrant treatment were provided with the full treatment described above but excluded from study analysis.

On admission to the NRU or to the OTP, a nurse performed a rapid clinical screen, assessing the degree of pitting oedema, hydration, diarrhoea, anaemia and signs of chest infection and filled out a patient monitoring card (see Appendix 3: The monitoring card used in the OTP, Dowa, Malawi). At each follow-up visit to the outpatient clinic, a nurse recorded follow-up weight, extent of pitting oedema and clinical condition. Outcome (death in the programme, discharge alive, default and non responder) was recorded on individual monitoring cards and in the programme's registers. An outcome and or

clinical condition for those defaulters that were followed up and found at home were also recorded on either the patient cards or in register books.

#### *9.4.4.2.3 Data coding*

Outcome data were coded as either 'recovered', 'died', 'default' or 'non responder'.

***Death***

Death whilst registered on the programme (within two weeks of failing to attend the OTP).

***Recovered***

Recovery was defined as discharged from the OTP after field staff assessed that the patient had fulfilled the following criteria for 2 consecutive weeks:

- a weight-for-height of more than or equal to 85% of the median NCHS reference;
- and a MUAC of > 11cm (children > 75cm);
- and absence of bilateral pitting oedema;
- and free from serious infective illness.

***Non responder***

Failure to attain recovery criteria after 122 days in the programme

***Default***

Failure to attend treatment on two consecutive occasions

Where ever possible defaulters were followed up at home and were coded in to one of the following categories:

- Seen well
- Died > 2 weeks < 1 month after default
- Died > 1 month after default
- Moved to an address outside Dowa
- Not found, lost to follow up

Any child that was transferred out of the programme to another medical facility either returned for treatment to the CTC or was followed up at the facility. In each case they were coded according to final outcome.

#### *9.4.4.2.4 Data analysis*

Programme outcomes were compared with the international Sphere standards for therapeutic care. The observed mortality rate was compared with the "expected" case fatality rate calculated with Prudhon's index (151) (see section 8.4.7.4). Prudhon's equation used to calculate "Prudhon's index" was calculated in Excel (146) using the formula:

1/ (1 + EXP (- (20.63 – 9.99*LOG(WT) / (HT*1.74)) +(1.36*OED)))

Where WT = weight; HT = height; OED = the presence (coded 1) or absence (coded 0) of oedema.

The Yates corrected Chi square test (148) was used to compare proportions, with the Fisher's exact test adopted for any comparison that contained a cell < n=5. In describing and comparing continuous data such as age, WFH z scores and weight gains, a combination of means and medians were used. If the data distributions approximated to a 'normal distribution', population means are quoted and comparisons made with the students t test (ANOVA). If the distributions were skewed, population median values were used and comparisons made with the Wilcoxon rank-sum (Mann-Whitney U) test performed by SPSS.

To control for seasonal variation in outcomes for an examination of the predictors of mortality and the impact of triage, outcomes from Aug-Dec 2002 (not triaged) are compared with the same 6 months the following year when children were triaged (section 9.4.4.1.6). Univariate assessment of factors related to death and recovery were done with the Fisher's exact test and a two-sided p-value. Odds ratios and 95% confidence intervals were obtained by the 'crosstabs' function in SPSS. Significant and borderline significant factors at the level of $p < 0.09$ from the univariate analysis of factors related to recovery were included in the multivariate analyses for recovery and, as a sub analysis, for mortality. To assess the association of clinical features at presentation and triage, with recovery and mortality, logistic regression analysis was performed by the 'enter' method of the binary logistic function in SPSS.

For additional research methods that describe measurement techniques, equipment and precision; data collection and supplementary data coding and data analysis techniques see core methods section 8.4.

## 9.4.5 Results

### 9.4.5.1 Admission characteristics

Admission data is presented in Table 10. Weight for height data was collected for 1527 participants and age for 1539. The participant sex ratio was similar: 50.6% female and 49.4% male. The median [IQ range] age of all participants was 26 [18-36] months. It was also 26 [19-36] months for girls and 26 [17-36] months for boys. 954 (60.7%) of admissions were kwashiorkor, 127 (8.1%) marasmic kwashiorkor, 254 (16.2%) marasmic and 220 (14.0%) children had either low MUAC or were > 6 months and less than 4kg. Children with kwashiorkor were older than wasted children (32 [24-42] months vs. 18 [13-24] months $p<0.001$). Overall, mean [SD] weight for height ratio at admission, in z scores, was -1.9 [1.3]. Mean scores at admission were -1.2 [1.0] for those children with kwashiorkor, -3.5 [0.4] for marasmic, -3.4 [0.5] for marasmic kwashiorkor, -2.5 [0.6] for children with low MUAC and -1.7 [0.6] for children <4kg. The weight for height score of this last group implies that these children were only mildly wasted, and likely to be stunted as a result of intra uterine growth retardation. Mean z score at admission for all survivors was -1.7 [1.3] and for patients who died was -2.2 [1.3].

**Table 10: Admission characteristics of children treated in study 3**

| Variable | | total | | kwashiorkor | | marasmus | | marasmic kwashiorkor | | muac <11cm | | > 6month < 4kg | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | median (IQ range) | n | median (IQ range) | n | median (IQ range) | n | median (IQ range) | n | median (IQ range) | n | median (IQ range) |
| age (months) | overall* | 1539 | 26 (18-36) | 945 | 32 (24-42) | 248 | 18 (13-24) | 126 | 23 (17-31) | 148 | 24 (15-29) | 65 | 8 (7-10) |
| | recovered | 1151 | 28 (20-36) | 777 | 32 (24-42) | 148 | 18 (13-24) | 70 | 24 (18-31) | 101 | 25 (16-31) | 52 | 8 (7-10) |
| | died | 111 | 28 (21-42) | 66 | 36 (24-50) | 14 | 23 (13-25) | 16 | 29 (19-34) | 11 | 21 (13-36) | 4 | 8 (7-9) |
| | non responder | 141 | 20 (14-27) | 34 | 28 (20-36) | 57 | 20 (14-26) | 22 | 18 (14-26) | 22 | 17 (13-24) | 4 | 9 (8-10) |
| | defaulted | 136 | 24 (14-36) | 68 | 28 (20-36) | 29 | 14 (12-24) | 18 | 23 (17-34) | 14 | 21 (16-31) | 5 | 12 (12-13) |
| | | | mean (SD) | | mean (SD) | | mean (SD) | | mean (SD) | | mean (SD) | | mean (SD) |
| admission weight for height (z-scores) | overall** | 1527 | -1.9 (1.3) | 926 | -1.2 (1.0) | 254 | -3.5 (0.4) | 127 | -3.4 (0.5) | 155 | -2.5 (0.6) | 65 | -1.7 (0.6) |
| | recovered | 1137 | -1.7 (1.3) | 770 | -1.1 (1.0) | 150 | -3.5 (0.4) | 71 | -3.4 (0.5) | 106 | -2.4 (0.7) | 52 | -1.6 (0.7) |
| | died | 105 | -2.2 (1.3) | 59 | -1.5 (1.1) | 15 | -3.5 (0.4) | 16 | -3.6 (0.6) | 11 | -2.6 (0.6) | 4 | -1.6 (0.4) |
| | non responder | 139 | -2.9 (1.0) | 31 | -1.7 (1.2) | 58 | -3.5 (0.4) | 22 | -3.3 (0.4) | 24 | -2.7 (0.5) | 4 | -1.6 (1.0) |
| | defaulted | 146 | -2.4 (1.1) | 66 | -1.9 (0.8) | 31 | -3.5 (0.5) | 18 | -3.5 (0.4) | 14 | -2.7 (0.5) | 5 | -2.0 (0.5) |

* Age not available for 33 out of 1572 children

** Weight and/or height not available for 45 out of 1572 children

#### 9.4.5.2 Mortality and recovery

Table 11 shows outcome data. Overall, 1167 children (74.2%) recovered, with a median [IQ range] time to recovery of 42 [28-71] days and 115 children (7.3%) died with a median time to death of 11 [4-28] days.

#### 9.4.5.3 Default

144 children (9.2%) defaulted with a median stay in the programme of 21 [7-42] days. At baseline children that defaulted were more likely (borderline significance) to have marasmus kwashiorkor or marasmus ($p= 0.05$ & $0.07$ respectively) and were more wasted (difference between groups: -0.7 WFH z score $p<0.001$) than children that recovered.

#### 9.4.5.4 Non response

146 children (9.3%) were classified as non responders. Their median stay in the programme was 154 [140-182] days.

#### 9.4.5.5 Outcomes against international standards

Table 12 shows study outcomes compared with the Sphere standard indicators (72) for therapeutic feeding. Both mortality and default rates were considerably better than those stipulated by Sphere. The study recovery rate was just outside the Sphere standard indicator.

**Table 11: Outcomes by category of malnutrition**

| | | total* | | Kwashiorkor | | Marasmus-Kwashiorkor | | Marasmus | | MUAC<11cm | | >6 months <4kg | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) |
| **outcome** | overall | 1572 | 100 | 954 | 100.0 | 127 | 100.0 | 254 | 100 | 155 | 103 | 65 | 102 |
| | recovered | 1167 | 74.2 | 784 | 82.2 | 71 | 55.9 | 150 | 59.1 | 106 | 68.4 | 52 | 80.0 |
| | died | 115 | 7.3 | 68 | 7.1 | 16 | 12.6 | 15 | 5.9 | 11 | 10.4 | 4 | 7.7 |
| | non-responder | 146 | 9.3 | 34 | 3.6 | 22 | 17.3 | 58 | 22.8 | 24 | 15.5 | 4 | 6.2 |
| | defaulted | 144 | 9.2 | 68 | 7.1 | 18 | 14.2 | 31 | 12.2 | 14 | 9.0 | 5 | 7.7 |
| | | | median (IQ range) | | median (IQ range) | | median (IQ range) | | median (IQ range) | | median (IQ range) | | median (IQ range) |
| **length of stay (days)** | overall | 1537 | 42 (28-71) | 939 | 42 (28-56) | 126 | 64 (42-98) | 247 | 70 (42-112) | 149 | 56 (35-84) | 63 | 56 (42-90) |
| | recovered | 1165 | 42 (28-69) | 782 | 42 (28-56) | 71 | 63 (42-84) | 150 | 62 (42-84) | 106 | 56 (42-76) | 52 | 56 (42-84) |
| | died | 109 | 11 (4-28) | 64 | 11 (4-26) | 16 | 11 (4-27) | 14 | 13 (3-42) | 11 | 25 (12-56) | 4 | 19 (8-35) |
| | non-responder | 137 | 154 (140-182) | 33 | 161 (135-182) | 22 | 158 (140-205) | 55 | 154 (140-189) | 19 | 140 (136-166) | 4 | 134 (126-162) |
| | defaulted | 126 | 21 (7-42) | 60 | 19 (9-42) | 17 | 37 (29-76) | 28 | 22 (9-55) | 13 | 14 (6-34) | 3 | 21 (4-90) |
| **weight gain (g/kg/day)** | overall | 1501 | 4.8 (2.5-7.5) | 904 | 4.8 (2.3-7.4) | 123 | 5.6 (3.3-8.1) | 248 | 4.8 (2.8-7.9) | 154 | 3.9 (2.0-6.4) | 64 | 6.0 (3.8-8.3) |
| | recovered | 1128 | 5.4 (3.4-7.9) | 753 | 5.0 (2.9-7.5) | 69 | 6.6 (5.0-9.6) | 147 | 6.6 (4.4-9.2) | 106 | 4.7 (3.4-7.3) | 52 | 6.2 (4.7-8.3) |
| | died | 104 | 0.0 (0-6.1) | 58 | 0 (0-9.9) | 16 | 0.3 (0-7.4) | 15 | 0 (0-5.7) | 11 | -2.2 (-4.8-3.9) | 4 | 1.1 (-3.5-8.6) |
| | non-responder | 139 | 2.6 (1.6-3.5) | 31 | 2.5 (1.4-4.0) | 21 | 3.2 (2.5-4.3) | 58 | 2.7 (1.8-3.5) | 24 | 1.6 (1.0-2.6) | 4 | 3.9 (3.2-6.8) |
| | defaulted | 130 | 1.8 (0-8.6) | 62 | 1.3 (0-7.8) | 17 | 5.7 (1.8-7.7) | 28 | 3.1 (0.9-9.2) | 13 | 0.9 (0-2.9) | 4 | 0.8 (0-10.4) |

* includes 17 children that were admitted without enough admission data to calculate admission criteria

**Table 12: Outcomes against the Sphere standard indicators**

| Key indicator | Sphere standard | Study result |
|---|---|---|
| Proportion of exits from a therapeutic feeding programme who have died | < 10% | 7.3% |
| Proportion of exits from a therapeutic feeding programme who have recovered | > 75% | 74.2% |
| Proportion of exits from a therapeutic feeding programme who have defaulted | < 15% | 9.2% |
| Length of stay (days) | 30-40 | 42 |
| Minimum mean rate of weight gain (g/kg/person/day) | >8 | 5.4 |

131 of the children (89.7%) classified as non responders recovered with follow up of, on average, an additional 32 days (IQ range: 14-60) of treatment after being classified as a non responder (see Figure 13). When outcomes from this group of children are included in overall study outcomes the study recovery rate increases to 82.6% which is considerably better than the Sphere indicator.

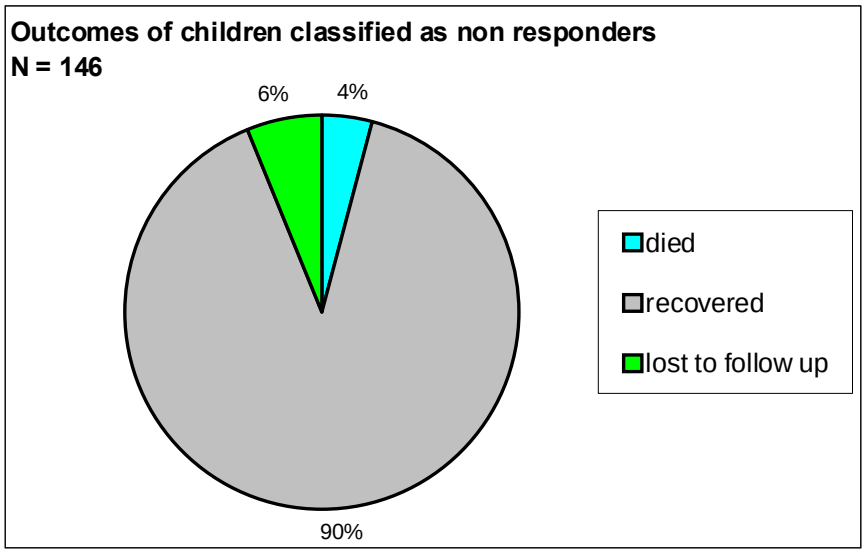



**Figure 13: Final outcomes of children classified as non responders**

This study was able to trace 58.8% of the 153 children that defaulted during treatment. Of these 10.5% had died < 1 month after leaving the programme (Figure 14).

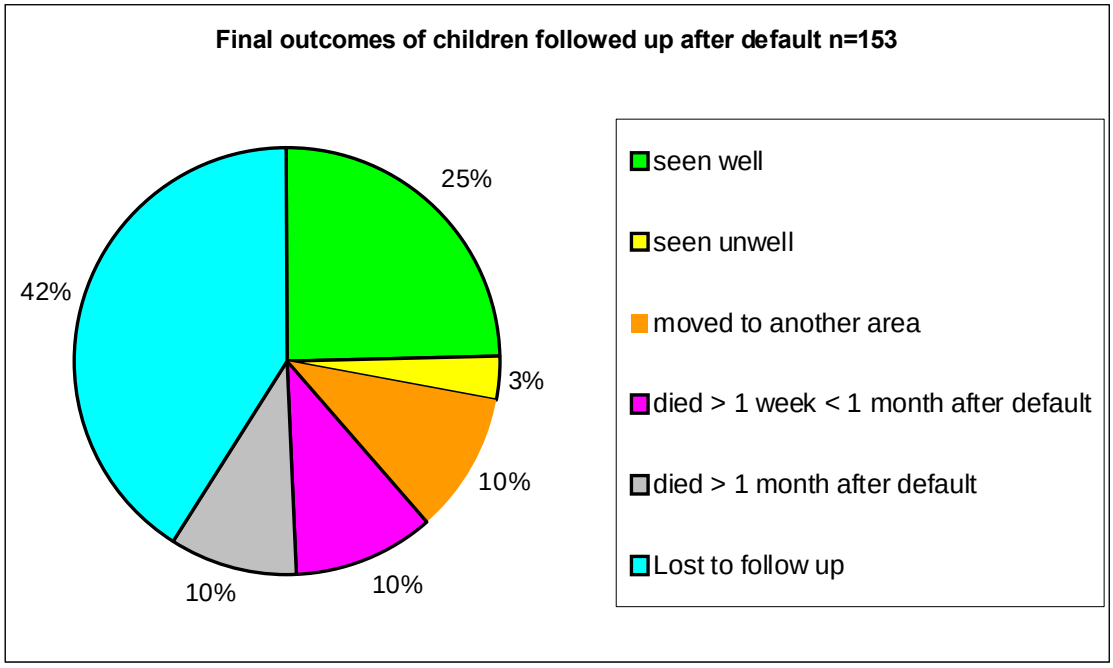



**Figure 14: Final outcomes of children followed up after default**

### 9.4.5.6 Outcomes in the NRUs and the OTP

Table 13 presents outcomes disaggregated by level of treatment (i.e. inpatient or outpatient). Outcomes at each level of treatment remained within the Sphere standard indicators for mortality, recovery and default.

**Table 13: Outcomes in the NRUs and the OTP**

| | | total | | NRU | | OTP | |
|---|---|---|---|---|---|---|---|
| | | n | (%) | n | (%) | n | (%) |
| outcome | overall | 1572 | 100 | 792 | 100.0 | 1461 | 100.0 |
| | recovered | 1167 | 74.2 | 709 | 89.5 | 1139 | 78.0 |
| | died | 115 | 7.3 | 64 | 8.1 | 51 | 3.5 |
| | non-responder | 146 | 9.3 | 0 | 0.0 | 146 | 10.0 |
| | defaulted* | 144 | 9.2 | 19 | 2.4 | 125 | 8.6 |
| | | | median (IQ range) | | median (IQ range) | | median (IQ range) |
| length of stay (days) | overall | 1537 | 42 (28-71) | 744 | 7 (5-11) | 1364 | 40 (25-67) |
| | recovered | 1165 | 42 (28-69) | 520 | 7 (5-10) | 1115 | 38 (25-56) |
| | died | 109 | 11 (4-28) | 74 | 8 (3-13) | 45 | 27 (14-41) |
| | non-responder | 137 | 154 (140-182) | 67 | 6 (5-10) | 133 | 142 (126-175) |
| | defaulted | 126 | 21 (7-42) | 83 | 7 (5-12) | 71 | 28 (20-56) |

*default in the NRU included children that defaulted from treatment or that were transferred to another facility and no final outcome was available.

There was a significantly higher number of deaths observed in the whole programme than the number of expected deaths calculated by Prudhon's index (115 vs. 65 RR = 1.26 95% CI 1.1, 1.4 p = 0.001, excess mortality = 3.1%). However, when the Prudhon index is used to calculate the expected number of deaths in the NRU and OTP separately it suggests that this excess mortality occurred in the NRU where observed deaths = 64/726 compared to 40/726 expected deaths. In the OTP observed deaths were 51/1217 compared to 60/1217 expected by the Prudhon index.

Figure 15 and Figure 16 present the number of deaths, the number of excess deaths (calculated using the Prudhon Index) and the number of inpatients or outpatients in the NRUs and the OTP during the study. The number of both inpatients and outpatients rises considerably during the rainy season. In the NRUs the number of excess deaths is significantly positively correlated with the number of inpatients (pearson coefficient: 0.58 p = 0.02). Although, from figure 16, the trend appears similar in the OTP, the correlation between number of excess deaths and number of outpatients is not significant (pearson coefficient: 0.45, p = 0.07).

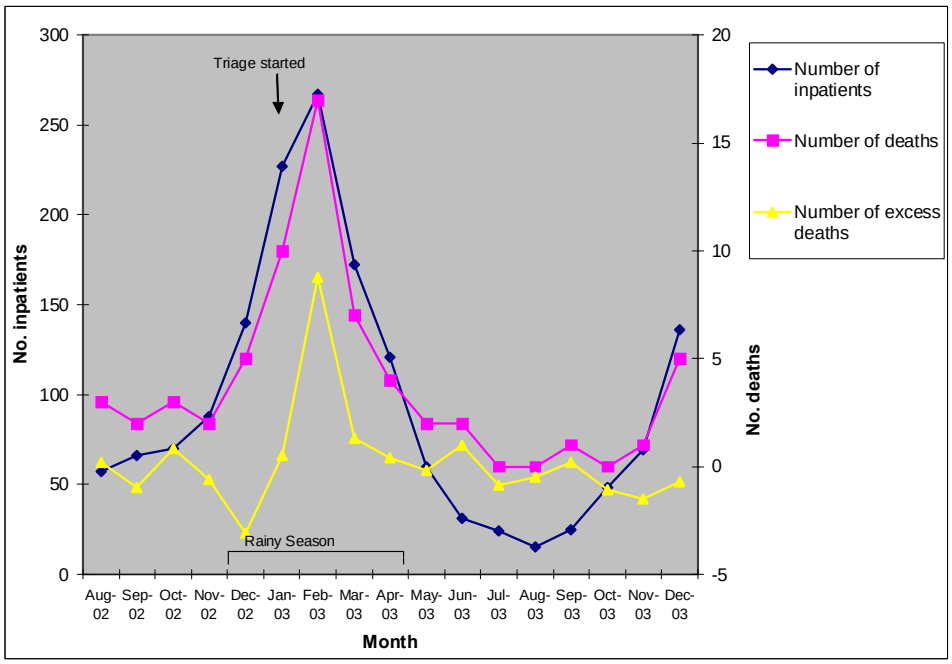



**Figure 15: Number of inpatients (left hand axis) and number of deaths in the NRUs (right hand axis) by month**

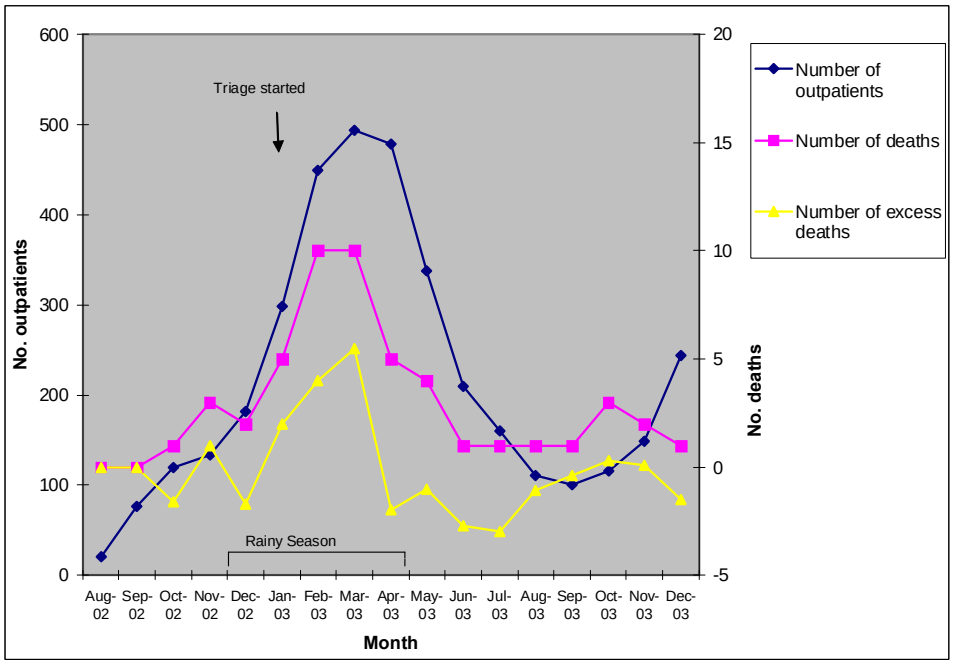



**Figure 16: Number of outpatients (left hand axis) and number of deaths (right hand axis) in the OTP by month**

#### *9.4.5.6.1 Timing of deaths in the OTP*

45 out of 1114 (4.0%) discharged from phase 1 treatment in the NRU into the OTP died. Fourteen (31%) of these deaths happened in the first two weeks after discharge (Figure 17). Of those that died after being directly admitted in to the OTP, 3 (43%) of them died in the first two weeks after admission (Figure 18).

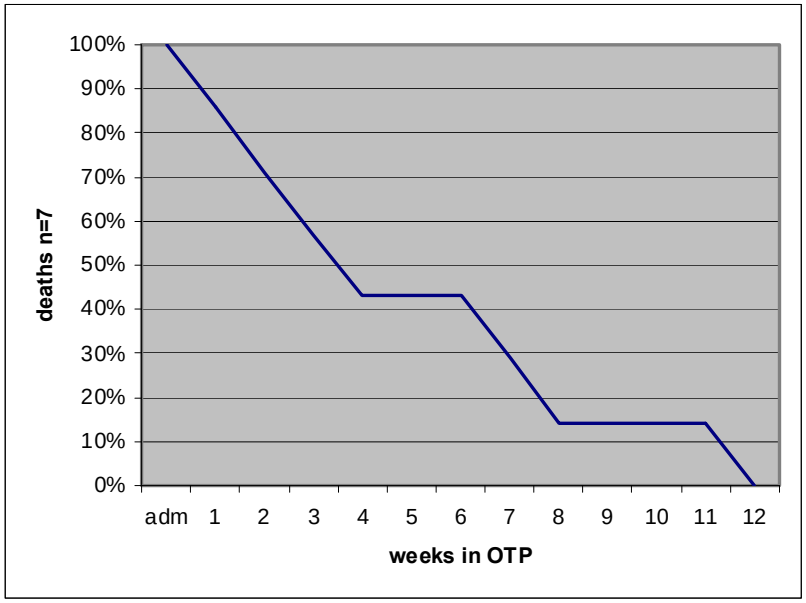



**Figure 17: Timing of deaths after direct admission into the outpatient therapeutic programme (OTP) (n = 7)**

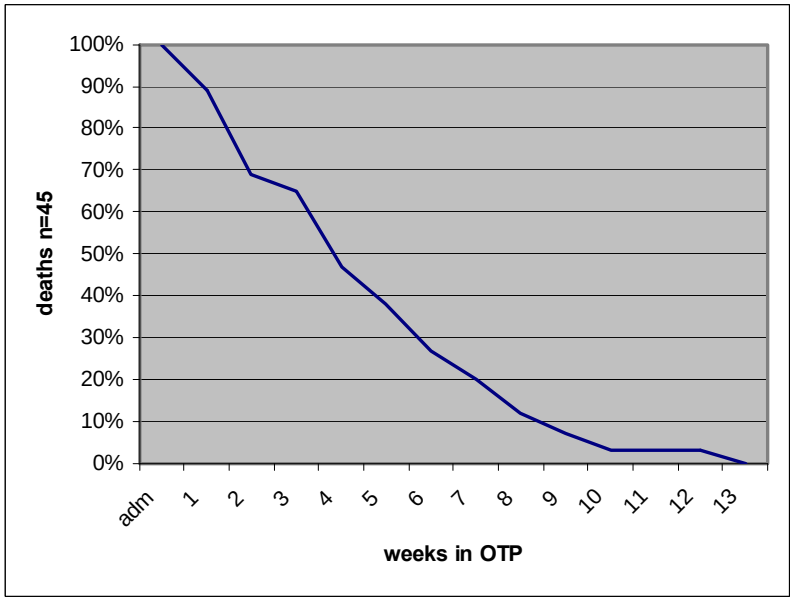



**Figure 18: Timing of deaths after discharge from the NRU into the outpatient therapeutic programme (OTP) (n = 45)**

#### 9.4.5.7 Outcomes by type of treatment and category of malnutrition

Table 14 shows overall outcome data according to the type of treatment (direct to OTP or indirect to inpatient care followed by OTP) that children received. This study admitted 351 (22.3%) of the total participants directly to OTP and 1221 (77.7%) first to phase one inpatient treatment followed by OTP. Overall, mortality in the group treated directly in OTP was significantly lower than that in the group that first received inpatient care ($\chi^2$ = 17.9 p<0.0001). This is mirrored across all grades of oedema. The number of deaths overall and for all categories of malnutrition observed in direct treatment was lower than the expected number of deaths calculated by the Prudhon Index, although this was non significant (RR 0.63 95% CI 0.34, 1.16 p=0.13) (Table 15).

**Table 14: Outcomes by category of malnutrition and type of treatment**

| | All* | | Oedema + | | Oedema ++ | | Oedema +++ | | Maras-kwash | | Marasmus | | MUAC < 11cm | | > 6 mths < 4kg | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Outcome (%)** | **Direct n=351** | **Indirect n=1221** | **Direct n=165** | **Indirect n=128** | **Direct n=19** | **Indirect n=348** | **Direct n=5** | **Indirect n=286** | **Direct n=25** | **Indirect n=102** | **Direct n=71** | **Indirect n=200** | **Direct n=52** | **Indirect n=103** | **Direct n=11** | **Indirect n=54** |
| Recovered | 78.6 | 73.0 | 89.1 | 75.8 | 100.0 | 81.0 | 100.0 | 80.8 | 44.0 | 58.8 | 57.7 | 56.5 | 76.9 | 64.1 | 90.9 | 77.8 |
| Died | 2.0 | 8.8 | 1.8 | 8.6 | 0.0 | 5.2 | 0.0 | 12.6 | 8.0 | 13.7 | 1.4 | 7.5 | 0.0 | 10.7 | 9.1 | 5.6 |
| Non-responder | 11.4 | 8.7 | 3.6 | 5.5 | 0.0 | 4.3 | 0.0 | 2.1 | 24.0 | 15.7 | 28.2 | 21.0 | 15.4 | 15.5 | 0.0 | 7.4 |
| Defaulted | 8.0 | 9.5 | 5.5 | 10.2 | 0.0 | 9.5 | 0.0 | 4.5 | 24.0 | 11.8 | 12.7 | 15.0 | 7.7 | 9.7 | 0.0 | 9.3 |

* includes 3 children with oedema but no grade specified

**Direct:** encompassing only outpatient treatment with RUTF

**Indirect:** encompassing phase 1 inpatient treatment followed by outpatient treatment with RUTF

**Table 15: Observed deaths in direct OTP compared with expected deaths calculated by the Prudhon Index**

| **No. Deaths** | **Observed n** | **Prudhon Expected n** |
|---|---|---|
| All | 7 | 15 |
| Oedema + | 3 | 4 |
| Oedema ++ | 0 | 1 |
| Oedema +++ | 0 | 1 |
| Marasmus | 1 | 4 |
| Maras-kwash | 2 | 3 |
| MUAC < 11cm | 0 | 1 |
| > 6 mths < 4kg | 1 | 1 |

Overall, children with kwashiorkor demonstrated a significantly higher recovery rate than all groups apart from children >6 months and <4kg (82.2% vs. 55.9% for marasmic kwashiorkor $\chi^2 = 48.8$ $p<0.0001$, 59.1% for marasmus $\chi^2 = 59.9$ $p<0.0001$ and 68.4% for children with MUAC<11cm $\chi^2 = 14.1$ $p<0.001$) (see Table 11). Case fatality rates were 68 (7.1%) of 954 for kwashiorkor patients, 16 (12.6%) of 127 for marasmic kwashiorkor patients, 15 (5.9%) of 254 for patients with marasmus, 11 (10.4%) of 155 for patients admitted with MUAC < 11cm and 4 (7.7%) of 65 for those children > 6 months and < 4kg. Overall, the case fatality rate was significantly higher (although at borderline level) in the marasmic kwashiorkor group than that for children with either kwashiorkor or marasmus ($\chi^2 = 4.0$ p=0.0.047 and $\chi^2 = 4.2$ p=0.04 respectively) (Table 11). Children with marasmic kwashiorkor had higher mortality in both direct and indirect treatment than all other categories of malnutrition (Direct: MK 8.0% vs. All 2.0% and Indirect: MK 13.7% vs. All 8.8% respectively) (Table 14). Differences in mortality between these groups were not significant. The mortality rate of 9.1% in direct treatment of the > 6 month < 4kg group relates to 1 child that was referred to the NRU but whose mother refused admission to inpatient treatment.

Both default and non response were lower in children with kwashiorkor compared to other groups (see Table 11): both default and non response were significantly higher for children with marasmus ($\chi^2 = 6.2$ p=0.01 and $\chi^2 = 103$ $p<0.0001$ respectively) and marasmic kwashiorkor ($\chi^2 = 6.7$ p=0.009 and $\chi^2 = 40.4$ $p<0.0001$ respectively). The rate of non response was also significantly higher in children with MUAC < 11cm than for those with kwashiorkor ($\chi^2 = 35.9$ $p<0.0001$). Table 14 shows that the highest rates of both non response and default occurred in the marasmic kwashiorkor group that was treated directly in OTP. They were not however significantly higher than the rates seen in indirect treatment in the same group.

#### 9.4.5.8 Outcomes by age group

Overall, there was no significant difference in age between those that died and those that recovered (see Table 10). However, Table 16 shows that in Dowa it was not the youngest age group (6-12 months) but the oldest age group (> 60 months) that had a higher risk of mortality than other groups (> 60 months vs. 6-12 months $\chi^2$ 7.1 p=0.008 and > 60 mths vs. all ages $\chi^2$ 7.6 p=0.006). Mortality was low in direct OTP across all age groups (Table 17). The youngest age groups did appear to have a higher risk of both non

response and default than many of the older age groups in both direct and indirect treatment, although in this study differences between age groups for these outcomes were not significant.

**Table 16: Outcomes by age group**

| | Total | | 6-12 months | | 13-24 months | | 25-36 months | | 37-48 months | | 49-60 months | | > 60 months | | >6 months <4kg | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **n** | **(%)** | **n** | **(%)** | **n** | **(%)** | **n** | **(%)** | **n** | **(%)** | **n** | **(%)** | **n** | **(%)** | **n** | **(%)** |
| overall | 1539 | 100.0 | 182 | 100.0 | 494 | 100.0 | 521 | 100 | 194 | 100 | 85 | 100 | 63 | 100 | 65 | 102 |
| recovered | 1151 | 74.8 | 124 | 68.1 | 333 | 67.4 | 415 | 79.7 | 165 | 85.1 | 66 | 77.6 | 48 | 76.2 | 52 | 80.0 |
| died | 111 | 7.2 | 10 | 5.5 | 38 | 7.7 | 31 | 6.0 | 12 | 6.2 | 9 | 10.6 | 11 | 17.5 | 4 | 7.7 |
| non-responder | 141 | 9.2 | 27 | 14.8 | 66 | 13.4 | 40 | 7.7 | 3 | 1.5 | 5 | 5.9 | 0 | 0.0 | 4 | 6.2 |
| defaulted | 136 | 8.8 | 21 | 11.5 | 57 | 11.5 | 35 | 6.7 | 14 | 7.2 | 5 | 5.9 | 4 | 6.3 | 5 | 7.7 |

**Table 17: Outcomes by age group and type of treatment**

| | Total | | 6-12 months | | 13-24 months | | 25-36 months | | 37-48 months | | 49-60 months | | >60 months | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Outcome (%)** | **Direct n=334** | **Indirect n=1205** | **Direct n=42** | **Indirect n=140** | **Direct n=133** | **Indirect n=361** | **Direct n=105** | **Indirect n=416** | **Direct n=29** | **Indirect n=165** | **Direct n=15** | **Indirect n=70** | **Direct n=10** | **Indirect n=53** |
| Recovered | 79.6 | 73.4 | 76.2 | 65.7 | 69.2 | 66.8 | 89.5 | 77.2 | 86.2 | 84.8 | 86.7 | 75.7 | 100.0 | 71.7 |
| Died | 1.8 | 8.7 | 2.4 | 6.4 | 3.0 | 9.4 | 1.0 | 7.2 | 0.0 | 7.3 | 0.0 | 12.9 | 0.0 | 20.8 |
| Non-responder | 11.4 | 8.5 | 14.3 | 15.0 | 18.0 | 11.6 | 5.7 | 8.2 | 3.4 | 1.2 | 6.7 | 5.7 | 0.0 | 0.0 |
| Defaulted | 7.2 | 9.3 | 7.1 | 12.9 | 9.8 | 12.2 | 3.8 | 7.5 | 10.3 | 6.7 | 6.7 | 5.7 | 0.0 | 7.5 |

**Direct:** encompassing only outpatient treatment with RUTF
**Indirect:** encompassing phase 1 inpatient treatment followed by outpatient treatment with RUTF

#### 9.4.5.9 Weight gain and length of stay

Overall, median [IQ range] rate of weight gain was 4.8 g $kg^{-1}$ $day^{-1}$ [2.5-7.5] and median [IQ range] length of stay was 42 [28-71] days (see Table 11). Amongst patients who recovered median weight gain was 5.4 g $kg^{-1}$ $day^{-1}$ [3.4-7.9] and length of stay 42 [28-69] days. Weight gain was significantly lower in those children that died, defaulted or did not respond to treatment ($p < 0.001$).

Table 11 shows that children that recovered from kwashiorkor had the lowest weight gain and shortest length of stay compared to all other recovered groups. For recovered children with marasmic kwashiorkor, marasmus and those admitted > 6 months and < 4kg weight gain was significantly higher than for those with kwashiorkor ($p = 0.007$, $p< 0.001$ and $p < 0.001$ respectively). All categories of malnutrition (marasmus, marasmic kwashiorkor, MUAC <11cm and > 6 months < 4kg)) also took significantly longer to recover than those with kwashiorkor ($p< 0.001$ for all groups). Median [IQ range] time to clinical resolution of oedema was 5 days [3-9]: 5 days [3-10] for marasmic kwashiorkor and 5 days (3-9) for kwashiorkor patients.

Overall, the average weight gain was significantly lower (3.8 g $kg^{-1}$ $day^{-1}$ [2.3-6.2] vs. 5.3 g $kg^{-1}$ $day^{-1}$ [3.4-7.9] $p < 0.0001$) for those children that were treated and recovered directly in the OTP compared to those that first received inpatient care. There was no significant difference in length of stay for direct OTP compared to indirect (56 [28-84] days vs. 48 [32-75] days respectively $p = 0.5$) (not shown in tables).

#### 9.4.5.10 The impact of triage

Between August and December 2002 all children (n=343) received phase 1 inpatient treatment (non triaged) in an NRU. During the same period the following year all children (n=347) were triaged into either first receiving phase 1 inpatient treatment (indirect) or going directly to outpatient treatment. Table 18 details the triage profile, according to the clinical characteristics used to triage, of those children admitted directly and indirectly in to outpatient care between August and December 2003. Anorexia and oedema ++ or +++ were the most common reason for referral to inpatient care.

**Table 18: Proportion of children that presented with each clinical criterion used to triage children between August and December 2003**

| | Direct | Indirect |
|---|---|---|
| n | 113 | 234 |
| | % | % |
| Oedema +++ or ++ | 4.4 | 60.3 |
| Marasmic-Kwashiorkor | 4.4 | 7.3 |
| Anorexic | 3.5 | 43.2 |
| Fever (>39 $^0$c) | 0 | 1.3 |
| Hypothermia (<35 $^0$c) | 0 | 1.7 |
| LRTI* | 1.8 | 9.8 |
| Mod-Sev anaemia*** | 0.9 | 3.8 |
| Severe superficial infection**** | 1.8 | 3.8 |
| Mod-Sev dehydration** | 0 | 1.3 |

* Measured by standard resp rate definition
** Measured by recent history of diarrhoea, vomi
*** Pale conjunctiva & breathlessness
**** Raw and/or peeling skin

Comparison of the admission characteristics of the triaged and non triaged groups shows that there were significantly more males in the triaged group (p=0.005), that the triaged group had a significantly higher mean MUAC at admission than the non triaged group (p< 0.001) and significantly fewer cases of severe oedemas (p<0.001) (Table 19).

**Table 19: Baseline characteristics of the non triaged and the triaged groups**

| | | Non-triaged Aug-Dec 02 | | | Triaged Aug-Dec 03 | | p value |
|---|---|---|---|---|---|---|---|
| N | n | 343 | | n | 347 | | |
| Median Age (months) | 338 | 26 | | 339 | 25 | | 0.7* |
| (Z score) | 337 | -2.0 | | 339 | -1.9 | | 0.4** |
| MUAC (cm) | 248 | 11.1 | | 295 | 11.9 | | <0.001* |
| Sex | 341 | *m* | *f* | 345 | *m* | *f* | |
| | | 150 | 191 | | 190 | 155 | 0.005 |
| Maras-Kwash | 341 | *yes* | *no* | 345 | *yes* | *no* | |
| | | 31 | 310 | | 26 | 319 | 0.6 |
| Admission oedema grade *** | 194 | *sev* | *mild* | 254 | *sev* | *mild* | |
| | | 81 | 81 | | 62 | 192 | <0.001 |
| Admission appetite | 343 | *good* | *poor* | 347 | *good* | *poor* | |
| | | 226 | 117 | | 241 | 106 | 0.4 |

* Mann-Whitney (for non normally distributed data)
** ANOVA for normally distributed
*** sev +++ mild ++ +

The programme recovery rate was significantly lower (71.4%) and mortality rate significantly higher (9.0%) in the non triaged group than that seen in the triaged group (79.8% p=0.01 and 5.2% p=0.04 respectively) (see Table 20). There was no difference in the expected number of deaths using Prudhon's index and the number of deaths observed for either the non triaged (Expected: 20 vs. Observed: 31 RR = 1.2 95% CI 0.96, 1.56 p = 0.2) or the triaged group (Expected:15 vs. Observed:18 RR = 1.1 95% CI 0.8, 1.5 p = 0.7).

**Table 20: Outcomes by non triaged and triaged groups.**

| | | Programme | | | |
|---|---|---|---|---|---|
| | | Non-triaged Aug-Dec 02 | | Triaged Aug-Dec 03 | p value |
| N | n | 343 | n | 347 | |
| Dead | 276 | 31 | 295 | 18 | 0.04 |
| Recovered | 343 | 245 | 347 | 277 | 0.01 |
| Non responder | 343 | 41 | 347 | 19 | 0.004 |
| Defaulted | 343 | 26 | 347 | 33 | 0.4 |
| | | median (IQ range) | | median (IQ range) | |
| LOS (recovered) | 281 | 56.0 (37-84) | 292 | 42.0 (31-63) | < 0.001 |
| Weight gain (recovered) | 279 | 5.5 (3.8-8.3) | 276 | 4.8 (2.4-7.3) | 0.01 |

### 9.4.5.11 Predictors of mortality

Admission characteristics that were significantly associated with reducing odds of recovery across both the triaged and non triaged groups were (in order of strength of association) MUAC ≤ 11cm, marasmic-kwashiorkor, weight for height ≤ -3 z scores and anorexia (See Table 21). Only triage was significantly associated with increasing odds of recovery. In univariate analyses only MUAC ≤ 11cm was significantly associated with increasing odds of mortality and triage significantly associated with lowering odds of mortality. Severe oedema appeared to have a borderline significant association with both increased recovery and a (less significant) association with increased mortality.

In multivariate analyses using recovery and mortality as the dependent factors, the only significant factors independently associated with recovery were MUAC ≤ 11cm and the presence of anorexia that reduced the odds of recovery by 0.6 (p=0.03) and 0.4 (p<0.0001) respectively. The only significant independent risk factor that remained for death was MUAC ≤ 11cm that increased the odds of death by 2.6 (p=0.03). There was a

borderline significant association of mortality with severe oedema in the direction of a 2.4 increase in odds of death in the presence of severe oedema (p=0.06) and with triage which reduced the odds of death in the direction of half (p=0.07) (Table 21).

**Table 21: Univariate and multivariate regression analyses for recovery and mortality**

| Dependent variable | Independent risk factors (at admission) | OR | 95% CI | p value | Adjusted OR | 95% CI | p value |
|---|---|---|---|---|---|---|---|
| Recovered | Triaged | 1.58 | 1.11-2.25 | 0.013 | 1.36 | 0.87-2.10 | 0.18 |
| (n=538) | WHZ < -3 | 0.39 | 0.27-0.57 | <0.0001 | 0.69 | 0.41-1.18 | 0.17 |
| | MUAC < 11cm | 0.31 | 0.20-0.47 | <0.0001 | 0.39 | 0.23-0.66 | < 0.0001 |
| | Oedema +++ | 1.7 | 1.0-2.9 | 0.06 | 1.06 | 0.56-1.99 | 0.86 |
| | Anorexia | 0.58 | 0.41-0.83 | 0.003 | 0.61 | 0.39-0.94 | 0.03 |
| | Marasmic kwashiorkor | 0.37 | 0.21-0.64 | 0.001 | 0.71 | 0.33-1.53 | 0.38 |
| | Female sex | 1.18 | 0.83-1.68 | 0.37 | ** | | |
| | Age < 12 months | 0.74 | 0.47-1.18 | 0.21 | ** | | |
| | Age > 48 months | 1.37 | 0.67-2.80 | 0.50 | ** | | |
| | Lower respiratory tract infection | 1.28 | 0.70-2.32 | 0.47 | ** | | |
| Dead | Triaged | 0.51 | 0.28-0.94 | 0.036 | 0.52 | 0.26-1.06 | 0.07 |
| (n=458) | WHZ < -3 | 1.37 | 0.68-2.73 | 0.35 | 1.14 | 0.46-2.84 | 0.78 |
| | MUAC < 11cm | 2.2 | 1.15-4.28 | 0.02 | 2.64 | 1.12-6.21 | 0.03 |
| | Oedema +++ | 1.31 | 0.68-2.52 | 0.16 | 2.37 | 0.98-5.74 | 0.06 |
| | Anorexia | 1.4 | 0.76-2.58 | 0.33 | 1.29 | 0.64-2.59 | 0.48 |
| | Marasmic kwashiorkor | 1.77 | 0.66-4.80 | 0.23 | 1.83 | 0.56-5.95 | 0.32 |
| | Female sex | 0.87 | 0.48-1.60 | 0.65 | ** | | |
| | Age < 12 months | 1.18 | 0.53-2.61 | 0.67 | ** | | |
| | Age > 48 months | 1.57 | 0.63-3.90 | 0.29 | ** | | |
| | Lower respiratory tract infection | 1.56 | 0.70-3.49 | 0.25 | ** | | |

### 9.4.6 Discussion

This study presents outcomes from an integrated inpatient/outpatient programme that adopted the principles of the CTC approach as described in chapter 7. It referred the majority (78%) of severely malnourished children first for phase one treatment in inpatient care, for an average of 7 days, and then to outpatient care for recovery. It also utilised triage criteria to refer a small proportion (22%) of children directly to outpatient care. All treatment was administered through existing primary health care structures and MoH staff with support from an external NGO, Concern.

#### 9.4.6.1 Mortality & Recovery

Overall, the mortality rate was significantly lower than the Sphere Standard indicator for this outcome (p=0.009). This suggests that this model of treatment can deliver care of adequate quality as defined by Sphere. The recovery rate was just below the Sphere standard for this indictor.

#### 9.4.6.2 Default

The default rate met the Sphere Standard indicator for this outcome. This indicator is generally used to monitor the level of accessibility (for example, distance of treatment from the community) and acceptability (for example, the perceived quality of treatment) of the treatment provided in selective feeding programmes. The low levels of default seen here suggest that treatment was accessible and acceptable to most participants. This is discussed further in relation to the programme's coverage in the next chapter.

##### *9.4.6.2.1 Follow up of defaulters*

Follow up was attempted of all children that defaulted from treatment and 58.8% of them were found. At baseline, children that defaulted were more likely to have marasmic kwashiorkor or marasmus and were more wasted than children that recovered. This is reflected in a seemingly higher < 1 month mortality rate at follow up (10.5%) (Figure 14) than the mortality rate in the whole programme (7.3%) although this difference is not significant. If we take 10.5% of all defaulters and add these deaths to 'within programme mortality' the programme case fatality rate rises to 8.3% (131/1572). This remains within the Sphere standard indicator for mortality of therapeutic feeding programmes.

#### 9.4.6.3 Non response

9.3% of children had a length of stay of more than 122 days and were classified as 'non responders'. However treatment in the programme continued for all of these children until final outcome. A particularly long length of stay such as this can occur as a result of a number of factors; recurrent episodes of acute illness such as diarrhoea, chronic illness such as HIV or TB, socio-economic factors at home that interfere with recovery (for example poor care environment or destitution). It is likely that a combination of these factors contributed to the rate of non recovery in Dowa, although this was not examined specifically. Most of these children recovered eventually, and when the final outcomes of these children are included in the overall programme outcomes, the programme recovery rate rises to meet the Sphere standard.

#### 9.4.6.4 Mid study outcomes compared to the National TFC programme

At the time of this study the National NRU strategy was also scaling up to treat severe malnutrition in Districts outside Dowa and Nkhotakota. Figure 19 compares these data with CTC programme data up to the end of December 2002, the period for which the National data were available. This shows that at this point, the Dowa programme had superior cure, mortality and default rates compared to the National centre based programme. More recent data, discussed by Linneman *et al* 2007, have suggested that high mortality and default rates in the national TFC programme continued well in to 2006 (100). Comparison of these results must remain tentative as there is no way of adjusting for the severity of malnutrition at admission. However, it is possible that the clinical outcomes from the CTC strategy in Dowa were considerably better than those produced by the National NRU strategy. In addition, although confined to only one of the 25 districts in Malawi, the programme in Dowa had admitted a similar number of patients by December 2003 (n=342) to the nationwide NRU strategy (n=379). This suggests a far superior coverage of the target population (see chapter 10 below for a discussion of the coverage of this programme) by the CTC programme.

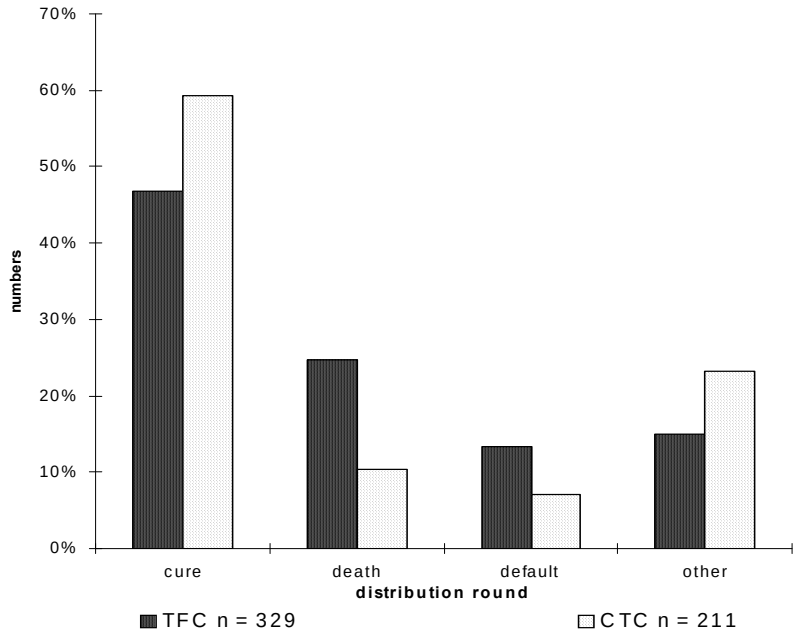



**Figure 19: Comparison of impact indicators of CTC and NRU strategies in Malawi August - December 2002**

### 9.4.6.5 Outcomes in the NRUs and the OTP

Recovery, mortality and default rates all remain within Sphere standard indicators when they are disaggregated to those that occurred in the inpatient (NRU) and in the OTP components of the programme.

#### *9.4.6.5.1 Mortality in the NRUs and the OTP*

Mortality is, unsurprisingly, significantly higher in the NRUs than in the OTP (8.1% vs. 3.5% $\chi^2$ 21.4 $p<0.0001$). This is because the most complicated cases were always treated in inpatient care and children are usually at higher risk of mortality at the beginning of treatment. When OTP and NRU mortality is compared to the expected mortality calculated by the Prudhon index, although differences are not significant, mortality in NRU treatment is in the direction of a 2.2% excess (expected: 5.5% observed: 7.7%) and mortality in OTP treatment is less than that expected (expected: 4.9% observed: 4.1%). Figure 15 and Figure 16 show that both the NRUs and the OTP experienced a similar pattern of excess mortality over the rainy season when the number of inpatients was highest. However, whilst excess mortality is significantly correlated with numbers of inpatients in the NRUs there is no significant correlation between these variables in the OTP. Despite direct admission being in place from January 2003, staff were cautious

with its use (only 22% were referred directly to the OTP Jan-Dec 2003). This resulted in 70% of the children still passing through NRUs (compared to many subsequent CTC programmes that referred up to 90% of children directly to the OTP – see chapter 11 Going to Scale with CTC) and was not sufficient, especially during the rainy season, to alleviate problems associated with poorly resourced units struggling to cope with the high numbers requiring treatment. When the number of inpatients is very high the staff : patient ratio reduces considerably and the patient density in NRUs increases. As a result it is more difficult for staff to deliver high quality care and the risk of cross infection increases. This may have contributed to the excess mortality seen and is comparable with other findings from large TFC studies that have attributed excess mortality to under resourced centres being unable to implement protocols to a high enough standard for large numbers of patients (78) (see also section 6.5).

However, this does not explain the similar pattern of mortality seen in the OTP and in this study we have not controlled for differences in case severity between seasons. Cases of diarrhoea and acute respiratory infections, common complications of SAM, often increase during the rainy season. This may also have increased 'difficult to treat' malnutrition over this time and may have contributed to the excess mortality seen. It is also possible however, that malnutrition outside the rainy season in Malawi is less likely to be a direct cause of food shortage and more likely to occur as a result of chronic disease, such as HIV, and/or particularly poor socio economic circumstances at home. This also can make malnutrition 'difficult to treat'. This would need further study.

#### 9.4.6.6 Outcomes by type of treatment

Table 14: Outcomes by category of malnutrition and type of treatment, presents the outcomes of children treated during this study disaggregated by whether they received only direct outpatient treatment or a combination of initial inpatient treatment followed by early discharge into outpatient treatment (indirect). A direct comparison between these two groups is inappropriate as the children admitted into inpatient care were, from January 2003, those whom the staff considered to be most sick. However, Table 14 suggests that children with SAM including those with grades one or two oedema, who are not suffering from additional serious medical complications, can be treated successfully with outpatient treatment alone. The number of deaths that occurred for all categories of malnutrition in direct treatment was lower than the expected number

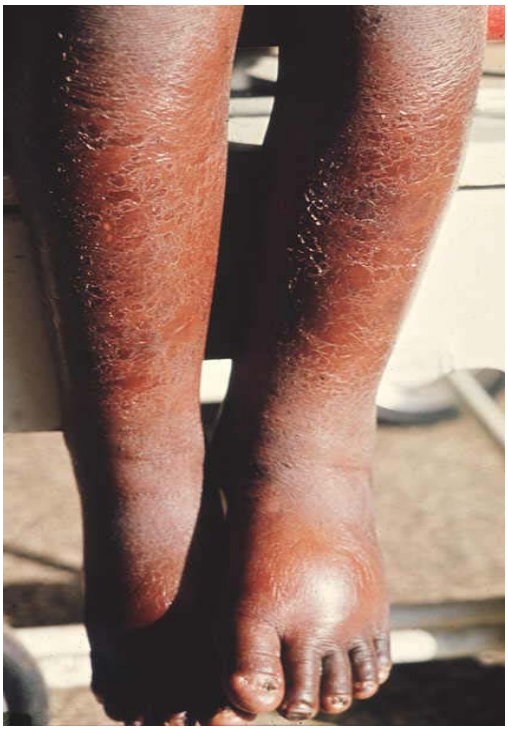
calculated by the Prudhon Index, although, due to small numbers, at a non significant level. This suggests that, with these triage criteria, there is no excess mortality attached to direct treatment in outpatient care for any category of malnutrition. These results concur with other more recent studies in Malawi and elsewhere that have also found low mortality among oedematous children with good appetite treated directly in outpatient care (100;132) and suggest that the caution adopted by others that have used, for example, the presence of oedema as criteria for referral to inpatient treatment, may not be necessary (136).

#### 9.4.6.7 Outcomes by category of malnutrition

##### *9.4.6.7.1 Kwashiorkor*

It is important to note that children suffering from kwashiorkor made up the majority (60.7%) of admissions in this study. This is typical for Malawi where oedematous malnutrition (including marasmic-kwashiorkor) accounts for 75% of all admissions to NRUs across the country (89). The Ethiopian study discussed in section 9.2 treated a much higher proportion of wasting with a low case fatality rate, but it is important that the findings here are repeated in large scale operational studies in populations with higher rates of wasting, before any broad statements about the effectiveness of the approach are made (see discussion chapter 11).

In this study it is children with kwashiorkor that had the highest recovery rate; significantly more so than all groups apart from those children <4kg, and one of the lowest case fatality rates (significantly lower than children with marasmic kwashiorkor). They also had lower rates of non response and default than that seen among the children that were wasted. Kwashiorkor, in this context, appears to demonstrate better outcomes than other categories of malnutrition. Why might this be so, when the condition is so often described in the literature as being characterised by anorexia, irritability and ulceration and presented as complex and 'difficult' to treat? (20;26;89). It is likely that the reason for this comes back to the design of the CTC programme, which, by improving access to and reducing opportunity costs of treatment, encouraged much earlier presentation. During this study many children presented with mild nutritional oedema and did not suffer from the additional complications so often associated with the condition. It seems that many mothers, instead of waiting until their children were very sick were presenting at treatment sites almost as soon as swelling (or oedema) was noted.



This allowed the majority of oedematous grade I cases (165/293, 56%) to be treated directly in outpatient care with very low mortality (1.8%). This concurs with recent findings of other home-based treatment programmes that also treated the majority of oedematous patients at home with low mortality (100) but contradicts previous observation in Malawi by Brewster *et al* that kwashiorkor in the Malawi region is more severe than in other regions of the world. They speculated that this was an important contributor to the poor outcomes in their study (89).

**Figure 20: An example of oedema grade 2: successfully treated directly in outpatient care.**

The evidence presented here would suggest that more importantly, encouraging earlier presentation of the condition might result in very different and less complicated cases for treatment.

#### *9.4.6.7.2 Treatment of oedema*

To address, in part, a concern of study 1 that providing RUTF to oedematous children was the cause, through encouraging metabolic imbalance, of longer than usual time for oedema resolution (76;161) this study provided RUTF as a quantity proportional to a child's weight (rather then the set quantity delivered during study 1) according to WHO protocol. The number of days to clinical resolution of oedema was significantly less in this study than that seen in Ethiopia (5 days [3-9] vs. 28 days [21-35] $p < 0.01$) and this may be due in part to the provision of more appropriate diets. However, this comparison does not control for the grade of oedema which may have been more severe in Ethiopia.

#### *9.4.6.7.3 Marasmic kwashiorkor*

Children with marasmic kwashiorkor are the only group that demonstrate a mortality rate that falls outside the Sphere standard. This group often suffers from profound metabolic dys-adaptation, are invariably infected and often anorexic (3). As a result of the Ethiopia

study findings, any child with marasmic kwashiorkor, should have been referred for inpatient treatment and not treated directly in the OTP. Twenty five children with marasmic kwashiorkor in this study were referred in to direct treatment either because mothers refused to go to an NRU or because anorexia and other signs of complications were not present. The results presented here show that although there does not appear to be any increased risk of mortality (8% in direct OTP vs. 13.7% in indirect treatment), nor any excess mortality with direct treatment in this group, an increased risk of both non response and default can not be ruled out. The numbers of children suffering from marasmic kwashiorkor treated here are also small and therefore, until larger studies are implemented, marasmic kwashiorkor should remain as a characteristic that defines 'complicated malnutrition' for referral to inpatient care.

#### *9.4.6.7.4 Marasmus*

Children with marasmus also presented with more complications in this study: only 26% of wasted children were admitted directly to OTP as having malnutrition with no complications compared to 56% with oedema grade I. It is probable that one of the reasons for this is that wasting is now closely associated with HIV and other chronic conditions such as TB in Africa which in turn are associated with a poor response to treatment of malnutrition (101). A recent study by Bahwere *et al* showed that HIV infected children that were treated in the CTC programme in Dowa were more likely to be admitted with MUAC < 110 mm and less likely to have oedema than uninfected children (162). This was also observed in the previous study described in section 9.3 that found HIV prevalence to be significantly higher among wasted children than oedematous. Alternatively, it is possible that weight loss is less likely to be noticed by mothers and health workers than swelling or oedema early on in the progression of malnutrition and hence, at presentation, it is more complicated to treat. Probably as a result of these chronic complications the marasmic group experienced a higher rate of non response and default than those in the kwashiorkor group (see Table 11). Possible causes include reduced intake due to poor appetite, nutrient malabsorption, increased incidence of infections that were unresponsive to the broad-spectrum antibiotics used, and increased nutrient requirements due to HIV (163). This has resulted in their recovery rate falling outside the international standard.

The longer length of stay demonstrated by wasted children may also be one of the reasons for the high rate of default in this group (marasmic kwashiorkor: 14.2% and marasmic: 12.2%) as the opportunity costs of prolonged treatment outweigh carer's perceived benefit of treatment (see Table 11). In addition, this study traced 52.7% (78/148) of children that defaulted and from these final outcome data (Figure 14) it seems that raised mortality after default (10.8% in the marasmus kwashiorkor group and 16.7% in the marasmic group vs. 7.9% in the kwashiorkor group $p > 0.05$) may also have contributed to a proportion of the raised rate of default in the wasted group, although, as numbers are so small, these differences are not significant. A raised mortality after default in a group with a higher prevalence of HIV would concur with other work in Dowa that also showed higher mortality after programme exit in HIV positive children (162).

In the context of HIV where recovery rates from conditions such as SAM are likely to be prolonged, treatment and support programmes such as CTC need to further examine ways of improving effectiveness and reducing the beneficiary's perceived opportunity cost of treatment. HIV positive children may need more RUTF than HIV negative children to achieve similar rates of recovery and improvements in other nutritional indices. Increasing the amount of daily energy offered to HIV infected children may improve their weight gain and reduce their length of stay in the programme. In addition, where HIV is prevalent, adapting CTC routine antibiotic treatment to the epidemiology of HIV-associated infections and inclusion of routine prophylactic cotrimoxazole for HIV-positive children, as currently recommended by WHO, may improve outcomes in this group (162;164). As discussed above in study 2 section 9.3.6.3, it will also be vital that CTC programmes are linked to HIV diagnostic and treatment facilities using well defined referral criteria.

Consideration needs to be given as to whether the high rate of non response in the wasted group is strong enough evidence to include marasmus as a criteria for inpatient referral. Firstly, treating wasted children in direct OTP with the triage criteria used in this study does not appear to increase the risk of non response in this group ($\chi^2 = 1.2$ $p=0.3$). Also, it does not seem to have led to higher default in this group (compared to indirect treatment) suggesting that direct treatment remains an acceptable option for many and does not lead to significant death outside the programme (Table 14). Secondly, if long

length of stay in this group is related to chronic illness such as HIV, unless malnutrition is complicated by signs that may lead to increased risk of mortality such as anorexia, treatment of immunocompromised patients in the community, rather than in crowded inpatient units, may be preferable. It is easily integrated in to home-based care programmes that are a common support mechanism for HIV positive people in the developing world and are generally accepted to be more appropriate for long term support strategies (165).

#### 9.4.6.8 Outcomes by age group

There have been concerns that CTC would not be suitable for very young children (i.e. in the 6-12 month category) as they have tended to experience higher mortality as a result of SAM . Particularly, there were concerns about treating this group directly in outpatient care with no inpatient treatment. Table 16 and Table 17 shows that overall in Dowa it was not the youngest age group (6-12 months) but the oldest age group (> 60 months) that suffered higher mortality than other groups. It is not unusual to see older children suffer from malnutrition that is secondary to chronic illness other than HIV, which is more common among the younger age groups. In this study for example children > 60 months with complicated malnutrition were 2.2, 3.5 and 4.9 times more likely to be suffering from LRTI than the three youngest groups respectively, a condition very often indicative of TB (20/33 vs. 23/123 $p=0.007$, 42/327 $p<0.001$ and 32/387 $p<0.001$ in the three youngest age groups). To reduce mortality further for these children, better referral and a higher standard of treatment for conditions such as TB might improve response to treatment.

Despite appearing to demonstrate a higher risk of mortality overall in this study, treating the older or the younger age groups directly in OTP appeared to carry no additional risk of mortality (Table 17). This would suggest that any child of > 6 months suffering from malnutrition with no complications can be safely treated directly in outpatient care.

#### 9.4.6.9 Weight gain and length of stay

Overall, the average rate of weight gain of children that recovered during this study was 5.4 g $kg^{-1}$ $day^{-1}$ [3.4-7.9], lower than those stipulated in the Sphere standards and lower than those seen in well functioning TFCs. Average length of stay was correspondingly longer (42 [28-71] days) than the target in the Sphere guidelines. In comparison with

weight gains seen in the Ethiopian study however, there does seem to be some improvement. The Ethiopian study observed a weight gain among recovered children of 3.7 [2.3-6.3] g $kg^{-1}$ $day^{-1}$ , significantly lower than that seen in this study (p=0.003). Adapting the ration size of RUTF to mirror more closely the WHO protocol and the provision of more community support to participant families through community health workers and volunteers during this study may have contributed to this improvement.

As seen in the Ethiopia study, slower rates of recovery than stipulated by international standards did not result overall in high mortality rates in the programme, supporting the view that treatment in the OTP entails little if any increased risk to the malnourished child (see discussion section 9.2.5.3). The high proportion of oedematous children in this population, many of whom, at the point of oedema loss, were not wasted, will almost certainly have reduced weight gain overall and is consistent with other outpatient programmes that have treated a large proportion of oedematous children (100;132). Other CTC and outpatient programmes that have had a lower proportion of oedematous children making up admissions have achieved higher weight gains (see Chapter 10, Table 27 : Outcomes from children presenting to CTC programmes between Feb. 03 and Dec. 05 (N = 20,418): Ethiopia Harage and Ethiopia Sidama and references (135;136)). It is likely that community-based programmes, particularly those treating very high numbers of oedematous children, will rarely achieve the rates of weight gain laid out in the Sphere standards and this should be considered when evaluating such programmes. A recent review of community-based treatment programmes used weight gain of > 5g $kg^{-1}$ $day^{-1}$ as an indicator of programme effectiveness (130) and this may be a more realistic target for such programmes .

It is important to note however that low weight gain and slower recovery rates will impact on the costs of programme delivery. This would need to be balanced against the costs of delivering care through an equivalent number of inpatients units that includes the increased opportunity costs borne by the programme participants. This requires further study.

As the results of the Ethiopia study and other work have suggested, this lower weight gain (vs. the Sphere standards indicator) is also likely to be, in part, caused by sharing of the RUTF ration with other children in the household or community not registered on the

programme (134). In Dowa this was confirmed during work carried out by sociologists and anthropologists. Many mothers questioned acknowledged that rations were shared between children (166). Sharing of rations is often seen as a 'negative' aspect of home-based care programmes (130;167). However, this work also highlighted that having food to share in the house (and this included the blended food ration given out with the RUTF) was seen as a very positive aspect of the CTC programme by carers of malnourished children. From their perspective it helped to ensure that no child would starve to death during a time when many households were suffering particularly acute food insecurity and it helped to strengthen family cohesion, by ensuring that there was enough good quality food to share and eat together at family meal times. In the light of these findings, is it appropriate that emergency feeding programmes put large amounts of resources in to preventing sharing of rations? This is a question that can not be answered by this thesis, but it is possible that it might be more culturally appropriate to incorporate the possibility of sharing in to CTC programme design.

#### 9.4.6.10 The need for follow up and support at home

Study 1 suggested that forming community groups might help, as a support strategy, to improve response rates in outpatient programmes. This was not possible in Malawi due to the geographical dispersion of households with a severely malnourished child in the programme. There were rarely more than 1-2 children from the same village in the programme at any one time. Forming groups that met in between OTP visits therefore was not feasible. This will be a problem for most programmes dealing with a relatively rare event such as SAM. In Malawi, the use of community outreach was a more feasible form of providing ad hoc support in the home to those that needed it. However, Figure 17 and Figure 18 show that 31% of the mortality experienced by children that were discharged from the NRU in to the OTP, and 43% of the mortality that occurred among those treated directly in the OTP happened in the first two weeks of OTP treatment. These data are difficult to interpret as there are many unknowns. The causes of death in the OTP, the proportion of cases that were voluntary discharges by carers taking very sick children home to die or that, despite fulfilling NRU referral criteria refused inpatient care; the proportion of these deaths that could have been avoided with prolonged inpatient care and the proportion of children who would have acquired infections and died had they been referred to or kept longer in the NRU are all unknown. It is clear however, that a high proportion of the mortality in the OTP tends to occur in the first two

weeks of treatment and thereafter is low. This has implication for follow-up and in future the CTC action protocol should better reflect the need for more consistent follow up at home during the first two weeks after admission into the OTP.

#### 9.4.6.11 The use and impact of triage

In 2002 there was concern in the international nutrition community that using triage criteria to treat severely malnourished children directly in outpatient care would be dangerous in some contexts (70). Initially, the nutrition community in Malawi were concerned about the potential risk of treating severely malnourished children as outpatients and the NRU facilities has sufficient space to take all children for phase 1 treatment. Therefore, for the first 5 months of the programme (1st August-31st December 2002) whilst numbers allowed, all children admitted to the programme received phase 1 treatment in the hospital or one of the supported NRUs, followed by outpatient care in the OTP. During this first 6 months programme monitoring clearly showed that there was no increased mortality risk attached to outpatient care and that, as admissions increased, the NRUs were getting very overcrowded. Therefore, from 1st January 2003, triage criteria were introduced that allowed children suffering from severe acute malnutrition with no complications to be treated directly in the OTP.

In order to control for the influence of season on mortality and to examine the impact of using triage in the treatment of SAM, outcomes from two subgroups of the whole study population were compared. The first group (non triaged) were treated between August and December 2002 and the second (triaged) between August and December 2003. A comparison of mortality and recovery in the triaged and non triaged groups suggests that triage may increase the chance of recovery and reduce the risk of mortality (see Table 20). However, the non triaged group had lower MUAC and more severe oedema at admission than the triaged (see Table 19). When triage is entered in to the multivariate analysis of risk factors for mortality and non recovery, the use of triage does not reduce recovery nor increase mortality during treatment, and may reduce mortality in the direction of half (p=0.07). The case fatality in each group when compared with the expected case fatality using the Prudhon index shows no significant differences, but does indicate a trend towards higher excess mortality in the non triaged group. Reduced mortality in the triaged group could be due to less overcrowding in inpatient units that allows staff to focus resources on those at highest risk of mortality and/or a reduction in

acquired infection, a common problem in busy inpatient settings that treat immunocompromised patients (121;168).

However, the triaged group in this study was treated 1 year later than the non triaged group and, although this gives some control for the influence of season on clinical outcome, we could not control for increasing staff experience in implementing treatment protocols over time. More experienced staff may have improved the quality of care given and therefore the clinical effectiveness of treatment. In addition, the operational nature of these data and the fact that the use of triage was new in Malawi and therefore adopted with some caution, may have introduced error in to the triage process. It is likely for example, that if there was any doubt at all of the suitability of a child for direct outpatient care, staff are likely to have acted 'safely' and referred to inpatient treatment first. This may mean that risk of mortality in those children admitted directly to OTP in this programme was lower than other programmes that might use triage less cautiously. Both of these factors limit the interpretation of these results. However, the mortality seen in the direct outpatient group (2.0% in the whole programme: Table 14) is comparable to other programmes that have used triage more widely and which have used similar outpatient protocols using RUTF. Linneman *et al* in 2007 for example reported a mortality rate of 1.4% (95% CI 0.9, 2.0) among children that were admitted directly to outpatient care in Southern Malawi (100).

#### 9.4.6.12 Predictors of mortality and defining SAM with complications

Table 21 shows that WFH ≤-3 z scores, MUAC ≤ 11cm and the presence of marasmic kwashiorkor or anorexia were all strong predictors of a poor outcome i.e. non recovery; MUAC ≤ 11cm was also associated with increased risk of death. Severe oedema appeared to have a borderline significant association with both increased recovery and a (less significant) association with increased mortality. This is likely to be due to the significantly higher chance of default among other grades of oedema (++ and +) ( OR = 5.66 p=0.001) which reduced the recovery rate in this group and bought it closer to that of the recovery rate in the severe oedema group.

The association between many of these indicators and poor outcome has been documented previously (169-171). In this study, a combination of these indicators in a multivariate model strengthened the association between MUAC ≤ 11cm, the presence of

anorexia and the presence of severe oedema with mortality and/or non recovery. This suggests that a combination of anthropometric and clinical indicators (MUAC ≤ 11cm with anorexia for example) as used in this study is a more effective mechanism for the selection of children that have a high risk of mortality and therefore require more intensive inpatient treatment than the use of a single indicator such as MUAC ≤ 11cm.

## 9.5 Conclusion

The title of this chapter asked the question 'Can CTC achieve clinical effectiveness?' and went on to present an in depth analysis of the clinical outcomes of 2819 children with SAM that were treated in the first outpatient programmes in Ethiopia and Malawi. Overall, the data presented provide evidence that CTC can be a highly effective model of nutritional intervention in humanitarian emergencies and can provide substantial advantages over inpatient treatment modalities. Where the full CTC model was implemented study outcomes indicated average mortality rates that were considerably lower than the minimum international standard stipulated by Sphere and that compared favourably with those TFC outcomes reported by Grellety (78), the Malawi inpatient programme and by many of the inpatient studies reported in the literature (see section 6.5.1). In study 2, where the model of decentralised outpatient treatment was not used, mortality remained significantly higher than the indicator given by Sphere. One reason for this is likely to be because the children treated in this study presented much later for treatment and were therefore considerably sicker than those treated in studies 1 and 3. Another reason is that the HIV prevalence in the group treated in study 2 was much higher than that treated in study 3. CTC programmes need to further examine mechanisms for improving effectiveness of treatment in this group.

Importantly, the examination of the use of triage as an independent risk factor for recovery and mortality in study 3 suggested that the use of triage does not reduce the chance of recovery and may reduce the risk of mortality, although this would need further study. The number of deaths that occurred for all categories of malnutrition and all age groups in direct outpatient treatment (i.e. where no inpatient care was provided) in study 3 was low and was lower than the expected number of deaths calculated by the Prudhon index. This suggests that, with the right triage criteria, there is no excess mortality attached to direct treatment in outpatient care for any category of malnutrition.

However, kwashiorkor made up the majority of the admissions to this study and only a relatively small proportion of children were treated directly in outpatient care. For this reason, it was important that the findings presented here were tested more widely in populations with higher rates of wasting, and in programmes where direct treatment in outpatient care was used less cautiously, before any broad statements about the effectiveness of the approach were made. Chapter 10 goes some way towards doing this.

Results presented in this chapter do suggest that outpatient treatment will slow the rate of recovery compared to that seen in well resourced inpatient units. None of the studies reported here achieved the international standard for weight gain stipulated by Sphere of 8g $kg^{-1}$ $day^{-1}$ nor the standard for length of stay of 30 days. This will impact on programme costs and needs to be studied further.

# 10 Can CTC Achieve High Coverage? : Comparing the coverage of CTC and a centre-based therapeutic feeding programme in Malawi

## *10.1 Introduction*

One of the core principals of CTC programmes is that treatment should be decentralised, improving access to multiple treatment sites and thus facilitating high coverage of target populations. The measurement of programme coverage during this research was therefore vital for the assessment of the overall effectiveness and impact of CTC interventions.

This chapter first describes the basis for previous coverage survey methods and their important limitations. The development of a novel coverage survey method is then explained, a process in which the author played a significant role as a member of the research team. The developed method was then piloted in Malawi by the author and subsequently used to examine the level of coverage achieved by the CTC programme in Dowa Malawi in comparison to that achieved by a centre-based therapeutic feeding programme in a neighbouring District. This chapter describes the survey results and discusses the major factors affecting access to, and utilisation of, the CTC programme in Dowa.

## *10.2 Study 4: A new survey method to compare the programme coverage of two therapeutic feeding interventions implemented in neighbouring districts of Malawi*

See Appendix 1 sections 14.1.4 and 14.1.5 for published articles (112;172)

### 10.2.1 Introduction

#### 10.2.1.1 The need for a new technique to measure coverage

In 2004, specific coverage indicators for selective feeding programs were included in the Sphere project's humanitarian guidelines for the first time (72). Traditionally, approaches to estimate therapeutic feeding programme coverage have relied on taking data from the

'standard' nutrition survey used to estimate the prevalence of acute malnutrition in a programme area. The survey method usually adopted is an adaptation of the WHO Expanded Programme on Immunisation (EPI) coverage survey method (173-175). This is a two-stage cluster sampling approach which begins by dividing a population into geographic sections for which population estimates are available. A set of clusters is allocated to these sections in the first sampling stage. The probability of a particular cluster being allocated to a section is proportional to the size of the population in that section. Sections with large populations are more likely to be allocated clusters than those with small populations. This sampling procedure, called probability proportional to size (PPS), helps to ensure that individuals in the programme area have an equal chance of being sampled when a quota sample is taken in the second stage of the survey (176). In recognition of the difficulties of drawing a random sample in many developing countries (177), the EPI method uses a quasi-random sampling method in the second stage. The most commonly used second stage sampling method is a proximity technique. The first household to be sampled is chosen by selecting a random direction from the centre of the cluster, counting the houses along that route, and picking one at random. Subsequent households are sampled by their physical proximity to the previously sampled household. Sampling continues until a fixed sample size has been collected (quota sampling) or until a set number of households have been visited. Sampling is simple and requires neither mapping nor enumeration of households. It is, consequently, usually both quicker and cheaper than using simple random sampling in the second stage of the survey (178).

Once data are collected coverage is estimated either directly using survey data or indirectly using survey data, programme enrolment data, and population estimates. Interpretation of the results of both methods usually assume that coverage is similar throughout the entire survey area and both can provide only a single wide-area coverage estimate.

The EPI method does, however, have problems. The PPS approach is unsatisfactory because:

- The bulk of data are collected from the most populous communities. This may leave areas of low population density (i.e. those areas consisting of communities likely to be distant from health facilities, feeding centres, and distribution points)

unrepresented in the sample. This may cause surveys to evaluate coverage as being adequate even when coverage is poor or non-existent in areas out side of urban centres.

- There is no guarantee of an even spatial sampling. This is true even when the population of the survey area is evenly distributed. Again, PPS will usually leave some areas unrepresented in the sample.
- It relies on population estimates which may be inaccurate in emergency contexts, particularly if population displacement, migration, or high mortality has occurred in the target population.
- The sample size used in these surveys is usually 900 children collected in thirty clusters . This sample size allows the prevalence of acute malnutrition to be estimated with reasonable precision, but when the aim of the survey is to estimate the coverage of a feeding programme for severe acute malnutrition, the sample size will usually be too small to estimate coverage with reasonable precision. There is a similar problem with calculating coverage indirectly. Survey sample sizes are usually too small to estimate the prevalence of severe acute malnutrition with useful precision. This results in prevalence estimates with confidence intervals that are wide relative to the magnitude of the estimate, leading to similarly imprecise estimates of programme coverage.
- The proximity method is unlikely to return a representative sample at the level of the cluster. It is not possible to estimate coverage reliably for a cluster without taking a representative sample from the cluster location (section).
- Even if a representative sample were taken at the cluster level, the normal within-cluster sample size is too small to estimate coverage at the cluster level with reasonable precision.

Thus, when applied to the problem of assessing the coverage of selective feeding programmes, the EPI method has important limitations.

This study presents a trial of an alternative method of measuring therapeutic feeding programme coverage and, using this new method, compares the coverage achieved by a

centre-based therapeutic feeding programme and a CTC programme operating in neighbouring Districts in Malawi during 2003.

### 10.2.2 Objectives

To test a survey method applicable to estimating the coverage of selective feeding programmes in humanitarian emergencies and to use this method to compare therapeutic feeding programme coverage for severely malnourished children achieved by a Community-based Therapeutic Care (CTC) programme and a Therapeutic Feeding Centre (TFC) programme operating in neighbouring Districts in Malawi.

### 10.2.3 Methods

#### 10.2.3.1 Trial Location

See section 9.4.3.1 for background to the nutritional emergency in Malawi in 2002.

In March 2003, seven months into implementation of the national TFC strategy and the CTC programme in Dowa District, we implemented a study to compare the coverage of the CTC programme in Dowa and of a centre-based therapeutic feeding program for the treatment of severe malnutrition in a similar neighbouring District to Dowa, Mchinji. Both districts are located in the central region of Malawi and had been subject to prolonged food shortages (179). The high national prevalence of HIV further aggravated this situation, resulting in elevated levels of acute malnutrition.

Dowa and Mchinji districts are similar in their demographic and socio-economic profiles (see Table 22).

**Table 22: Demographic and socio-economic characteristics of the two target areas for study 4.**

| | Dowa | Mchinji |
|---|---|---|
| Size (km sq) | 3041 | 3156 |
| Population | 411,000 | 324,941 |
| Under five population | 73,980 | 58,489 |
| Main religion | > 90% Christian | > 90% Christian |
| Percentage population in formal employment | 1% | 8% |
| Percentage land under cultivation | 47% | 62% |
| Prevalence of global acute malnutrition (weight-for-height z-score < -2) | 4.5% (Feb 03) | 2.9% (Dec 02) |
| Average population per health centre | 20,360 | 26,839 |
| Average population per doctor | 101,000 | 348,903 |
| Leading cause of mortality | Malaria | Malaria |
| Hospital beds per 1000 population | 0.9 | 1.1 |
| General ration distribution start date | June 2002 | June 2002 |
| General ration distribution target population (no. households) | 20,218 | 10,232 |

In accordance with the national strategy for the treatment of acute malnutrition, an international NGO provided training and support in Mchinji for two NRUs, based at government health facilities, to provide inpatient TFC treatment for children with severe malnutrition. An additional NRU, at a mission hospital run by the Christian Health Association of Malawi (CHAM), was also given some support. All supported NRUs provided phase 1, 2 and 3 inpatient care for severely malnourished children according to WHO and National protocols. In addition, a supplementary feeding programme (SFP) was supported at each treatment site. The Mchinji programme typified the level of support being provided under the national strategy for the treatment of acute malnutrition.

In Dowa the CTC intervention, described in study 3, established four stabilisation centres for the treatment of severe malnutrition with complications within mission and government run hospitals and NRUs. These provided phase 1 inpatient care according to WHO and National

protocols for those children that needed it. In addition, 18 outpatient treatment sites were established within health centres across the district. Each outpatient treatment site implemented an outpatient therapeutic programme (OTP) and a SFP. NGO staff made up mobile support teams which rotated around treatment points and supported the MoH staff with service delivery.

Programmes in both Districts were established within existing Ministry of Health structures and therapeutic care was delivered by Ministry of Health staff in health centres and NRUs. Table 23 describes the additional inputs provided by each NGO and UN organisations to support the Ministry of Health staff during programme implementation.

**Table 23: Programme inputs provided by supporting agency in the two study areas.**

| | CTC programme Dowa | TFC programme Mchinji |
|---|---|---|
| NGO staff: Direct patient care | 1x nutritionist (expatriate)<br>Health centre/community support:<br>2x team leaders<br>2x nurses<br>2x registration staff<br>2x community educators<br>2x drivers<br>NRU support:<br>2x nurses<br>2x feeding attendants | 1x doctor/nutritionist (expatriate)<br>1x nurse<br>1x nutritionist<br>1x driver |
| Consultant staff: CTC development and monitoring * | 1x doctor (expatriate)<br>1x nutritionist (expatriate)<br>1x anthropologist (expatriate) | |
| Food | To all health centres and NRUs:<br>Ready-to-use therapeutic food (RUTF)<br>Corn-soya blend (from WFP)<br>To all NRUs:<br>Therapeutic milks (from UNICEF) | To all NRUs:<br>Therapeutic milks (from UNICEF)<br>Corn-soya blend (from WFP) |
| Medicines | IDA drug kits that include the routine medicines required to treat severe malnutrition provided to each treatment site (a proportion from UNICEF) | IDA drug kits that include the routine medicines required to treat severe malnutrition provided to each treatment site (from UNICEF) |
| Non food items | Soap | |
| Transport | 2x four wheel drive vehicle | 1x four wheel drive vehicle |
| Method of motivation for partner MoH staff in health centres, NRUs and community. | Training and ongoing support from programme staff during programme implementation | Training and ongoing support from programme staff during programme implementation |

* Consultant staff were research staff on short term support visits.

Around the time of the surveys reported here (March 2003) the prevalence of severe acute malnutrition among children < 5 years in Mchinji was estimated to be 2.9% and in Dowa to be 4.5% (180;181).

#### 10.2.3.2 Survey Design

Two surveys were implemented simultaneously, one in Dowa District and one in Mchinji District. The surveys used a stratified design with strata defined using the centric systematic area sample method (182). This method involves dividing the survey area into non-overlapping squares of equal area (quadrats) and sampling the community or communities located closest to the centre of each quadrat. A 1:50,000 scale map of each district was available from the 1998 Malawi national census. A ten-by-ten kilometre grid was overlaid onto each map. All quadrats with more than half of their area inside the district were sampled. Thirty 100 $km^2$ quadrats were sampled. The selected quadrats covered approximately 3000 $km^2$ in each district. That's 89.4% of the 3356 $km^2$ total land area of Mchinji district and 98% of the 2770 $km^2$ total land area of Dowa district. Communities located closest to the centre of each quadrat were then sampled using a case-finding approach. The number of communities sampled from each quadrat was limited by the number of communities in that quadrat which could be sampled by a survey team in a single day. This varied between quadrats and depended on the size of each community (in terms of both population and physical extent) and the distances between communities. Once sampling started in a community, it continued until no further cases could be found. No communities were partially sampled. The location of the centre of each quadrat was identified by reference to the map. A list of communities to be sampled from each quadrat was made prior to the survey team visiting the quadrat. The order of this list (which was also the order in which the communities were sampled) was determined by the proximity of each community to the centre of the quadrat, with the community closest to the centre of the quadrat being sampled first.

#### 10.2.3.3 Sample Size

The sample size was calculated using EpiInfo v6.04d (148) and was based on an estimated feeding programme coverage of 55.5% and 35.5% and an estimated prevalence of severe malnutrition of 4.5% and 2.9% for Dowa and Mchinji Districts respectively. These estimates were based on previous nutritional surveys in the two study areas. The population in each

study District was estimated using data from the 1998 Population and Housing Census and village populations were supplied by each District Assemblies Office (156). An α risk (significance) of 0.05 and β (power) of 0.8 were used. This gave a required sample size of 106 severely malnourished children in each District.

#### 10.2.3.4 Case-finding

For the within-community samples, a case-finding approach was adopted. Two methods were investigated. These were:

1. Screening of all children in a single community at a central location in their home community.
2. Screening, in their homes, of children identified as thin, sick, or oedematous by the community health worker. Additional children were also identified by mothers in each of the screened households.

Each method identified the same children. The second method was considerably more efficient than the first, allowing a survey team to screen up to six communities in one day, and was adopted as the case-finding method for the trial survey.

#### 10.2.3.5 Case-definitions

Cases were defined as children aged under five years with < 70% of the weight-for-height median of the NCHS reference population or bilateral pitting oedema. This was also the entry criteria used for the therapeutic feeding programme. Receipt of treatment was ascertained by the child's presence in a therapeutic feeding centre, confirmed by visiting the centre at the end of the day, or by documentary evidence (i.e. possession of a programme card or identity bracelet).

The surveys used two different definitions of coverage. The first definition was used to provide an estimation of coverage for the recent period preceding the survey (period estimate, see formula 1, Figure 21). This definition is equivalent to that traditionally used by agencies such as WHO and MSF (37) to estimate coverage in centre based programmes and to that used in coverage standards laid out by the Sphere Project (72). It included all those cases that were malnourished at the time of the survey and in addition, it included all children registered in a therapeutic feeding programme. This definition therefore included children registered in the programme who were no longer severely malnourished but had not

yet attained the treatment programme discharge criteria. In this definition cases were defined as children aged under five years with ≤ 70% of the weight-for-height median of the NCHS reference population or bilateral pitting oedema plus any children registered in a therapeutic feeding programme.

The second definition was used to provide an estimation of coverage at the exact point in time of the survey (point estimate, see formula 2, Figure 21). This definition included only cases that were malnourished at the time of the survey. Cases were defined as children aged under five years with ≤ 70% of the weight-for-height median of the NCHS reference population or bilateral pitting oedema.

1. **Period coverage** is calculated using the following formula:

$$\frac{\text{number attending the feeding programme}}{\text{number of cases not attending the feeding programme + number attending the feeding programme}} \times 100$$

2. **Point coverage** is calculated using the following formula:

$$\frac{\text{number of cases attending the feeding programme}}{\text{total number of cases}} \times 100$$

**Figure 21: Formulas 1 and 2 for calculating period and point coverage**

#### 10.2.3.6 Programme Coverage

Coverage in each quadrat was estimated in two ways, a period estimate that used the first definition of coverage and a point estimate that used the second definition. For each estimate, coverage was calculated as the ratio of cases receiving treatment found in the sample to the total number of cases found in the sample. Overall coverage was estimated by treating each quadrat as a stratum in a stratified sample (183) with sample weights derived from the population of the communities sampled in each quadrat.

#### 10.2.3.7 Data handling

Data were entered, checked, cleaned and analysed using Excel (146). An excel based CSAS coverage calculator was developed by a consultant epidemiologist employed to support the development of the methodologies used for these surveys. It was this calculator that was

used by the author to perform the stratified analysis for calculation of the overall coverage estimates (weighted by population), the coverage in each quadrat and to present the spatial distribution of coverage with histograms and mesh maps (184). The mesh maps were then exported by the author in to the programme Microsoft 'Paint' for further revision (185).

### 10.2.4 Results

The survey method proved relatively simple to implement and data collection took three survey teams ten days to complete in each District. An example of data collected from the Mchinji survey are shown in Table 24.

#### 10.2.4.1 Period estimation of coverage

Overall the period coverage was 24.6% (95% C.I. 17.8%, 31.4%) in Mchinji and 73.6% (95% C.I. 66.0%, 81.3%) in Dowa. The distribution of per-quadrat coverage for each District is shown in Figure 22 and Figure 23. Coverage ranged between zero (in five quadrats) and fifty percent (in two quadrats) in Mchinji and between zero (in one quadrat) and one hundred percent (in ten quadrats) in Dowa.

#### 10.2.4.2 Point estimation of coverage

Overall the point coverage was 20.0% (95% C.I. 13.8%, 26.3%) in Mchinji and 59.9% (95% C.I. 51.4%, 68.5%) in Dowa. Coverage ranged between zero (in nine quadrats) and fifty percent (in one quadrat) in Mchinji and between zero (in four quadrats) and one hundred percent (in ten quadrats) in Dowa.

#### 10.2.4.3 Patterns of coverage

The spatial distribution of per-quadrat period coverage for each District is shown in Figure 24 and Figure 25. Full grey squares represent 100% coverage, whilst an empty, white square represents 0% coverage. The approximate locations of the nutritional rehabilitation units in each District are marked and thin black lines indicate the approximate location of major roads. The spatial distribution of per-quadrat point coverage for each District is very similar to that shown for the period coverage in Figure 24 and Figure 25 and therefore is not presented here. Both period and point coverage appeared more uniform in Dowa than in Mchinji. In Mchinji, five quadrats (13%) had zero period coverage and only two quadrats (7%) met the Sphere coverage standard. In Dowa, period coverage met the Sphere Project standard in twenty-seven out of thirty (90%) quadrats and in only one quadrat (3%) was it

zero. In Mchinji, nine quadrats (30%) had zero point coverage and in only one quadrat (3%) was coverage > 50%. In Dowa, point coverage was > 50% in twenty-one out of thirty (70%) quadrats and in only four quadrats (13%) was it zero.

**Table 24: Data from the Mchinji survey**

| Quadrat* | | Communities Visited | Population < 5 years | Children Screened | Cases Found | Cases Covered | Point Cover (%) |
|---|---|---|---|---|---|---|---|
| *x* | *y* | | | | | | |
| 3 | 7 | 6 | 433 | 55 | 7 | 2 | 28.6% |
| 4 | 5 | 5 | 362 | 46 | 4 | 0 | 0.0% |
| 4 | 6 | 5 | 233 | 43 | 4 | 1 | 25.0% |
| 4 | 7 | 6 | 346 | 53 | 3 | 1 | 33.3% |
| 4 | 8 | 5 | 186 | 53 | 3 | 1 | 33.3% |
| 4 | 9 | 4 | 246 | 39 | 5 | 1 | 20.0% |
| 5 | 3 | 5 | 256 | 36 | 3 | 0 | 0.0% |
| 5 | 4 | 6 | 270 | 53 | 2 | 0 | 0.0% |
| 5 | 5 | 5 | 175 | 52 | 3 | 0 | 0.0% |
| 5 | 6 | 3 | 138 | 37 | 3 | 1 | 0.0% |
| 5 | 7 | 5 | 268 | 48 | 5 | 2 | 40.0% |
| 5 | 8 | 6 | 301 | 57 | 2 | 0 | 0.0% |
| 5 | 9 | 4 | 274 | 36 | 4 | 1 | 25.0% |
| 5 | 10 | 6 | 351 | 52 | 5 | 0 | 0.0% |
| 6 | 4 | 5 | 358 | 51 | 5 | 2 | 0.0% |
| 6 | 5 | 3 | 391 | 29 | 8 | 1 | 12.5% |
| 6 | 6 | 4 | 276 | 35 | 6 | 0 | 0.0% |
| 6 | 7 | 6 | 366 | 49 | 6 | 1 | 16.7% |
| 6 | 8 | 4 | 189 | 38 | 3 | 1 | 33.3% |
| 6 | 9 | 5 | 385 | 51 | 5 | 1 | 20.0% |
| 6 | 10 | 5 | 173 | 46 | 6 | 2 | 33.3% |
| 7 | 4 | 6 | 237 | 53 | 5 | 1 | 20.0% |
| 7 | 5 | 5 | 227 | 48 | 3 | 1 | 33.3% |
| 7 | 6 | 5 | 262 | 47 | 4 | 0 | 0.0% |
| 7 | 7 | 5 | 287 | 48 | 6 | 3 | 50.0% |
| 7 | 8 | 6 | 268 | 55 | 4 | 0 | 0.0% |
| 8 | 3 | 6 | 380 | 50 | 8 | 2 | 25.0% |
| 8 | 4 | 6 | 345 | 57 | 5 | 2 | 40.0% |
| 8 | 6 | 3 | 345 | 37 | 6 | 1 | 16.7% |
| 8 | 7 | 6 | 231 | 49 | 3 | 1 | 33.3% |

* Specified as west to east (*x*) and south to north (*y*) co-ordinates in the sampling grid

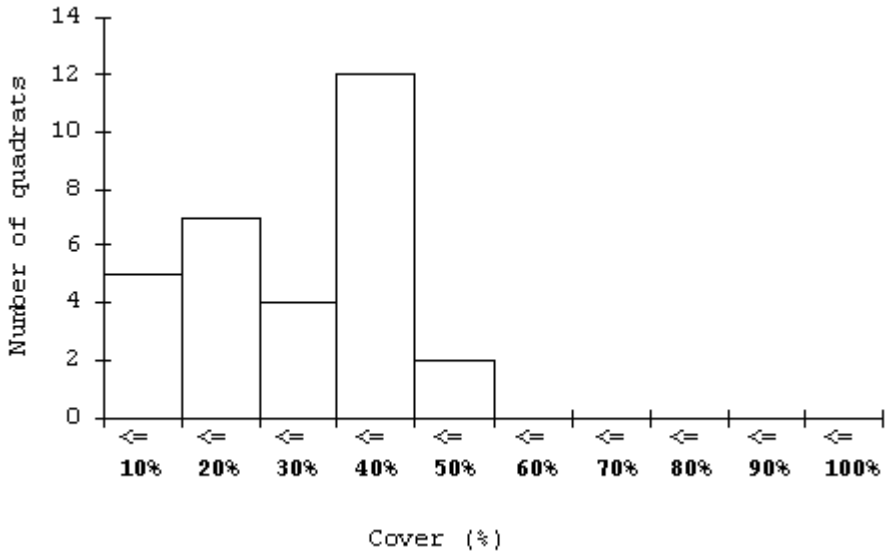



**Figure 22: Distribution of per-quadrat period coverage in the therapeutic feeding centre (TFC) programme in Mchinji**

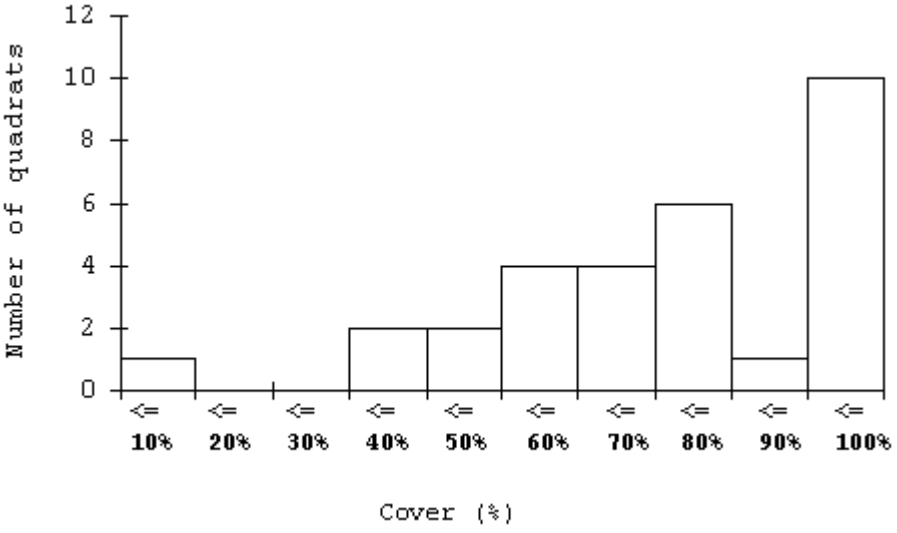



**Figure 23 : Distribution of per-quadrat period coverage in the community-based therapeutic care (CTC) programme in Dowa**

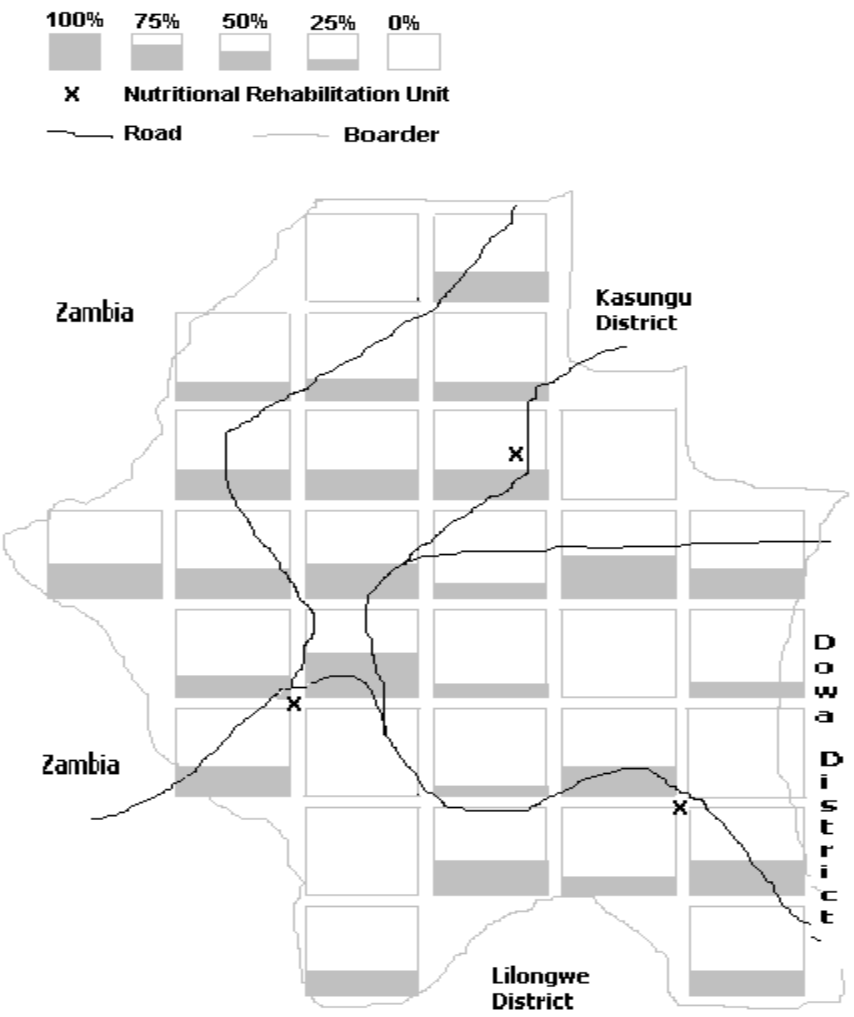



**Figure 24: Spatial distribution of per-quadrat period coverage in the therapeutic feeding centre (TFC) programme in Mchinji**

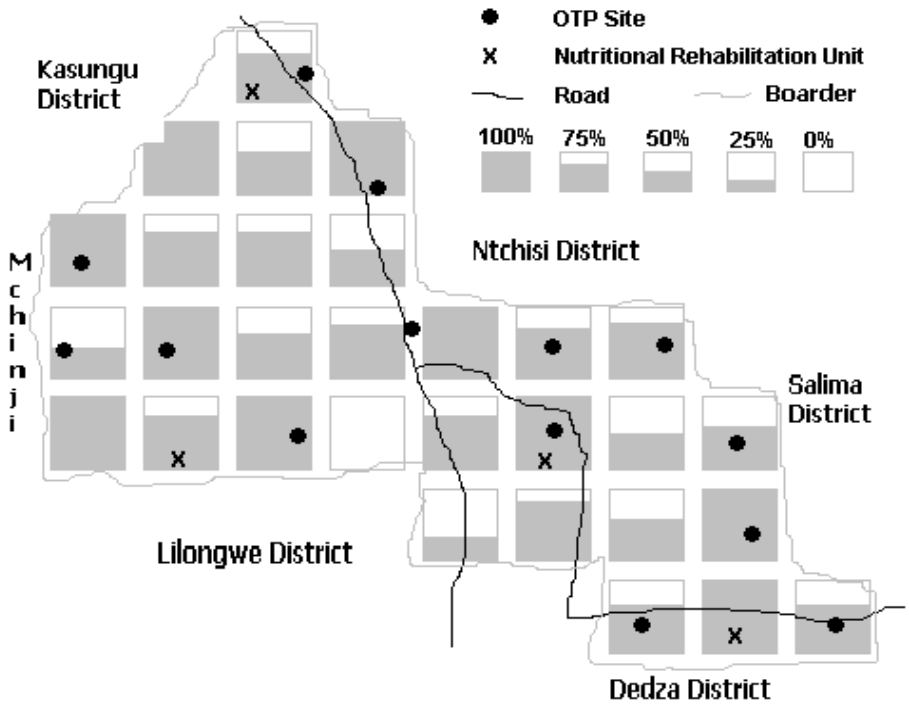



**Figure 25: Spatial distribution of per-quadrat period coverage in the community-based therapeutic care (CTC) programme in Dowa**

## 10.2.5 Discussion

### 10.2.5.1 Appropriateness of the survey methodology

Centric systematic area sampling is widely used in ecology to ascertain the spatial distribution of abundance of plant and animal species over wide areas, and in human geography to investigate point phenomena such as the distribution of specific types of retail businesses (182;186). Its principal advantages are reported to be simplicity of use in the field, the ability to sample evenly across a wide area, simplicity of data handling (183), and the addition of a spatial dimension to survey data (182). In practice, the method proved simple to use in the field although this may not be the case if useful maps are not available. Even spatial sampling is virtually guaranteed by the use of a sampling grid and is only likely to be compromised when, for example, poor security prevents some quadrats from being sampled. The terrain of the trial survey location made it feasible to define quadrats by overlaying a simple grid onto a map of the programme area. More difficult terrains (for example programme areas divided by impassable rivers, gorges, or front-lines) may require more imaginative quadrat location strategies.

Entry and management of data was considerably quicker than for a two-stage cluster sampled survey since data analysis procedures require only summary data for each quadrat. Data handling procedures are simple enough to be performed using a spreadsheet package, such as excel, although charting the spatial distribution of per-quadrat coverage is likely to require more versatile charting functions than are available in such packages; 'Paint' was used for the mesh maps produced here. The use of case-finding, as opposed to probability sampling, in the second stage provides a sample that is designed to be exhaustive. The case finding approach is likely to identify all, or nearly all, cases in sampled communities. This allows per-quadrat coverage to be calculated precisely and meaningful comparisons of per-quadrat coverage to be made. The ability to calculate per-quadrat coverage allows a spatial assessment of coverage, providing information useful for programme management: In Mchinji District for example, the survey results would cause action to be taken to address the zero coverage in the south-west corner of the programme area. In different contexts it may be necessary to develop and test case-finding procedures in order to ensure exhaustive within-community samples.

The method may prove to be less useful for estimating the coverage of less restrictive programmes (for example supplementary feeding programmes) where case-finding procedures may provide a less exhaustive sample than proved possible in the trial survey. This may be addressed by estimating the exhaustiveness of case-finding procedures using capture-recapture methods and using this estimate to correct for under-reporting (187). Estimating the exhaustiveness of the case-finding procedure would also enable the method to yield estimates of both prevalence and coverage from a single survey. The trial survey estimated the prevalence of severe acute malnutrition as 1.6% in Mchinji District and 0.8% in Dowa District, calculated as the ratio of the number of cases found in the sample to the total population under five years in the sampled communities and assuming a completely exhaustive case-finding procedure. This estimate is broadly in line with that reported by nutrition surveys of the same populations implemented around the same time as this study (180;181).

There are potential problems with the proposed survey method. The centric systematic area sampling method, like any systematic sampling method, can produce biased estimates if there is periodic geographic variation in coverage and the sampling locations tend to coincide with this. This is difficult to control against without prior knowledge of the periodic variation although simple checks, such as ensuring that sampling locations are not (for example) all in valleys or all on hilltops and adjusting the grid position accordingly, should help to minimise this problem. The trial survey used a proximity method to select the centrally located communities to be sampled in each quadrat. A more rigorous sampling procedure such as selecting communities at random in each quadrat or using a finer grid and selecting a single central community from each quadrat could be adopted but this would increase the cost of surveys and is likely to yield little increase in the accuracy (183). The proposed survey method assumes homogeneity of coverage within quadrats. The area of each quadrat is, however, considerably smaller than the programme area (approximately one-thirtieth of the programme area in the case of the trial surveys) making this assumption more plausible than that of homogeneity over an entire programme area that often underlies EPI-derived methods. Census population estimates were used to derive sample weights. It has already been noted that census data may be unreliable in some emergency contexts. The method is, however, likely to be robust to such unreliability and, when accurate population estimates are not available, data may be analysed as arising from a simple random sample [21] i.e. there is no need to weight by population.

An advantage of the proposed method is that it is likely to sample considerably more communities than would usually be sampled in an EPI-derived survey. The trial survey sampled 151 communities compared to the maximum of 30 communities usually sampled in EPI-derived surveys. It should be noted that the PPS procedure often causes more than one cluster to be sampled from larger communities causing many EPI-derived surveys to sample fewer than the maximum 30 communities. Table 25 compares the results of the trial survey in Mchinji with the results of a survey of Mchinji district using an EPI-derived method undertaken in December 2002 (181). The trial survey method screened more children from more communities and found more cases than the EPI-derived method, resulting in a more precise estimate of programme coverage. The trial method was able to identify areas of low

or zero coverage whereas the EPI-derived method was limited to providing a single district-wide estimate.

**Table 25 : Methods, sample sizes, and results for two different surveys**

| | EPI-derived survey | Trial survey |
|---|---|---|
| Design | Cluster | Stratified |
| First-stage sampling | PPS | Centric systematic area |
| Second stage sampling | Proximity | Exhaustive (case-finding) |
| Communities sampled | 30 | 151 |
| Children screened | 1025 | 1403 |
| Staff required (person-days)* | 81 | 123 |
| Cases found | 10 | 136 |
| Cases covered | 1 | 29 |
| Cover (%) | 10.0% | 20.0% |
| 95% confidence interval | 0.2%, 44.5% | 13.8%, 26.3% |
| Prevalence (%) | 0.98% | 1.59% |
| 95% confidence interval | 0.47%, 1.79% | NA |

*Includes training, supervision, survey days, data-entry, and data analysis but excludes testing and evaluation of case-finding methods for the trial survey

The trial survey took longer to complete than the EPI-derived survey. This is because one survey team took one day to sample one quadrat whereas a survey team can usually sample two clusters per day in an EPI-derived survey. The proposed survey method could, however, be as efficient as EPI-derived methods in higher prevalence situations and in less compact survey areas. Importantly, active case-finding is central to both successful programme implementation and the proposed survey method. This means that the estimate of coverage could be integrated with programme outreach, although this would need to be confirmed by more operational research. This would allow continued estimation of coverage and prevalence as part of routine programme activity, removing the need for expensive and repeated cross-sectional surveys.

This new survey method addressed many of the shortcomings of EPI-derived methods as applied to the problem of estimating coverage in selective feeding programmes. Particularly, it allows identification of areas with poor coverage within a programme area. The results indicate that the method should be used, in preference to EPI-derived survey methods, for estimating the coverage of selective feeding programmes. It should also be considered when

evaluating the coverage of other selective entry programmes or when coverage is likely to be spatially inhomogeneous.

#### 10.2.5.2 Coverage of the TFC and the CTC programme

Using both the period and point definitions of coverage, the coverage of the CTC programme in Dowa was substantially higher than that found in the TFC programme in Mchinji. Period coverage, the measure that is comparable with existing international measures of coverage, in Dowa falls well within the Sphere standard of > 50% for rural areas. In Mchinji however the period coverage does not meet this standard.

Both period and point coverage were also more homogenous in Dowa than in Mchinji. In Mchinji for example, there was great variation in the coverage rates with 4 quadrats (13%) having zero period coverage and only 2 quadrats (7%) meeting the Sphere coverage standard of > 50%. By contrast, in Dowa, there was less variation in coverage rates across the district. Here, programme period coverage meets the Sphere Project standard of > 50% in 27 out of 30 (90%) quadrats and in only one quadrat (3%) is it zero. In Mchinji, coverage is highest around the NRUs and follows the main routes of communication. In Dowa, where coverage is much higher, service delivery was far more decentralised, the distances that people had to travel to attend treatment centres were much lower and the length of stay in inpatient care much shorter. This suggests that the ease of geographic accessibility to treatment and the lower opportunity cost that this implies for the carer is a major determinant of programme coverage and hence impact of this CTC programme.

It is important to note however, that the active case finding and referral employed by the CTC programme in Dowa, through MoH HSAs, is likely to have been an additional important factor affecting coverage of this programme compared to the centre-based programme in Mchinji that did not use active case finding in this way.

However, despite the active case finding and the higher level of support and inputs given to the CTC programme (shown in Table 23), figure 25 above does show that there were other important factors that are very likely to have influenced the coverage of the CTC programme. These factors; including easier geographic access and lower opportunity costs

attached to treatment as a result of shorter distances to travel and less time spent away from home; could not have been addressed in the TFC programme with the addition of case finding and more resources and it is likely therefore that the improved geographic access to services and the reduced opportunity cost to carers and not the level of resourcing, was an important determinant of both higher coverage and a more equitable spread of coverage through the district. Putting additional resources into the set up of new NRUs across Mchinji and in to active case finding might have served to increase geographic accessibility to services and increase the number of referrals made to TFCs, but would not have reduced the opportunity cost associated with inpatient care and the barriers to seeking and complying with treatment that this presents to the families of malnourished children.

# 11 Going to Scale with CTC

## *11.1 Introduction*

The results of studies one to four helped to define certain conditions in which the outpatient treatment of SAM could be both clinically effective and achieve high coverage of a target population. They showed that decentralisation of treatment, and understanding and participation of beneficiary communities were vital to encourage early presentation of children suffering from SAM and for achieving high coverage of a target population. They also helped to define, in the particular circumstances in which the studies occurred, the clinical profile of a child suffering from SAM with no complications that could be safely treated in outpatient care alone with no increased risk of mortality

The original intention of this thesis was to use the initial research projects in Ethiopia and Malawi to define parameters for a final randomised controlled trial that compared outcomes of an inpatient-based (or TFC) programme and a CTC programme. However, as the CTC research project in Malawi developed (Study 3) it became clear that a randomised controlled study design to compare TFC and CTC programmes would be difficult to implement. Participants in the CTC programme in Malawi had voiced a strong preference for outpatient care and the common societal value, that to be fair each member should receive similar treatment (known locally as communitarianism but common across sub Saharan Africa) would have made any randomization difficult (132). This, together with papers from authors such as Habicht and Victora that have questioned the value of RCTs in evidence-based public health (143) and developed frameworks within which non randomised, adequacy trials could be reported with rigour (188), allowed the author and colleagues to take the decision against an RCT. Instead, it was necessary to demonstrate adequate outcomes of CTC programmes within many different populations and epidemiological contexts. The ‘research and development’ phase of CTC therefore continued with 17 programmes implemented subsequent to the Malawi Dowa programme presented above. These programmes used a very similar treatment model to that used in Dowa (with slight variations according to national protocols) and all were monitored closely by the Valid International CTC research and

development team which included the author. The monitoring data for these programmes were collected and compiled by the author and are presented here.

## *11.2 Study 5, Monitoring CTC 2003-2005: a multi-country evaluation*

See Appendix 1, section 14.1.6 for paper (189)

### 11.2.1 Introduction to each programme site

This section provides a brief background explaining the need for a programme that treated SAM, and the epidemiological, population and geographic profile for each of the programme areas for which data is presented.

#### 11.2.1.1 Malawi, Dowa District

Section 9.4.3.1 above presents an introduction to this programme and section 9.4.5 detailed data analysis from the first year and a half of implementation (August 2002 – December 2003). The research programme went on to run until July 2005 and the data for this latter phase of the programme are included in Table 27.

#### 11.2.1.2 Malawi, Nkhotakota District

Nkhotakota district is in the central region of Malawi and is similar in environment and epidemiological profile to Dowa. It has an area of 7,500 $km^2$ of which half is covered by Lake Malawi and the remainder lies at between 50 and 1000 metres above sea level. The District's population is around 230,000 of whom the majority live in a predominantly rural locality and rely mainly on subsistence agriculture to survive. It is bordered in the east with Lake Malawi and therefore fishing also forms an important source of food and income. Population density is thought to be around 114 persons per $km^2$. Like Dowa, most of the District is fairly accessible, especially outside the rainy season. As in Dowa, Concern Worldwide started working in the District in 2002 in response to the national nutritional emergency. The CTC intervention for the treatment of children suffering from SAM started in July 2003.

#### 11.2.1.3 Ethiopia, Dessie Zuria and Kalu Districts, South Wollo Zone

South Wollo Zone is in Amhara Region in the Northern Highlands of Ethiopia. The vast majority of the 450,000 people that live across the two districts are subsistence farmers and live in rural villages. The population density in the area is 183 people per $km^2$. The region is extremely mountainous; the altitude ranges from 1,700 to 3,807 metres above sea level. The infrastructure is poor: there are some roads but most of these require a

four-wheel drive vehicle. Many villages can only be reached on foot or by mule (up to 6 hours walk from the closest road).

In December 2002, nutrition surveys carried out by Concern Worldwide, in collaboration with Amhara Region Disasters, Preparedness and Prevention Bureau (DPPB), reported global acute malnutrition levels of 17.2% and 3.1% severe acute malnutrition across both districts. At the same time a multi agency crop assessment reported the harvest to be 25% below normal and identified half of the population to be in need of food aid. In response to these findings, the CTC programme started at the beginning of 2003.

#### 11.2.1.4 Ethiopia, Damot Weyde District, Wolayita Zone

Wolayita is situated in the north-eastern corner of the North Omo Zone of the Southern Nations, Nationalities and Peoples' Region (SNNPR). It is 385 kilometres south of Addis Ababa and, due to the relatively high population density of between 125-742 people per $km^2$ pressures on land and the consequent agricultural practices make the area unique in Ethiopia. The population of the District is estimated at 170,114 people (Concern census, 2001) of which *circa* 90% are subsistence farmers. The area is characterised by a rugged, mountainous topography together with large plains, valleys and gorges. The altitude ranges from 1,250 to 1,800 metres above sea level. The soil in the area is dominantly sandy loam with poor fertility and dramatic soil erosion is a prominent feature.

Damot Weyde has suffered a history of drought: most famously in 1984 and then again from 1997 to 2000 and 2002 to 2004. In this period the people of Damot Weyde have faced repeated and significant harvest losses. Due to small land holdings, poor soil fertility, low productivity and erratic rainfall, the area consistently fails to meet food needs. Concern started a CTC intervention in April 2003 in response to increasing levels of GAM and SAM and deteriorating food security.

#### 11.2.1.5 Ethiopia, Awassa Zuria District, Sidama Zone

Sidama zone, located in SNNPR in the southern part of Ethiopia, was also affected by the severe drought between 2002 and 2004. The area has a similar demographic and geographic profile to Wolayita and suffers the same population pressure. A SC US CTC

intervention started here in 2003 in response to increasing levels of acute malnutrition and rapidly deteriorating food security.

#### 11.2.1.6 South Sudan, Aweil North/West counties, Bahr el Ghazal Region (BEG)

Northern Bahr el Ghazal is one of the most food insecure regions in southern Sudan. It is inhabited mainly by the Dinka people, who make their living through subsistence farming and nomadic cattle herding. High population density forces people to farm the same small plots of land over and over again, exhausting the soil and producing yields that provide food for just a few months of each year. The rural economy was destroyed during the long civil war, and agricultural practices are very rudimentary. Lack of access to clean water and the nearly total absence of primary healthcare aggravate a very fragile food security situation. Year after year, disease-induced malnutrition rates in northern Bahr el Ghazal are among the worst in south Sudan: rates of acute malnutrition of >20% are chronic in the region between May and August. The area is very remote and the few roads into the area are cut off during the rainy season. This results in very little trade to complement people's diets. In response to these high levels of acute malnutrition and ongoing poor food security Concern and Tearfund, with Valid International, started CTC here in mid-2003.

#### 11.2.1.7 North Sudan, Darfur Region

Darfur Region is 1000 km to the west of Khartoum and one of the most food insecure regions in Sudan. It is an area the size of France but inhabited by only 6 million people, divided into three federal states; north Darfur, west Darfur and south Darfur. The population comprises nomadic tribes, mainly Arab and Zaghawa, and farming tribes, mainly Fur. Much of the region is characterised by low hills of sandy soils, known as goz, sandstone hills and desert. The area has a long history of severe food shortages caused by rainfall shortage and political and economic marginalisation by the federal government. Access to health care in the Region is extremely limited. In 2003, in response to increasing levels of acute malnutrition and a poor food security outlook Concern, Goal and Caritas, in partnership with Valid International, set up CTC programmes in targeted locations in the northern and western States.

**Figure 26: An outpatient therapeutic programme site in Darfur**

#### 11.2.1.8 Niger, Maradi

Niger is ranked last on the United Nations Development Programme Human Development Index (159). Life expectancy at birth is 44.3 years and 54 percent are without access to a clean water source. The majority of the population is engaged in subsistence farming, which is vulnerable to drought, desertification and locust infestations, whilst a smaller proportion, coming mainly from the Tuareg and Fulani tribes, are nomadic. In 2005, Niger experienced the second worst food crisis in its modern history, and a third of the population was threatened by famine. Poor harvests in 2004 due to insufficient rain and locust infestations meant that most households ran out of supplies. Although food was available, prices more than doubled, putting it out of reach of the majority of the population (190). The epicenter of this crisis was Maradi region, where MSF with support from Valid International set up a large CTC programme in 2005.

### 11.2.2 Methods

#### 11.2.2.1 Programme methods

Describing each of the 17 programmes and their protocols in detail goes beyond the scope of this thesis. Therefore, I have summarised the main differences between the protocol used in each programme and that used in the Malawi CTC programme (section 9.4.4.1) in Table 26.

**Table 26: Description of basic protocols for each CTC programme examined in study 5 relative to those used in Dowa, Malawi (Study 3)**

| | Dowa, Malawi | Nkhotakota Malawi | South Wollo Ethiopia | Wolayita Ethiopia | Sidama Ethiopia |
|---|---|---|---|---|---|
| **Community mobilisation & referral** | Paid outreach by MoH and NGO community agents followed by series of meetings with key community leaders and community health workers to encourage their long term involvment (unpaid) in screening and referral | same as Dowa | as Dowa + use of regular FGDs in the community to monitor reasons for non attendance. Soap given as 'compensation' for those referred to programme sites by CHW but not admitted | same as S Wollo | Community leaders and community health and nutrition workers (unpaid) |
| **Screening criteria** | MUAC < 13cm and/or visible signs of SAM | same as Dowa | same as Dowa | same as Dowa | same as Dowa |
| **Admission and discharge criteria** | Admission : WFH < 70% of the median and/or pitting oedema and/or MUAC < 11cm (if height > 75cm or age > 1 year) and/or (age >6 months & weight <4kg) Discharge: WFH >= 85% of the median and no oedema and MUAC > 11cm and no serious illness for 2 visits | same as Dowa | as dowa apart from admission criteria did not include > 6 mths < 4kg and where SFP present discharge criteria WFH > 80% of the median | same as S Wollo | same as S Wollo |
| **Referral to inpatient care*** | Age < 6 months; oedema ++ or +++; anorexic; temp >= $39^0$c or <= $35^0$c; resp rate outside normal range; severe dehydration; severe anaemia; serious superficial infection; general signs of serious illness | same as Dowa | Criteria for referral as Dowa apart from: oedema +++ (NOT ++) | same as S Wollo | same as Dowa |
| **Nutritional treatment in inpatient care** | Phase 1: formula 75 at 100 kcal kg-1 day-1 by 8 feeds per day; cautious introduction of RUTF | same as Dowa | same as Dowa | same as Dowa | same as Dowa |
| **Nutritional treatment in outpatient care** | RUTF at 175-200 kcal kg-1 day-1 and 3.75kg of blended flour fortnightly | same as Dowa | same as Dowa | same as Dowa | same as Dowa |
| **Medical treatment$^{\alpha}$** | For all children: Vitamin A; folic acid; fansidar; amoxycillin; albendazole. Further medical treatment prescribed according to symptoms | same as Dowa | same as Dowa | same as Dowa | same as Dowa |
| **Followup in the OTP** | Weekly medical and nutritional assessment | same as Dowa | same as Dowa | same as Dowa | same as Dowa |
| **Followup at home$^{\beta}$** | Home visit by community health worker arranged if child defaulted from treatment or if child not recovering as expected. Support given adhoc | same as Dowa | as Dowa + some home visit support provided by mothers of recovered children to other mothers with children in the programme. Visits were more structured than Dowa, with community health workers using checklists of issues to observe including appetite and signs of infection. | same as S Wollo | same as S Wollo |

**Table 26 contd.**

| | Hararge Ethiopia | BEG South Sudan | W Darfur North Sudan | N Darfur North Sudan | Awassa Ethiopia | Maradi Niger |
|---|---|---|---|---|---|---|
| **Community mobilisation & referral** | Community leaders and community health and nutrition workers (unpaid) | community health and nutrition workers (unpaid) | community health and nutrition workers (unpaid) | community health and nutrition workers (paid phased in to unpaid) | community health and nutrition workers (unpaid) | Outreach by MoH community agents and community health workers: small paid incentive provided |
| **Screening criteria** | same as Dowa | same as Dowa | same as Dowa | same as Dowa | same as Dowa | MUAC < 12.5cm and/or visible signs of SAM |
| **Admission and discharge criteria** | as S Wollo apart from admission/discharge criteria did not include MUAC | same as S Wollo | same as S Wollo | as S Wollo apart from discharge criteria included MUAC > 12cm | as S Wollo + 2nd twin and MUAC < 11cm for age > 11 months | as Dowa apart from admission criteria did not include > 6 mths < 4kg |
| **Referral to inpatient care*** | same as S Wollo | same as S Wollo | same as S Wollo | same as S Wollo | same as S Wollo | same as S Wollo |
| **Nutritional treatment in inpatient care** | same as Dowa | asDowa apart from 6 feeds per day | as Dowa apart from 6 feeds per day | as Dowa apart from 6 feeds per day | same as Dowa | same as Dowa |
| **Nutritional treatment in outpatient care** | same as Dowa | as Dowa apart from 4kg blended flour fortnightly | as BEG | as BEG apart from no blended flour given as family ration for first phase of programme | same as Dowa | as Dowa apart from 3.3 kg blended flour fortnightly |
| **Medical treatment$^{\alpha}$** | same as Dowa | same as Dowa | same as Dowa | same as Dowa | same as Dowa | same as Dowa |
| **Followup in the OTP** | same as Dowa | same as Dowa | same as Dowa | same as Dowa | same as Dowa | same as Dowa |
| **Followup at home$^{\beta}$** | same as Dowa | same as Dowa | same as Dowa | same as Dowa | same as Dowa | Consistent followup of defaulters by community agents and health workers. |

*Notes on table:*

WFH = weight for height; Nkk = Nkhotakota

* see table 8 for detailed description of clinical signs

α see appendix 8 section 14.8 for a detailed description of the medical protocol

β See appendix 9 section 14.9 for a detailed description of the action protocol for home visits

#### 11.2.2.2 Research methods

##### *11.2.2.2.1 Subjects*

Outcomes are presented from all children admitted to the CTC programmes listed in Table 26 between the dates specified. There were no exclusions.

##### *11.2.2.2.2 Data Collection*

These data were collected as part of routine programme monitoring. Outcome data i.e. numbers of children recovered, died, defaulted, transferred and non-recovered were recorded on reports as described in section 8.4.3.2 and appendix 4, section 14.4. All programmes maintained a database similar to that shown in appendix 5, section 14.5 from which the outcome data presented in Table 27 were extracted.

All available mid term and final programme evaluation narrative reports were reviewed. Any important lessons learnt, particularly in relation to maximizing demand and minimizing barriers to accessing treatment were recorded and are referred to below in the discussion.

##### *11.2.2.2.3 Data coding*

Outcome data were coded as either 'recovered', 'died', 'default', transfer or 'non responder'. Definitions of 'recovered' for each programme are listed in Table 26. For most programmes this was defined as discharged from the OTP after field staff assessed that the patient had fulfilled the following criteria for 2 consecutive weeks:

- a weight-for-height of more than or equal to 85% of the median NCHS reference;
- and a MUAC of > 11cm (children > 75cm);
- and absence of bilateral pitting oedema;
- and free from serious infective illness.

In all programmes, patients who failed to attend the OTP on two consecutive weeks were recorded as a defaulter. Where ever possible, defaulters were followed up at home, although these follow up data was not available for this thesis.

Any child that was transferred out of the programme to another medical facility was coded as a transfer and any child that had not been discharged recovered by 120 days was coded as a 'non responder.

### 11.2.3 Results

**Table 27 : Outcomes from children presenting to CTC programmes between Feb. 03 and Dec. 05 (N = 20,418)**

| | | | | | *Outcomes: outpatient & inpatient treatment* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Country*** | ***Figures for Period*** | ***No. SAM treated (OTP + SC)**** | ***Direct OTP Admissions*** | ***Coverage ^*** | ***Recovery*** | ***Default*** | ***Death*** | ***Transfer*** ** | ***Non-responder*** | ***Comment^^*** | ***Rate wt gain g/kg/d*** | ***LOS**** ** |
| Malawi - Dowa+ | Jan 04 - Dec 04 | 1,553 | 45% | 72% ^ | 72.4 | 16.2 | 7.2 | 4.1 | 0.2 | | 5.7 | 46 |
| Malawi - Dowa | Jan 05 - Jul 05 | 1,696 | 63% | - | 80.5 | 12.5 | 4.2 | 2.7 | 0.1 | | 5.8 | 45 |
| Malawi - Nkhotakota | July 03 - Nov 03 | 105 | 27% | - | 58.9 | 27.8 | 10.0 | 3.3 | | | | |
| Malawi - Nkhotakota | Mar 04 - Dec 04 | 501 | 55% | - | 61.9 | 23.2 | 8.9 | 1.4 | 4.6 | | | |
| Malawi - Nkhotakota | Jan 05 - Jul 05 | 1,021 | 70% | - | 76.7 | 16.3 | 6.0 | 0.9 | - | | | |
| Ethiopia - South Wollo | Feb 03 - Dec 03 | 590 | 95% | 78% ^ | 74.6 | 9.7 | 7.5 | - | 8.3 | | 4.5 (M)/4.0 (K) | 80 |
| Ethiopia - South Wollo | Jan 04 - Dec 04 | 1,359 | 92% | - | 82.7 | 4.2 | 4.9 | - | 8.2 | | 3 | 82 |
| Ethiopia - South Wollo | Jan 05 - May 05 | 856 | 96% | 77%^ | 83.4 | 6.0 | 4.6 | - | 5.6 | | 3.2 | 85 |
| Ethiopia - Wolayita | Apr 03 - Dec 03 | 194 | 24% | - | 69.6 | 5.2 | 7.3 | 10.5 | - | 4 registered on closure | | |
| Ethiopia - Wolayita **** | Jan 04 - Dec 04 | 460 | 91% | - | 83.9 | 5.4 | 1.9 | 8.9 | - | no SC data available | | |
| Ethiopia - Wolayita | Jan 05 - Jun 05 | 245 | 100% | - | 92.9 | 5.6 | 1.6 | - | - | | | |
| Ethiopia - Sidama | Sept 03 - Aug 04 | 1,497 | 85% | 78% ^ | 84.8 | 5.9 | 1.2 | 2.9 | 5.2 | | 6.8 (M)/5.5 (K) | 45 (M), 41 (K) |
| Ethiopia – Hararge | Apr 03 - Jan 04 | 232 | 99% | 81% ^ | 85.8 | 6.0 | 4.9 | 3.3 | - | 49 registered on closure | | |
| South Sudan - BEG | Jun 03 - Jan 04 | 610 | 92% | - | 73.4 | 17.3 | 1.4 | 4.2 | 3.7 | 39 registered on closure | | |
| South Sudan - BEG | Apr 04 - Dec 04 | 439 | 80% | 82% ^ | 76.8 | 8.7 | 4.8 | 3.0 | 6.7 | | | |
| South Sudan - BEG | Jan 05 - Jun 05 | 387 | 88% | - | 61.5 | 14.5 | 2.5 | 4.5 | 16.5 | | | |
| South Sudan - BEG (2) | Jul 03 - Nov 03 | 696 | 71% | - | 81.8 | 15.4 | 1.4 | 1.4 | - | 58 registered on closure | | |
| Ethiopia - Hararge | Mar 04 - Oct 04 | 1,086 | 89% | 56% ^ | 76.0 | 18.0 | 2.0 | 3.7 | 0.4 | 241 registered on handover | 6.6 (M)/4 (K) | 44 (M), 38 (K) |
| Ethiopia - Harage (2) | Mar 04 - Oct 04 | 381 | 93% | 56% ^ | 69.5 | 24.3 | 2.4 | 3.7 | - | 7 registered on handover | 6.0 (M)/2.0 (K) | 60 (M), 44 (K) |
| Ethiopia - W.Hararge | Feb 04 - Oct 04 | 1,377 | 71% | 61% ^ | 88.0 | 6.8 | 3.4 | 1.1 | - | | | |
| Ethiopia - Wolayita (2) | Feb 04 - Oct 04 | 539 | no data | - | 90.4 | 2.4 | 1.4 | 3.4 | 2.4 | | | |
| North Sudan - West Darfur | Aug 04 - Jul 05 | 1,684 | 97% | 75% ^ | 80.0 | 13.9 | 1.4 | 5.0 | - | | | |
| North Sudan - West Darfur (2) | Sept 04 - May 05 | 115 | 86% | - | 58.6 | 36.2 | 3.4 | - | 1.4 | | | |
| North Sudan - North Darfur | Dec 04 - Sept 05 | 172 | 90% | - | 65.7 | 12.9 | 7.9 | - | 13.6 | | | |
| Ethiopia - Awassa | Jun 05 - Oct 05 | 353 | 92% | - | 95.0 | 3.9 | 1.1 | 0.0 | 0.0 | | | |
| Niger - Maradi | Aug 05 - Dec 05 | 2,270 | 96% | - | 87.7 | 4.3 | 2.6 | 4.6 | 0.4 | | | |
| **Total** | | **20,418** | **74%** | | **80.3%** | **10.8%** | **3.6%** | **2.9%** | **2.4%** | | | |

Adapted from Key Issues in the Success of Community-based Management of Severe Malnutrition. Collins S. Sadler K. *et al* (189)

*Notes on Table:*

(2) indicates a second programme running concurrently in the same area.

* For ongoing programmes total treated includes children still registered in the programme and for closed programmes those still registered on closure. For programmes that run up to year end and continue in January the following year the total does not include children registered in programme at the end of the year as they are included in the next year data.

** This represents transfers out of the programme, to another agency TFC or a hospital, for which no final outcome was available.

*** LOS: length of stay

**** No SC data available - therefore transfer percentage includes those transferred to SC

^^ Children still registered on programme closure are not included in the outcome calculations

^ calculated using centric systematic sampling design and 'optimally biased sampling' and using a recent period coverage calculation (see below)

+ Initially the Dowa programme in Malawi had to follow the Malawi national protocols that stipulated inpatient care for all severely malnourished children. It was only when the inpatient centres became over-crowded the CTC programme started direct admissions into OTP. Once direct admission into OTP was perceived by local people as successful restrictions on direct admission into OTP were relaxed.

The monitoring data presented in Table 27 include outcomes from 20,418 cases of severe acute malnutrition treated in 17 CTC programmes implemented in Malawi, Ethiopia, North & South Sudan and Niger between 2003 and 2005. Overall, these programmes achieved an average (range) recovery rate of 80.3% (58.6-95.0), mortality rate of 3.6% (1.1-10.0) and default rate of 10.8% (2.4-36.2). Transfer and non-recovery rates were 2.9% and 2.4% respectively. The proportion of severely malnourished children who were treated solely as outpatients was 74%, ranging from 27% to 100% and programme coverage, where it was measured, ranged between 56% and 82%. Rate of weight gain ranged between 3.0-6.8 g $kg^{-1}$ $day^{-1}$ with an average of 4.8 $kg^{-1}$ $day^{-1}$ and length of stay ranged between 38-85 days with an average of 55 days.

### 11.2.4 Discussion and lessons learnt

#### 11.2.4.1 Overall clinical effectiveness

Overall the recovery rate (80.3%) case fatality rate (3.6%) and default rate (10.8%) exceed international standards for therapeutic care; in particular mortality rates are under half the Sphere minimum standards (72). Mortality is also three to four times lower than that presented in the large TFC study discussed in section 6.5.1 (78) and 4-5 times lower than those often achieved by hospitals providing inpatient care to cases of SAM (87).

These data suggest that, overall, the approach is effective for populations that have both a large proportion of oedematous malnutrition (as seen in Malawi, study 3) and of wasting. Over 50% of admissions to programmes in Ethiopia, Niger and South and North Sudan were wasted.

However, these were highly pragmatic studies for which recovery rates may be elevated by the discharge criteria set at > 80% of the reference median (rather than > 85%) for most studies. Also, the Prudhon adjusted mortality has not been calculated for these data as it was for study 3. This limits analysis of any excess mortality risk that may have occurred in the scale up of CTC programmes.

#### 11.2.4.2 Direct outpatient care

On average, the programmes presented in Table 26 treated 74% of cases directly in outpatient care. These data strengthen the evidence presented in Study 3 that, with

appropriate triage criteria, children with uncomplicated SAM can be successfully treated in outpatient care alone. In Dowa and Nkhotakota, a relatively small proportion of cases of SAM (only 45% and 27% respectively), were admitted directly in to outpatient care. This was due to the MoH being cautious with direct referral to the OTP at the beginning of the programme and the inclusion of oedema +++ and ++ in the definition of 'complicated malnutrition'. Subsequently, programmes used only oedema +++ in the definition of 'complicated malnutrition', all other grades were found to respond well in direct outpatient treatment as long as no other signs of complications were identified. This helped programmes in countries like Ethiopia and Sudan, where access to inpatient care was extremely limited, to achieve high coverage.

#### 11.2.4.3 Coverage

Coverage was not measured in all programmes due to resource constraints. Where it was measured the average coverage in these programmes was 73%, substantially higher than the 50% coverage standard for rural populations stipulated in the second edition of the Sphere standards (191), and considerably higher than coverage rates reported for humanitarian centre-based therapeutic feeding programmes (114;192). However, there are a number of programmes, where coverage was not measured, that may not have reached this standard (see discussion section 11.2.4.5 below).

#### 11.2.4.4 Limitations

There are a number of limitations to these data. The clinical outcome data are from day to day programme monitoring and subject to all the errors discussed in section 8.4.2 and more. As there was no analysis at the individual level there was no way to verify that all children included in Table 27 were suffering from SAM according to definitions presented in this thesis. It is likely that some were not. These data have not been verified in the same way as the data in studies 1, 2 and 3 and are therefore likely to contain recording error and misclassification. However, the training given to all implementing staff and the supervision of each programme by the CTC research and development team reduces the chance of any error being systematic. The author can not however rule out the possibility of systematic error or measurement bias having occurred. The random errors introduced to these data are unlikely to significantly alter the proportion of children that died, recovered or defaulted in each programme.

Programme protocols were standardized across countries as far as possible. There are some differences however. These arose from the need to adapt protocols according to the country level (MoH or UN) protocols for the treatment of SAM that were in use at the time. Data collected did not allow for any control of health, nutrition, environmental or seasonal confounding factors that may have affected outcomes. All of these factors make it impossible to directly compare outcomes from the different programmes and countries.

Although the mortality rate of every programme, apart from one in Nkhotakota Malawi, falls within the international standard of < 10%, there is considerable variation in the default rates and, as a result of this, recovery rates between programmes. Default follow up data for all these programmes were not available for analysis for this thesis. It is not possible therefore to say with certainty that mortality was not an important cause of default, although there is some discussion of causes of default, gathered during programme monitoring and evaluation activities, below. This may increase the rate of mortality for those programmes that had high default rates. Coverage also varies considerably between programmes and coverage data are available for only two of the programmes with a high default rate (> 15%). It is these programmes (Ethiopia, Harage and Harage 2) that show the lowest coverage (56%).

#### 11.2.4.5 Increasing coverage and reducing default by maximising demand and acceptability

It is likely that programme coverage and default rates are often linked through the concept of 'acceptability' i.e. the more acceptable a programme is to clients the more likely they are to present for and comply with treatment until discharge (see Figure 27). It is possible, due to this relationship, that the programmes with high default rates in Table 27 will also have lower coverage than those with low default rates.

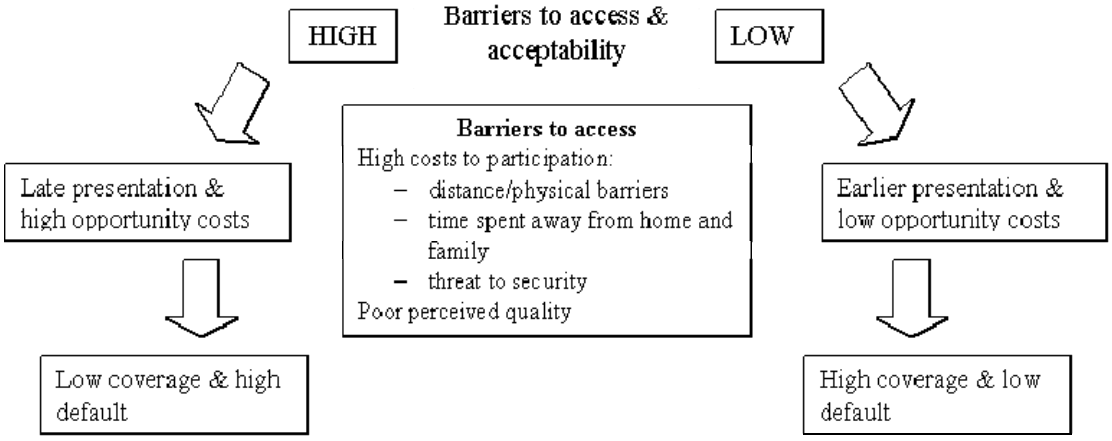



**Figure 27: The relationship between coverage, default and acceptability.**

Monitoring of these CTC programmes has confirmed that maximising both demand for (through knowledge about the programme and perceived need for services) and acceptability of CTC programmes (through minimising barriers to access) is vital to maximize coverage and minimize default from treatment.

#### *11.2.4.5.1 Maximising demand*

In several programmes the problem of primary caretakers not recognising SAM as requiring treatment, delayed and/or prevented carers presenting with their sick children at OTP sites. Low awareness among target communities about the existence or purpose of a CTC programme was also a problem in some areas. This underlines the need for CTC programmes to prioritise the use of activities like community sensitisation to provide clear messages about the target population; using local disease nomenclature and drawing attention to the visible characteristics of eligible children (swollen hands and feet, 'baggy trousers skin', recent weight loss etc.). Community sensitization should also define the nature of CTC services; the location of sites and admission procedures. Much has been learnt during this research programme about appropriate channels for this community sensitisation. Often these include the traditional authority networks and the traditional health workers.

In Dowa, Malawi for example, programme monitoring showed that simply decentralising treatment sites and reducing the opportunity costs to participating families of accessing treatment was not enough to achieve high coverage. During the planning stages of the CTC in Malawi, a poor understanding of the local ‘definitions’ of malnutrition, insufficient communication with existing formal structures and the initial omission of more informal or 'traditional' structures and community figures from programme planning and sensitisation activities had a substantial impact on initial programme coverage and uptake. The project's limited understanding of local understanding about the causes and consequences of malnutrition and of the perceptions of the programme delayed recognition of the communities' distrust of using unfamiliar ‘weight for height’ measurements to target assistance to a sub-group of children. This, coupled with an initial failure to inform and involve 'traditional' structures, such as Traditional Authorities (TAs) and Village Headmen, reduced initial attendance and programme coverage during the first three months of implementation. In response to the slow uptake of CTC services, investigation at community level has offered valuable insight into the perceptions of the beneficiary communities regarding CTC, while simultaneously highlighting some of these shortcomings. Changes in programme design and prioritisation based on these findings, in particular the more active and positive involvement of 'traditional' community structures in helping communities understand how to recognise malnutrition, and the objectives and target groups for the CTC programme, resulted in a rapid increase in the number of new cases of severe malnutrition presenting for treatment (see Figure 28 below).

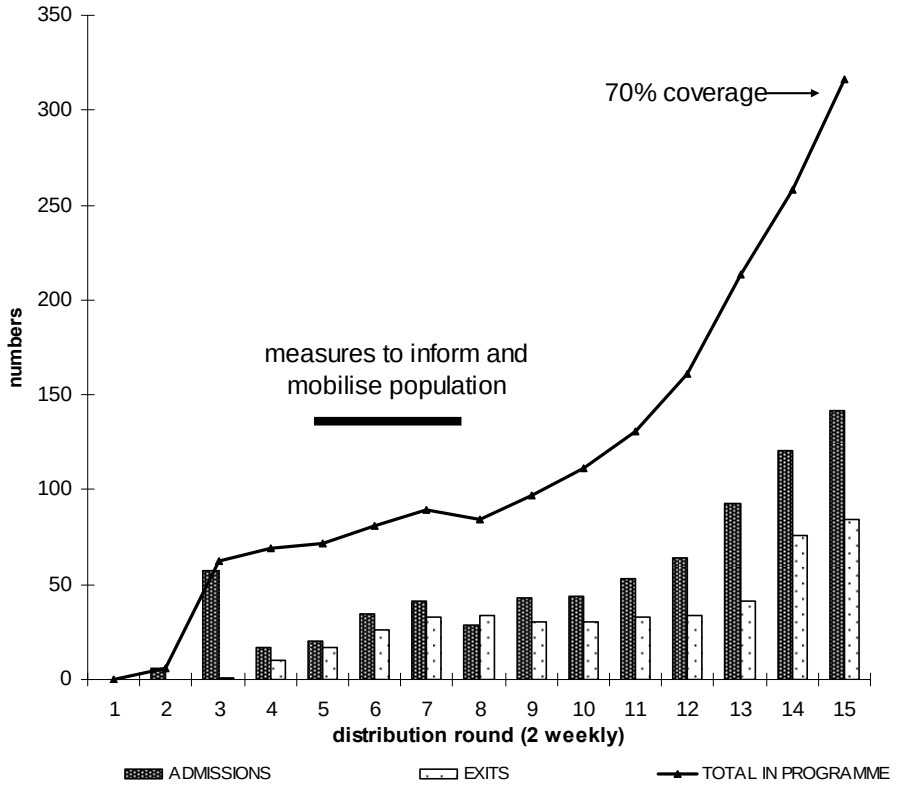



**Figure 28: Numbers of admissions and exits, OTP Dowa district, August to December 2002.**

### *11.2.4.5.2 Minimising barriers to access*

*Distance and physical barriers*

Although decentralisation is a vital component of CTC programmes to improve access, the choice of location of decentralised sites has been important. Some CTC programmes used sites that were easiest for health staff to access (i.e. near major towns and roads) rather than developing a spread of sites that maximised access for the largest number of beneficiaries. For example, CTC programmes serving local and Internally Displaced Persons (IDPs) populations in South Darfur encountered significant problems when local health structures were selected as distribution points as they were not equally accessible for both groups. This is likely to have reduced coverage and been a contributing factor to default.

Choosing treatment sites that are accessible for nomadic populations presents a particular challenge, and although some success has been achieved by choosing sites without

physical infrastructure but with a strong socio-economic tradition (for example sites traditionally used for food distribution during food insecurity), this remains a difficulty for many programmes. This was highlighted as one of the causes of the relatively high default rates in the South and North Sudan programmes.

Topography has also been an important consideration. The CTC programme in Bahr-El-Ghazal, South Sudan, had to consider the boat-owner fees for crossing the multiple rivers that lay between potential beneficiaries and treatment sites. Dialogue with community leaders and arrangements with local boat owners to provide services free of charge during distribution days helped to overcome this challenge.

*Time spent away from home*

The anthropological work in Dowa, Malawi (166) identified many reasons, related to reducing the time they spent away from their home and families, why carers preferred that their children received treatment in outpatient rather then inpatient care (see **Error! Reference source not found.**). These issues were important among target populations in all the programmes described here.

*Poor perceived quality*

An important factor in determining programme uptake for many programmes has been the initial experience of the caretakers during screening, either on site or by outreach workers in the community. In all supplementary and therapeutic feeding programmes, whether outpatient or inpatient, there has been a lack of technical coherence between diagnostic indicators for referral and for admission. Referrals have traditionally been made with an adequately sensitive MUAC threshold for screening (i.e. a MUAC threshold of 13 or 12.5 cm that is likely to identify all or almost all persons meeting WFH-based admission criteria for SFP or TFP) or from growth monitoring programmes based on a weight-for-age indicator. Many of the CTC programmes listed in Table 26 used these screening criteria and this resulted in many patients being referred for care who were then refused treatment because they did not meet the WFH admission criteria. As a result mothers with children suffering from SAM have reported not returning for subsequent screening, even when their child's condition had deteriorated or they had been referred again.

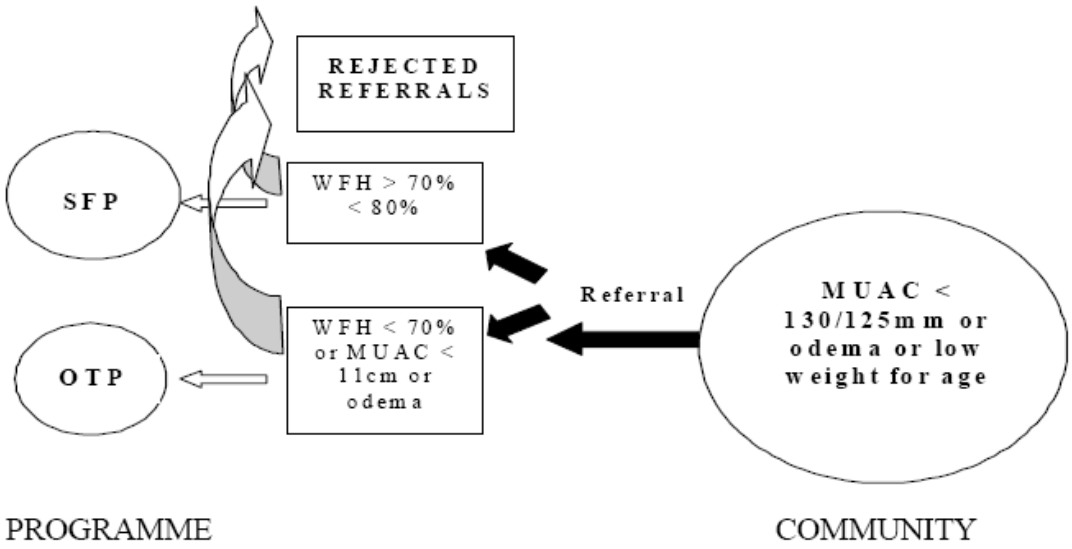



**Figure 29: Two stage screening using MUAC, oedema and weight for height**

The impact of 'negative feedback' on programme coverage is considerable. Data provided by coverage surveys suggests that negative feedback is an important factor limiting programme uptake. Results from coverage survey questionnaires reveal that previous rejection is responsible for 45% of non-attendance in the CTC programme in Bahr-el-Ghazal (South Sudan), 44% in South Wollo (Ethiopia) and 30% in Maradi (Niger) (193). In some programmes the problem of rejected referrals was solved by moving towards a unified MUAC-based referral and admission criteria. In other situations, where there was institutional resistance to the use of the same MUAC cut off for referral and admission, the problem of rejected referrals was partially solved by instituting a system of incentive payments for carers of referred children (39).

Another problem with the two stage referral and admission process described in Figure 31 is that it tends to lead to crowding and long waits at treatment sites for potential beneficiaries. Long waits at treatment centres negatively impacts upon the community's perception of programmes which can reduce coverage (123;194). Again this problem could be addressed by the use of a unified (i.e. single-stage) referral and admission system.

#### *11.2.4.5.3 Weight gain, length of stay and cost effectiveness*

Weight gain and length of stay was not routinely reported in this monitoring data. From the data available rates of weight gain in OTP programmes were between 3.0-6.8 g $kg^{-1}$

day$^{-1}$. As reported for the Dowa study these are lower than those recommended in the Sphere standards and lower than those seen in well functioning TFCs. Mean length of stay in these OTP programmes were also correspondingly longer, between 38-85 days, than that recommended by Sphere. From the data available, it is the children in CTC programmes in South Wollo, Ethiopia that have strikingly (compared with Malawi and other regions of Ethiopia) low weight gains (3.0-4.5 g kg$^{-1}$ day$^{-1}$) and long stays (80-85 days). Programme monitoring suggests that at least part of the reason for this was poor adherence to discharge protocols with staff tending to keep children in the programme past discharge criteria. Reports of this programme also identified particularly poor ongoing food security, poor water sources, endemic malaria, and sub-optimal caring practices at household level, all of which are likely to have contributed to the slow recovery rates. All these issues are common challenges of CTC programmes in sub Saharan Africa.

An important implication of slow recovery is the impact that it has on programme cost effectiveness. This has not been examined in this thesis but, as programmes move towards longer term interventions and integration of services within primary health care delivery this will be a vital area for further study.

#### 11.2.4.6 Conclusion

These results have confirmed those presented in chapters 8 and 9 and show that the outpatient treatment of SAM is feasible in a variety of epidemiological and geographic contexts and can achieve adequate outcomes when compared with international standards for recovery, mortality and coverage. However, the quality of engagement with target communities is a vital determinant of the success of a community-based therapeutic care programme. Community mobilisation is crucial for effective early case-finding and early case finding and the quality of OTP service provision are the two most important determinants of programme effectiveness and coverage. Further examination of the causes and outcomes of defaulting is necessary to strengthen CTC programme outcome date.

More work is required to elucidate aspects of slow recovery and programme costs, especially where length of stay is considerably longer than those stipulated by international standards. This will be important as some of the programmes described here

are integrated in to standard primary health care settings. Further development and evaluation of a unified (i.e. single-stage) referral and admission system will also be important to achieve maximum impact of future programming.

# 12 Conclusions and Way Forward

## *12.1 Effectiveness and impact*

The hypotheses of this work were that

1) A CTC strategy can treat children with severe acute malnutrition effectively as defined by international quality indicators

2) In areas with similar demographic and socio economic profile, a CTC strategy can achieve better population treatment coverage than a centre-based approach.

This thesis presents an in depth analysis of clinical outcomes of 2189 children with SAM who were treated in the first CTC programmes in Ethiopia and Malawi as well as programme monitoring and coverage data from an additional 17 programmes and 20,418 children. Overall, the data presented provide evidence that CTC can be a highly effective model of nutritional intervention in humanitarian emergencies and can provide substantial advantages over treatment modalities that use inpatient care alone. Without exception, study outcomes support average mortality rates that are considerably lower than the minimum international standard stipulated by Sphere and that compare favourably with those TFC outcomes reported by Grellety (78), the Malawi inpatient programme and by many of the inpatient studies reported in the literature (see section 6.5.1). Low mortality is shown in populations with both a high prevalence of oedematous malnutrition (Malawi) and of wasting (Ethiopia). Coverage rates are higher than international standards and, in Malawi, were seen to be significantly higher than that achieved by the inpatient NRU programme. In Malawi the approach was reported to be considerably more popular among the carers and families of programme beneficiaries than inpatient treatment alone. This is reflected in considerably lower default rates than international minimum standards and than reported in many TFC programmes.

Outpatient treatment has however slowed the rate of recovery compared to that seen in well resourced inpatient units. None of the studies reported here achieved the international standard for weight gain stipulated by Sphere of 8g $kg^{-1}$ $day^{-1}$ nor the standard for length of stay of 30 days. This is particularly true in programmes in Ethiopia where a combination of a high discharge criteria (85% WFH) and very poor prevailing food security with little general food available prolonged lengths of stay to > 80 days.

In Malawi, over 40% of the outpatient mortality occurred during the first two weeks or treatment, suggesting the need for some follow up mechanism at this stage of treatment. Neither children with oedema grade I or II nor children of any particular age group showed an increased risk of mortality in direct outpatient care. The examination of triage as an independent risk factor for recovery and mortality suggested that the use of triage does not reduce the chance of recovery and may reduce the risk of mortality, although this would need further study.

## *12.2 The mechanisms of minimising mortality and maximising coverage*

Evidence presented in this thesis suggests how the design of the programme has supported the effectiveness of treatment.

### 12.2.1 Reducing barriers to access to encourage early presentation and maximise coverage

Early presentation of SAM was evident in both studies 3 and 5 of this thesis. 69% of the oedematous cases in the Dowa programme (study 3) presented for treatment as either grade I or II and, of the grade I cases, the majority were without medical complications and were treated directly in outpatient care with low mortality. Study 5 presents data from 20,418 children suffering from SAM of whom an average of 74% did not have medical complications and were treated directly in outpatient care again without raising mortality above minimum standards. This could only occur with early presentation of SAM and both the Dowa study and those programmes presented in study 5 were designed to minimise barriers to accessing treatment. They were highly decentralised to reduce geographical barriers to access and did not require long stays away from home which minimised opportunity costs. They also included considerable community consultation and mobilisation to maximise understanding and participation. In contrast, the mortality rate in Study 2, even among HIV negative children, remained above international standards. Here, treatment was not decentralised and it seems likely that severity of illness, in part due to late presentation because of the opportunity costs of travelling to receive treatment, played some part in this high CFR.

These aspects of programme design also played a vital role in achieving high programme coverage. Study 4 in Dowa showed that decentralisation of outpatient treatment services played a vital role in achieving both high and homogenous coverage of the target population through reducing the distance that families had to travel to access care, by reducing the opportunity costs (i.e. time and effort) of attending treatment and by increasing the cultural acceptability of treatment (i.e. reducing time spent away from spouses and enabling continuation of other social responsibilities).

The Dowa study also showed that community understanding and demand for a programme is essential for good uptake, and that this 'community mobilisation' process could be supported by thoughtful engagement with traditional leaders and health workers. Ongoing monitoring of the programmes presented in study 5 confirmed that both maximising demand and reducing barriers to access, such as perceived poor programme quality, is vital for good programme uptake and compliance.

### 12.2.2 Defining complicated malnutrition and triage to outpatient or inpatient care

The use of outpatient treatment within CTC programmes required that there was some way of separating out those children that suffered from SAM with no complications, from those that did have complications and needed inpatient stabilisation in an SC. In Dowa, the use of a set of criteria including the presence or absence of appetite and other clinical signs based on those adopted by the WHO's IMCI guidelines were used for the first time to triage children in to either inpatient or outpatient treatment. A combination of the indicators used was shown to be a better predictor of risk of mortality than a single indicator. The low mortality (2%) and the absence of any excess mortality calculated using the Prudhon index in the outpatient component of the programme would suggest that this combination of criteria was effective in choosing the group of children for whom outpatient care was appropriate. Although study 3 used only oedema grade I in the definition of SAM with no complications, a number of oedema grade II cases were misclassified as uncomplicated and this presented the opportunity to examine the impact of direct outpatient care on this group. They responded well in direct OTP, and the subsequent role out of CTC programmes included oedema grade II in the model for defining SAM with no complications. This did not appear to increase mortality overall and will have considerably reduced the numbers referred to inpatient care.

The advantages of triage discussed in this thesis include reduced opportunity costs for participants, reduced overcrowding in inpatient units and increased resources available in inpatient units for the sickest patients. The finding that triage does not appear to increase the risk of poor outcome in a malnourished population suggests that triage could be a useful strategy for therapeutic feeding programmes across sub Saharan Africa. This is consistent with evidence from other recent operational studies (100;136). However, a recent publication has continued to question the evidence base behind community-based therapeutic care and other similar treatment strategies (195). Without data from a randomised controlled trial that formally demonstrates the impact of triage on the CFR of children treated for SAM, this critique can not be fully addressed. It would be extremely beneficial therefore, for such an RCT that compared outcomes of a programme that triaged children suffering from SAM to outpatient or inpatient care against a programme that admitted all children to inpatient care for phase 1, to be completed and published.

### 12.2.3 Decongesting inpatient units

Study 3 showed excess mortality in the NRU during the busy hungry season. This suggested that, through reducing cross infection and increasing quality of care, decongesting inpatient units further might go some way towards reducing mortality in these units. The results of Study 2 also suggested that less overcrowding led to reduced nosocomial infection and, in turn, to an increase in the quality of care delivered. This may, to some extent, have played a part in reducing inpatient mortality.

## *12.3 Conclusions*

The development and testing of CTC has highlighted a number of key factors that are important to achieving maximum programme impact. The first is that if malnourished people access nutritional care early in the evolution of their condition, and remain in a nutritional programme until they have recovered, then success rates are high. Conversely, if people access care late and/or they are deterred from staying in a nutritional programme for as long as they need to, then success rates are limited.

The basis of this understanding is that malnutrition is the result of a complex interaction of economic, social, political, nutritional and public health factors. The clinical course of

malnutrition is a gradual decline in nutritional status from normal adaptation towards metabolic complication, immunosuppression, infection that further complicates metabolism, increased immunosuppression, more infection and eventual death. The severity of the condition is primarily a function of the stage of its evolution. As these changes progress, treatment must become increasingly intensive (and costly) if it is to succeed, and units treating severe acute malnutrition are frequently confronted by extremely ill patients who require intensive medical and nursing care. However, most of these units are in the poorest parts of the poorest countries in the world, and have severe resource and staff constraints. In addition, the carers of the malnourished patients almost always come from the poorest families, have great demands on their time and cannot afford to leave home for long periods to stay with their malnourished child during treatment.

However, if the condition is caught in the early stages, the technical aspects of treatment are simple: all that is required is a balanced diet of sufficient quantity and quality. The composition of such diets is now well researched and as long as the patient has appetite they are easy to administer in the form of RUTFs. This helps to improve success rates and keep opportunity costs for treatment low. In practice, this means that finding and treating cases of acute malnutrition early in the progression of their condition, as well as the quality of treatment provided, becomes a major determinant of a successful programme.

A second important factor is that in order to present early and comply with treatment, people must understand, accept and participate in the programmes. To be effective, community-based programmes must involve the target populations. This is not unique to CTC or other SAM treatment approaches but should be integral to all community-based health and nutrition programmes. In practice, there are several important features of programme design that are required to promote participation. The first is to minimise barriers to access. Physical and logistical barriers to presentation can be overcome by providing access to services close to where the target population live. In the developmental setting, this involves delivering the OTP for children with SAM through primary health care structures such as local clinics, health posts or temporary EPI vaccination points. In humanitarian responses it often involves creating new temporary OTP access points.

Social and cultural barriers to access although more subtle are equally important. These must be overcome by a range of measures. Foremost is the need for service providers to make initial investments into understanding the socio-cultural milieu in which CTC programmes will operate. These investments are not necessarily expensive or particularly time consuming, but they have to be planned properly and have sufficient appropriate resources allocated to them. Even in MoH health care systems that employ "local" staff, there will still be socio-cultural issues that need to be explored if issues of vital importance to the target population are to be adequately addressed in programme design. Reducing socio-cultural barriers also requires sensitisation of the population to ensure that people understand the services that are available to them, and consultation to enable people to participate in programme development and implementation. This is vital in order to ensure that issues of importance to potential programme clients are factored into programme design. In particular, it is essential that programme designs take into account the socio-economic barriers (opportunity costs) of attendance, to enable people to access treatment easily and stay in treatment with the minimum of costs to them and their families.

The evidence presented in this thesis shows that, by designing programmes to maximise demand, encourage early presentation and reduce the opportunity costs of accessing treatment, many children suffering from severe acute malnutrition with no medical complications can be treated successfully as outpatients with RUTF. Admitting children with severe acute malnutrition without complications in to TFCs can have adverse consequences, both for patients and the management of emergency nutrition programmes. It needlessly exposes them to additional risks of cross infection and forces the caregiver to spend valuable time away from family and household activities. It can also lead to overcrowding in inpatient units and, potentially, this could decrease the quality of care provided there. On the other hand, not admitting cases of SAM with complications to inpatient care is very likely to increase mortality and decrease the impact of emergency nutrition programmes. On this basis the final model of CTC is developed.

## *12.4 The CTC Model*

The basic components of the CTC model of treatment: principles of treatment; treatment of SAM with complications in inpatient care in a stabilisation centre (SC) or NRU; treatment of SAM without complications in outpatient care in an outpatient therapeutic feeding programme (OTP) and community mobilisation were described very briefly in chapter 6. The data presented in this thesis have enabled a detailed description of both the principles of treatment of CTC, and the approach and protocols for each programme component, in an evidence-based field guide: "Community-based Therapeutic Care: A Field Manual" published by Valid International (196). Sections of this manual to which this thesis has contributed considerable evidence include:

### 12.4.1 Reclassification of severe acute malnutrition

The existing WHO manual for the treatment of severe acute malnutrition requires that all children defined as such be treated in inpatient care (29). This thesis tested a new classification of severe acute malnutrition that includes two categories: SAM with complications and SAM without complications. The new classification is used to decide whether a child needs inpatient or outpatient treatment. It ensures that all those who *can* be treated as outpatients *are* treated as outpatients, and only those who need inpatient care are treated in inpatient centres (139).

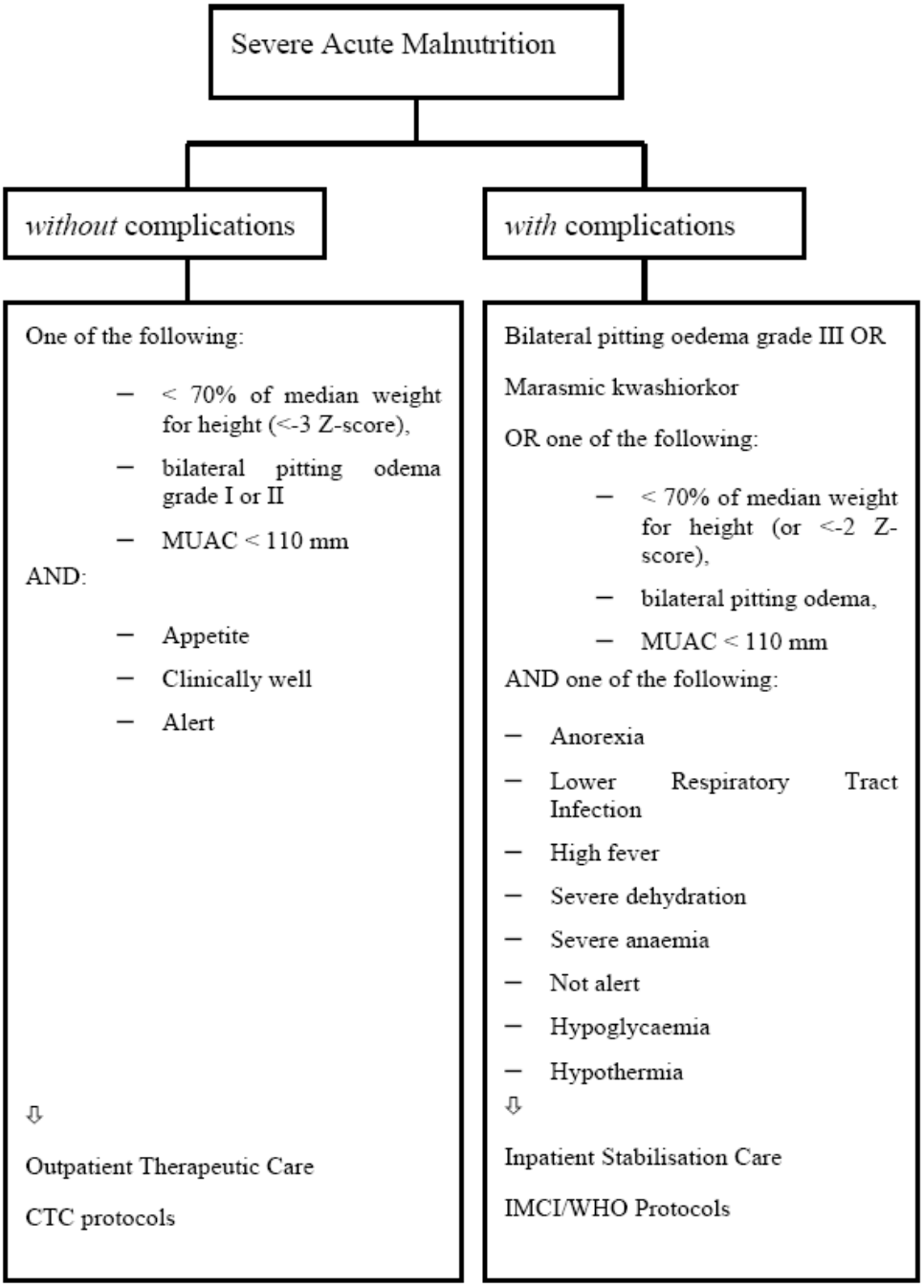



**Figure 30: Reclassification of severe acute malnutrition for use in CTC programmes.**

Adapted from Community-based Therapeutic Care: A Field Manual (196)

### 12.4.2 Community mobilisation

In the manual the term 'community mobilisation' refers to a range of activities designed to help implementers understand affected communities, build a relationship with them

and foster their participation in the programme. It discusses why mobilisation is important to CTC, describes the elements of a successful mobilisation effort and explains how to formulate and implement a mobilisation plan. Much of this builds on the experience described in study 3 and the scale up of CTC programmes described in study 5.

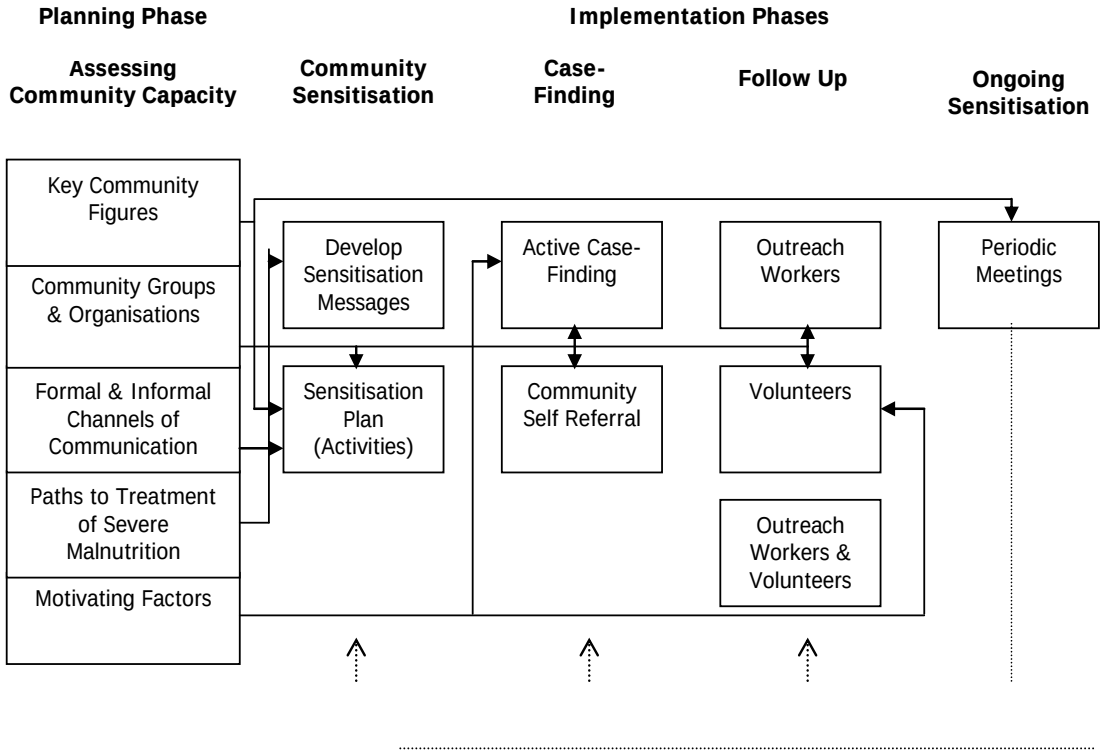



**Figure 31: Elements of community mobilisation:**

Adapted from Community-based Therapeutic Care: A Field Manual (196)

### 12.4.3 Outpatient therapeutic programme

This section of the manual describes, based on data presented in this thesis, the main target group (children aged 6-59 months) for treatment, admission criteria and the protocols for the provision of RUTF, routine medical treatment and follow up.

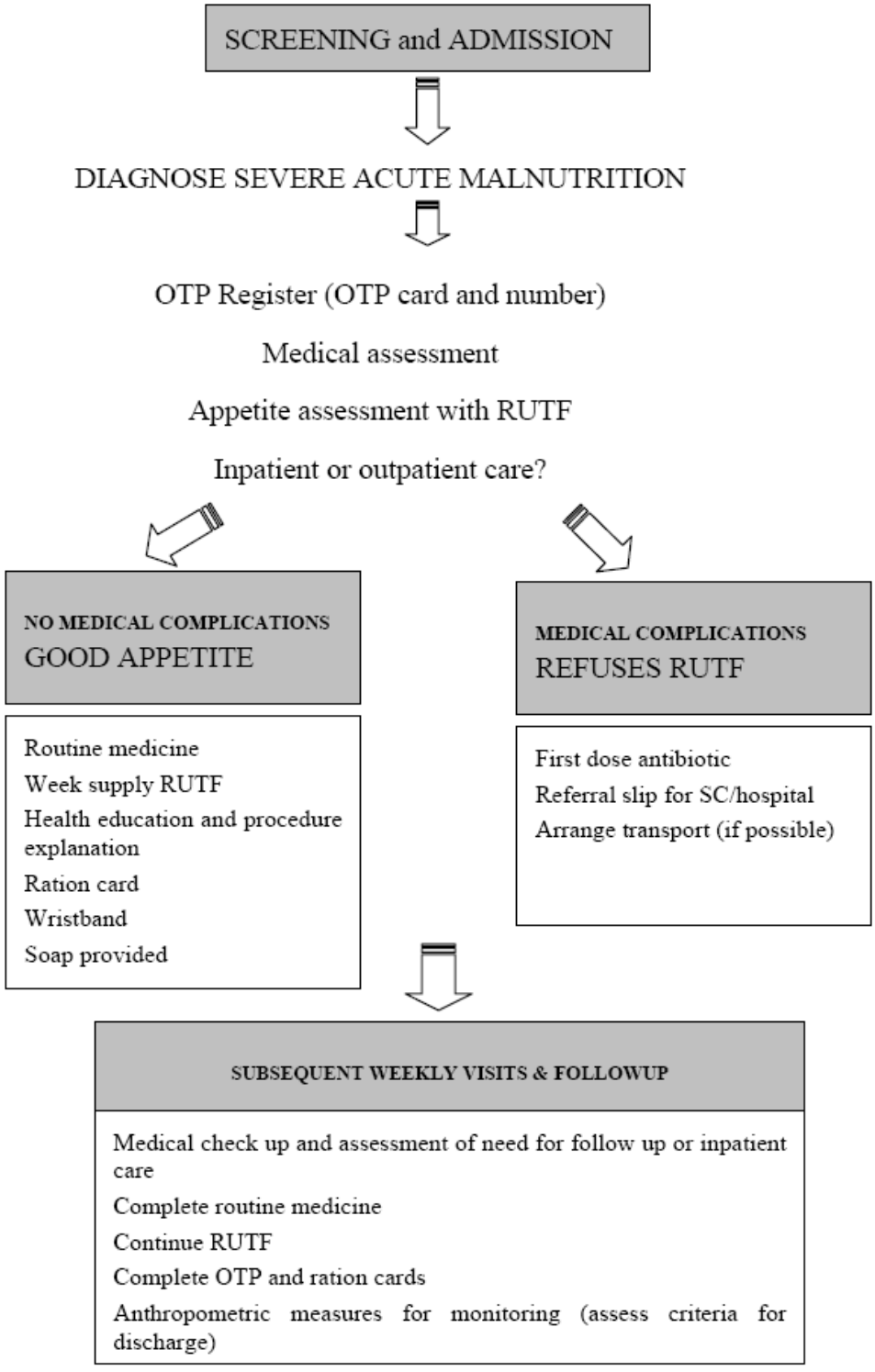



**Figure 32: OTP procedures.**

Adapted from Community-based Therapeutic Care: A Field Manual (196)

### 12.4.4 Programme Monitoring

The manual recommends use of the individual monitoring cards, the programme weekly report and the programme monitoring database (annexes 3-5, section 14.3-14.5) which

were developed as programme monitoring tools for the work described in this thesis. Coverage is highlighted as one of the most important indicators of how well a programme is meeting need, and recommends the survey methodology developed and tested in study 4 to do this.

## 12.5 Implications for policy and practice

Eradication of extreme poverty and hunger is the first of the eight UN MDGs, and reducing child mortality the fourth (4). In response to findings of high mortality in TFC studies, authors have advocated for staff training and support mechanisms to improve the quality of inpatient treatment delivery across developing nations (see section 6.5 of literature review) and for the adaptation of inpatient protocols to include, for example, different dietary regimes for different categories of malnutrition (78). Recently Jackson *et al* stated that "If all hospitals in developing countries followed the WHO case management guidelines for severe malnutrition, perhaps a million or more lives would be saved" (43). Unfortunately, with such low coverage rates achieved by inpatient treatment facilities that implement these guidelines, it is unlikely that they will reach enough severely malnourished children to achieve this goal (see section 6.5.2 of literature review).

As a result of this thesis, and work ongoing by others, the author would suggest that the roll out of the WHO guidelines alone is not the solution within the resource constraints of many inpatient units across the world. In addition to improved training and resources, simple treatment delivery through outpatient units that is designed to promote early presentation and easy access and reduce the caseload for inpatient care is likely to improve the effectiveness of response.

During the last 6 years, with the dissemination of findings presented in this thesis, many agencies that were opposed to this model of care only five years ago (see section 8.1), have now started to develop their own protocols for community and home-based treatment of the severely malnourished (135;197). In response to these advances, the WHO, UNICEF and the UN Standing Committee on Nutrition recently convened an informal consultation on the community-based management of severe malnutrition in children (40). This meeting began the process of incorporating these techniques into the

WHO guidelines, and at the beginning of 2007 a joint UN statement endorsed the use of community-based management techniques for the management of SAM (198):

> "*The community-based approach involves timely detection of severe acute malnutrition in the community and provision of treatment for those without medical complications with ready-to-use foods (cut)… at home. If properly combined with a facility-based approach (cut) ….community-based management of severe acute malnutrition could prevent the deaths of hundreds of thousands of children*."

This is a first step towards an effective treatment for SAM becoming more central to health care agendas in developing countries. It is this that has the potential to support progress towards MDGs one and four.

### 12.5.1 A note on the process of policy change in this context

There are interesting lessons to be taken from the way in which this work has changed international policy and practice. Traditionally, the gold standard of research, the randomised controlled trial (RCT), has been one of the only ways to introduce new approaches and products in to public health policy and practice. These are essential for evaluating the efficacy of clinical interventions where the causal chain between the agent and the outcome is relatively short and simple and where results may be safely extrapolated to other contexts (143). Demonstrating the effectiveness and impact of CTC however, used much simpler study designs that showed adequacy against international standards and, to some extent, plausibility of increased impact compared to inpatient programmes by the use of a non randomised control in the comparison of programme coverage, and by the use of historical TFC data. Scaling up the intervention and showing similar outcomes in many different contexts was also an important mechanism for demonstrating effectiveness. Wide and timely dissemination of results, through international research meetings, UN and INGO presentations and a variety of peer reviewed and practitioner journals, encouraged ongoing debate and opinion on the approach. This allowed organisations to adopt the treatment model when they were ready and, in doing so, to add to the effectiveness data available. It has been 6 years between the first CTC programme in Ethiopia in September 2000 and the release of the UN joint statement on community-based management of SAM at the beginning of 2007 (198).

This, for international policy change, is relatively rapid progress and has been achieved without the need for expensive and complicated RCTs.

## *12.6 Further work required*

There are a number of questions and areas that require further investigation concerning the design and impact of CTC programmes. These are summarised briefly below.

### 12.6.1 Strengthening the evidence base for the use of triage in the treatment of SAM

The release of the UN joint statement on community-based management of acute malnutrition (CMAM) in 2007, now means that service providers have the support of these UN agencies to continue to provide treatment for children suffering from uncomplicated forms of severe acute malnutrition directly from outpatient health services with ready-to-use foods (198). However, a randomised controlled trial, that compared outcomes of a programme that triaged children suffering from SAM to outpatient or inpatient care with that of a programme that admitted all children to inpatient care for phase 1, would serve to strengthen the evidence base for the CMAM model of treatment vs. inpatient models of treatment.

### 12.6.2 Follow up and support after discharge from inpatient care

The need for follow up and support at home for the first two weeks after discharge from the SC in to the OTP, is now included in the CTC action protocols as published in the manual referred to above (196). The mechanisms that are most effective at providing this support differ between contexts and countries. These need further investigation and documentation.

### 12.6.3 Long term follow up and relapse after discharge

The majority of children discharged from the OTP in all studies presented in this thesis were followed up for at least 3 months in the supplementary feeding programme. Their recovery during this period and after discharge from the SFP is an important indicator of the effectiveness of programmes that treat SAM. Many studies have shown a continued risk of morbidity and mortality well after discharge from treatment (199;200). Analysis of these data however was beyond the remit of this work and follow up after discharge from the SFP was not routinely done. However, a retrospective study implemented in 2004 by Valid International in Malawi followed up all children that had been through the programme in 2002-2003 with the aim of looking at HIV and nutritional status. Very few

of the HIV negative children re-measured had relapsed into acute malnutrition. By contrast, a greater proportion of the HIV positive children had relapsed (162). These are interesting results and this issue of relapse, and the most effective treatment regimes to prevent relapse, requires further examination.

### 12.6.4 Treatment and support for chronically sick and HIV positive children

In the context of high HIV prevalence where length of time to recovery from SAM is likely to be prolonged, treatment and support programmes such as CTC need to develop mechanisms of improving effectiveness and reducing the beneficiary's perceived opportunity cost of treatment. Approaches such as introducing a system of support and structured follow-up post discharge, ensuring good linkages with HIV counselling, testing and treatment services, increasing the amount of daily energy offered to HIV infected children, adapting CTC routine antibiotic treatment to the epidemiology of HIV-associated infections and inclusion of routine prophylactic cotrimoxazole for HIV-positive children may improve both short and longer term outcomes in this group.

### 12.6.5 The relationship between distance from treatment (and other barriers to access) and early presentation.

This thesis discusses the relationship between a number of barriers to access and the timing of presentation of children suffering from SAM. This relationship could be quantified further by, for example, the use of geographic positioning system (GPS) technology to quantify distances from home to treatment that are then linked to severity of SAM at admission and outcomes at discharge.

### 12.6.6 Redefine standards for expected weight gain and length of stay in outpatient treatment programmes.

International Sphere standard indicators for length of stay and weight gain for therapeutic feeding programmes are unrealistic for many community-based programmes. These need to be revised in light of the range of weight gain and length of stay outcomes that are now seen in outpatient programmes, and linked with functional outcomes such as relapse after discharge.

### 12.6.7 Examine the use of MUAC as an independent admission and discharge criteria

MUAC has been identified as one of the best (with good precision, specificity and sensitivity) case-detection methods for identifying children with a high risk of mortality for admission into programmes treating SAM. It has also been shown to be simple and

cheap to use within primary health care settings (39). It has recently been adopted by WHO, WFP, UN SCN and UNICEF as the preferred method of identifying children that require community-based management of severe acute malnutrition (198). Using MUAC as an independent admission criteria for treatment programmes does however raise a number of questions about which discharge criteria to use. Continuing to use weight for height based indicators for discharge has been shown to cause confusion, and programmes have therefore been using weight and length of stay for monitoring and discharge. Ideally, a MUAC-based discharge criteria would be used, but we currently know little about how it responds to nutritional support, nor about appropriate thresholds that would ensure adequate functional outcomes after discharge such as low risk of mortality and relapse.

### 12.6.8 Cost effectiveness of community-based care

We now have considerable effectiveness data from programmes implemented during nutritional emergencies when there are often increased resources available. Many of these programmes are implemented in populations chronically vulnerable to acute malnutrition. We now need to examine how good quality treatment can be sustained through primary health services in the longer term, both in terms of capacity building of local health services, and effectiveness and cost effectiveness of programmes. Any attempt at policy change and resource allocation to increase access to treatment is not served well by the absence of good cost effectiveness data for programmes that treat acute malnutrition (vs. other child survival programmes that are able to give accurate cost-benefit data for their interventions) (201).

### 12.6.9 The effective integration of CTC into the primary health care system

With the adoption of the UN joint statement on community-based management of acute malnutrition, it is now imperative to explore the effective integration of this approach in to standard child survival initiatives such as the IMCI and growth monitoring programmes. Until now these initiatives have not included any effective indicator of SAM, and this means that a huge number of acutely malnourished children with a high risk of mortality in marginalized communities have not been identified and referred for treatment. The development and field testing of simple tools and protocols for the identification, referral and treatment of acute malnutrition in community-based settings is vital to reduce the prevalence of this condition and to meet the MDGs (particularly MDG 1) laid out by the International Community.

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# 14 Appendices

## *14.1 Appendix 1: Papers published in peer reviewed journals on which the author is lead or contributing author.*

### 14.1.1 Management of severe acute malnutrition in children. Lancet 2006

### 14.1.2 The outpatient treatment of severe malnutrition during humanitarian relief programmes. Lancet 2002

### 14.1.3 Improving the Management of Severe Acute Malnutrition in an Area of High HIV Prevalence. Journal of Tropical Pediatrics 2008

### 14.1.4 A field trial of a survey method for estimating the coverage of selective feeding programmes. Bulletin of the WHO 2003

### 14.1.5 A comparison of the programme coverage of two therapeutic feeding interventions implemented in neighbouring districts of Malawi. Public Health Nutrition 2007

### 14.1.6 Key issues in the success of community-based management of severe malnutrition. Food and Nutrition Bulletin 2006

## *14.2 Appendix 2: Lancet letters discussing TFCs vs. CTC for the treatment of SAM*

## 14.3 Appendix 3: The monitoring card used in the OTP, Dowa, Malawi

**ADMISSION DETAILS: THERAPEUTIC FEEDING PROGRAMME**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Name | | | | | Reg. N° | | | |
| Date of admission | | | | | Referral centre | | | |
| Village & T/A | | | | | NRU admission | yes | no | |
| Address details | | | | | Readmission | yes | no | |
| Sex (M / F) | | Age (months) | | | NRU refused | yes | no | |
| Distance to home (hours) | | main carer | | | mother alive | yes | no | |
| Received general ration | yes | no | # brothers & sisters | | father alive | yes | no | |
| **Admission Anthropometry** | | | | | | | | |
| Admission criteria: *(Kwash/Mar/Kw-Mar/ MUAC />6mth<4kg/<6mth)* | | | oedema | yes | no | +++ | ++ | + |
| Height (cm) | | Weight (kg) | | % W / H | | MUAC (cm) | | |
| **Medical History** | | | | | | | | |
| Appetite | good | poor | none | | Vomiting | yes | no | |
| Diarrhoea | yes | no | | | Stools / day | 1-3 | 3-5 | 5+ |
| Breastfeeding | yes | no | | | Passing urine | yes | no | |
| Fever | yes | no | | | Family history of Tuberculosis | yes | no | |
| Cough | none | 1 week | > 2weeks | | TB score | | | |
| Swelling | none | feet | legs | other | How long swollen | days | weeks | |
| **Physical Examination** | | | | | | | | |
| Temperature °C | | Respir. rate *(# min)* | | | <30 | 30 - 39 | 40 - 49 | 50+ |
| Oedema depth | none | <5mm | 5 - 10mm | 10+ mm | Chest retractions | yes | no | |
| Conjunctiva | normal | pale | | | Eyes | normal | sunken | discharge |
| Mouth | normal | sore | candida | | Ears | normal | discharge | |
| Lymph nodes | none | groin | neck | | Peripheries | normal | cold | |
| Skin changes | none | ulcers / abcesses | raw | peeling | Radial pulse | present | absent | |
| Dehydration | normal | mild | moderate | severe | | | | |
| **Routine admission Medication, Measles Vaccination** | | | | | | | | |
| | *date* | *dosage* | | | | *date* | *dosage* | |
| Vitamin A | | | | | Albendazole | | | |
| Amoxycillin | | | | | | | | |
| Fansidar | | | | | | | | |
| Folic acid | | | | | measles vaccination | yes | no | |
| **General Ration** | | | | | | | | |
| Registered for general ration? | yes | no | If yes, when did you last receive a ration? | | When was the last distribution in your village? | | | |
| What did you receive? (type and quantity) | | | | | | | | |
| **Summary of inpatient care/advice for OTP (outcome from transfers)** | | | | | | | | |
| | | | | | | | | |
| **Outcome from Stabilisation (Phase I/Transition)** | | | | | | | | |
| Discharge outcome | OTP | defaulter | died | non-responder | transfer hospital | carers choice | Days in NRU | |
| Date of discharge | | | Name of OTP | | | | Days for oedema to go | |

**FOLLOW UP: OUTPATIENT THERAPEUTIC FEEDING PROGRAMME**

| NAME | | | | | | | | | | | REG N° | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Week** | discharge | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| **Date** | | | | | | | | | | | | | | | | | |
| **OTP / HC** | | | | | | | | | | | | | | | | | |
| **Anthropometry** | | | | | | | | | | | | | | | | | |
| **Weight** | | | | | | | | | | | | | | | | | |
| **Weight loss *** *(Y/N)* | | | | | | | | | | | | | | | | | |
| **Height (cm)** | | | | | | | | | | | | | | | | | |
| **Wt/Ht (%)** | | | | | | | | | | | | | | | | | |
| **MUAC (cm)** | | | | | | | | | | | | | | | | | |
| **Oedema (+ ++ +++)** | | | | | | | | | | | | | | | | | |
| **History** | | | | | | | | | | | | | | | | | |
| **Diarrhoea** *(# days)* | | | | | | | | | | | | | | | | | |
| **Vomiting** *(# days)* | | | | | | | | | | | | | | | | | |
| **Fever** *(# days)* | | | | | | | | | | | | | | | | | |
| **Cough** *(# days)* | | | | | | | | | | | | | | | | | |
| **Extra HC visits** *(#)* | | | | | | | | | | | | | | | | | |
| **Appetite** *(good/poor)* | | | | | | | | | | | | | | | | | |

*** WEIGHT CHANGES FOR MARASMICS: if below admission WT on week 3 refer to NRU  If no WT gain by week 5 refer to NRU**

| **Physical examination** | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Plumpynut Test** *(good/poor)* | | | | | | | | | | | | | | | | | |
| **Temp. $^0$C** | | | | | | | | | | | | | | | | | |
| **Resp. Rate** *(# / min)* | | | | | | | | | | | | | | | | | |
| **Dehydrated** *(Y/N)* | | | | | | | | | | | | | | | | | |
| **Anaemia** *(Y/N)* | | | | | | | | | | | | | | | | | |
| **Superficial Infection** *(Y/N)* | | | | | | | | | | | | | | | | | |
| **other problems / comments** | | | | | | | | | | | | | | | | | |
| **additional medicines** | | | | | | | | | | | | | | | | | |
| **Plumpynut** *(# sachets)* | | | | | | | | | | | | | | | | | |
| **PROBLEM** *(Y/N)* | | | | | | | | | | | | | | | | | |
| **Outcome **** | | | | | | | | | | | | | | | | | |
| **name examiner** | | | | | | | | | | | | | | | | | |

**** OUTCOME: A=absent  D=defaulter (2 consecutive visits)  R=readmission NRU  H=Hospital  D=died  SFP=discharged cured**

| **Transfers:** | **Died** | **YES** | **NO** | **If yes, days until died** | | **Cause** | |
|---|---|---|---|---|---|---|---|
| **Named community worker** | | | | | **HS A** | **CGM** | **CNV** |

## *14.4 Appendix 4: OTP weekly report, Dowa Malawi*

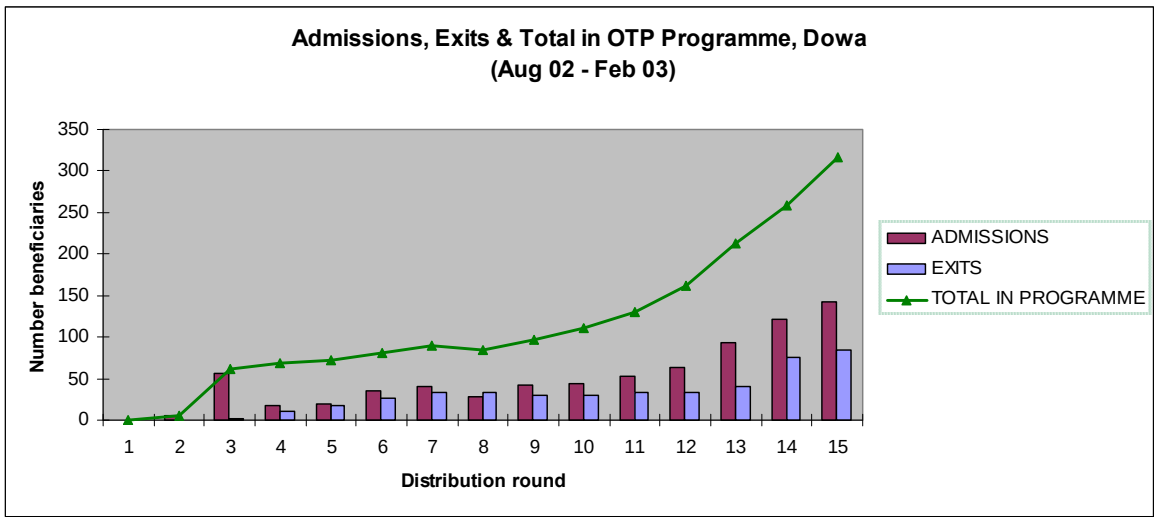
### Outpatient Therapeutic Programme (OTP) Malawi: Health centre weekly tally sheet

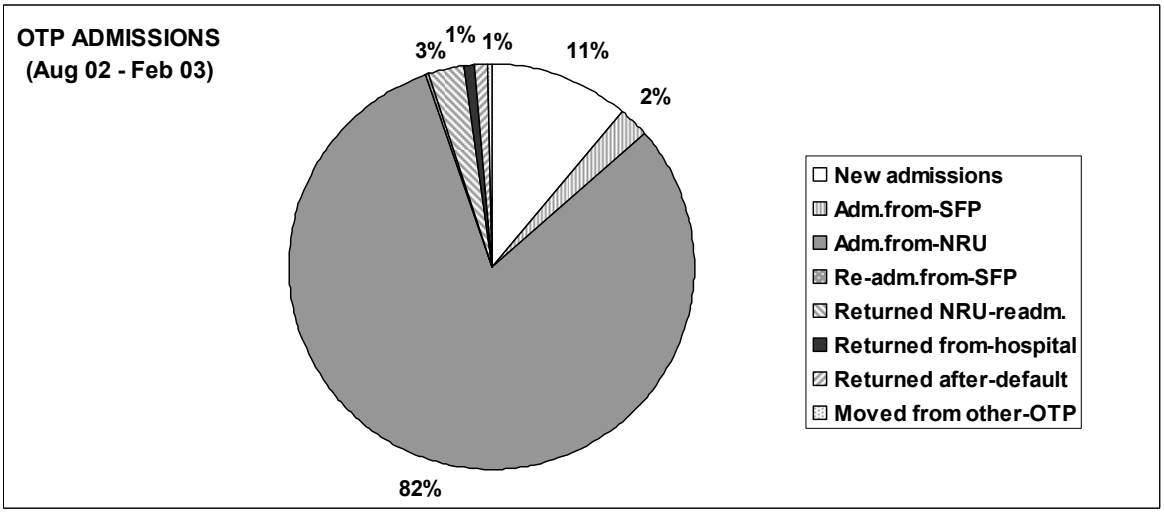
| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Health Centre | | | | | | | | | | | | | | | |
| | OTP Week | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| | DATE | | | | | | | | | | | | | | | | |
| ADMISSIONS | New Admission | | | | | | | | | | | | | | | | |
| | Re-admission | | | | | | | | | | | | | | | | |
| | Returned transfer | | | | | | | | | | | | | | | | |
| EXITS | Recovered | | | | | | | | | | | | | | | | |
| | Died | | | | | | | | | | | | | | | | |
| | Default | | | | | | | | | | | | | | | | |
| | Transfer | | | | | | | | | | | | | | | | |
| | NUMBER IN PROGRAMME | | | | | | | | | | | | | | | | |

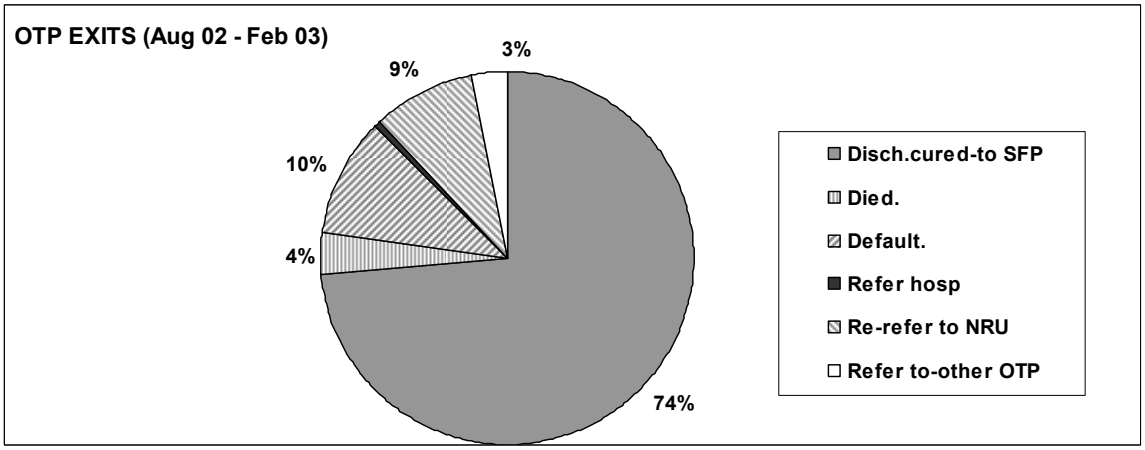
## 14.5 Appendix 5: Example of database for data input and a programme monitoring report, Dowa Malawi.

DOWA OTP DATABASE, MALAWI

| | | | | ADMISSIONS | | | | | | | | EXITS | | | | | | CHILDREN | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Dist. | Team | HC name | MONTH | New adm. | Adm. from SFP | Adm. from NRU | Re-adm. from SFP | returned NRU readm. | returned from hospital | returned after default | moved from other OTP | disch.cured to SFP | died | default | refer hosp. | re-refer NRU | refer to other OTP | TOTAL ADM'D | TOTAL EXITS | TOTAL END LAST DISTR. | TOTAL IN OTP |
| 3 | east | DOWA HOSPITAL | SEP | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 3 | 6 |
| 3 | east | CHANKHUNGU | SEP | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | - |
| 3 | east | THONJE | SEP | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 3 |
| 3 | east | MTENGOWATHENGA | SEP | 1 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 3 | 7 |
| 3 | east | MSAKAMBEWA | SEP | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 5 | 1 | 0 | 4 |
| 3 | east | NALUNGA | SEP | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | - |
| 3 | east | MATEKENYA | SEP | 2 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 4 |
| 3 | east | MVERA MISSION | SEP | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 3 |
| 3 | east | MADISI | | | | | | | | | | | | | | | | 0 | | | |
| 3 | west | NAMBUMA | SEP | 0 | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7 | 0 | 0 | 7 |
| 3 | west | DZOOLE | SEP | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 5 |
| 3 | west | KAYEMBE | SEP | 1 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 5 |
| 3 | west | CHISEPO | SEP | 0 | 0 | 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 11 | 0 | 0 | 11 |
| 3 | west | MPONELA | SEP | 1 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7 | 0 | 0 | 7 |
| 3 | west | CHAKHAZA | | | | | | | | | | | | | | | | 0 | | | |
| 3 | west | CHINKHWILI | | | | | | | | | | | | | | | | 0 | | | |
| 3 | west | BOWE | | | | | | | | | | | | | | | | 0 | | | |
| 4 | east | DOWA HOSPITAL | SEP | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 | 6 |
| 4 | east | CHANKHUNGU | SEP | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | - |
| 4 | east | THONJE | SEP | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 3 | 3 |
| 4 | east | MTENGOWATHENGA | SEP | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 7 | 7 |
| 4 | east | MSAKAMBEWA | SEP | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 4 | 5 |
| 4 | east | NALUNGA | SEP | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 2 |
| 4 | east | MATEKENYA | SEP | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 4 | 5 |
| 4 | east | MVERA MISSION | SEP | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 |
| 4 | east | MADISI | | | | | | | | | | | | | | | | 0 | | | |
| 4 | west | NAMBUMA | SEP | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 7 | 10 |
| 4 | west | DZOOLE | SEP | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 5 | 6 |
| 4 | west | KAYEMBE | SEP | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 5 | 5 |
| 4 | west | CHISEPO | SEP | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 6 | 6 | 11 | 11 |
| 4 | west | MPONELA | SEP | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 7 | 6 |
| 4 | west | CHAKHAZA | | | | | | | | | | | | | | | | 0 | | | |
| 4 | west | CHINKHWILI | | | | | | | | | | | | | | | | 0 | | | |
| 4 | west | BOWE | | | | | | | | | | | | | | | | 0 | | | |


Admissions, Exits & Total in OTP Programme, Dowa
(Aug 02 - Feb 03)
Number beneficiaries
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
Distribution round
ADMISSIONS
EXITS
TOTAL IN PROGRAMME


OTP ADMISSIONS
(Aug 02 - Feb 03)
3%
1%
1%
11%
2%
82%
New admissions
Adm.from-SFP
Adm.from-NRU
Re-adm.from-SFP
Returned NRU-readm.
Returned from-hospital
Returned after-default
Moved from other-OTP


OTP EXITS (Aug 02 - Feb 03)
3%
9%
10%
4%
74%
Disch.cured-to SFP
Died.
Default.
Refer hosp
Re-refer to NRU
Refer to-other OTP

## *14.6 Appendix 6: Programme procedures for implementing staff, Dowa Malawi*

Outpatient Therapeutic Programme (OTP) Malawi: Procedures for Health Centre Staff

**ON ADMISSION**

**STEP 1: ADMISSION**

Measure weight, height, MUAC and oedema
Calculate the admission criteria
Assign ID number, record on red bracelet and attach to child's wrist

**STEP 2: ASSESSMENT**

Complete the front page of the monitoring card:
- Take medical history
- Complete physical examination

Decide whether child needs NRU stabilisation (see 'Rapid Examination Checklist')
- If 'YES' refer child to the closest NRU
- If 'NO' give admission medication, 1 week supply of Plumpynut and 1 week supply Lukini Phala (or equivalent)

**STEP 3: ALLOCATE FOLLOW UP PERSONNEL**

All children returning home with a Plumpynut ration should be put in contact with a community worker. A community worker can be any person who has received training in conducting home support visits. This might be an HSA, a community volunteer/growth monitor, a TBA or a mother whose child has been successfully treated in the programme.
The community worker to discuss each message on the basic education message sheet with the mother.

**STEP 4: MAKE NEXT APPOINTMENT**

Before returning home, each mother should be given an appointment at the health centre for the same time the following week.

## FOLLOW UP VISITS TO HEALTH CENTRE

**STEP 1: ASSESSMENT**

Complete each section of the follow-up section on the monitoring card

- Anthropometry
- Medical history
- Physical examination

} Use 'Checklist for Rapid Examination'

Record any action taken and/or medication given in response to any health problems

Discuss with the mother/carer any action taken and advice for home care.

Refer back to an NRU if condition deteriorates significantly to fit criteria as listed on the 'checklist for rapid examination'

**STEP 2: HIGHLIGHT PRIORITIES FOR FOLLOW UP**

Look at each monitoring card with the relevant community worker and highlight areas for special attention during home visits.

**STEP 3: IDENTIFY NON RESPONDERS AND ACTION**

A child in the programme for 5 weeks with no weight gain or weight fluctuating between small gains and losses should be considered as a non responder.

Pay special attention to these children during medical assessment and prescribe a second line antibiotic where appropriate

A referral to hospital for tests (such as for TB) may be necessary.

Where referral is made follow up of test results and any treatment prescribed will be necessary.

As STEP 2, with the community worker, highlight areas for special attention during home visits. This might include an assessment of caring capacity/food security to help assess the risk of the Plumpynut being shared among household members. Advice, discussion and links with other community based support programmes can all be utilised to reduce this risk.

## ON DISCHARGE

**STEP 1: DISCHARGE**

Discharge according to criteria and admit for supplementary feeding support for 3 months

## REPORTING

**STEP 1: WEEKLY**

After each distribution fill in the weekly tally sheet report from the monitoring cards

File all admission and discharge cards

**STEP 2: MONTHLY**

At the end of each month fill in the monthly health centre reporting format

## *14.7 Appendix 7: RUTF ration chart for the OTP, Dowa*

| Weight of child (kg) | RUTF per Week | | RUTF per Day | |
|---|---|---|---|---|
| | *Sachets* | *Pots* | *Sachets* | *Pots* |
| 4.0 - 4.4 | 10 | 4 | 1.5 | 0.5 |
| 4.5 - 4.9 | 11 | 4 | 1.5 | 0.5 |
| 5.0 - 5.4 | 13 | 5 | 2 | 0.75 |
| 5.5 - 5.9 | 14 | 5 | 2 | 0.75 |
| 6.0 - 6.4 | 15 | 6 | 2 | 0.75 |
| 6.5 - 6.9 | 16 | 6 | 2.5 | 1.0 |
| 7.0 - 7.4 | 17 | 6 | 2.5 | 1.0 |
| 7.5 - 7.9 | 19 | 7 | 3 | 1.0 |
| 8.0 - 8.4 | 20 | 7 | 3 | 1.0 |
| 8.5 - 8.9 | 21 | 8 | 3 | 1.0 |
| 9.0 - 9.4 | 22 | 8 | 3 | 1.0 |
| 9.5 - 9.9 | 24 | 9 | 3.5 | 1.25 |
| 10.0 - 10.4 | 25 | 9 | 3.5 | 1.25 |
| 10.5 - 10.9 | 26 | 9 | 4 | 1.5 |
| 11.0 - 11.4 | 27 | 10 | 4 | 1.5 |
| 11.5 - 11.9 | 28 | 10 | 4 | 1.5 |
| 12.0 - 12.4 | 30 | 11 | 4.5 | 1.5 |
| 12.5 - 12.9 | 31 | 11 | 4.5 | 1.5 |
| 13.0 - 13.4 | 32 | 12 | 4.5 | 1.5 |
| 13.5 - 13.9 | 33 | 12 | 5 | 1.75 |
| 14.0 - 14.4 | 35 | 13 | 5 | 1.75 |
| 14.5 - 14.9 | 36 | 13 | 5 | 1.75 |
| > 15.0 | 37 | 13 | 5.5 | 2.0 |

## *14.8 Appendix 8: Medical protocol for the CTC programme, Dowa*

| NAME OF PRODUCT | ADMISSION | AGE | PRESCRIPTION | POSOLOGY | LENGTH OF TREATMENT |
|---|---|---|---|---|---|
| **VITAMIN A** (curative dose) | YES | < 6 months | **50 000 IU** | 1 drops (1/4 capsule) | One dose at admission, day 2 and day 14 |
| | | 6 months to < 1 year | **100 000 IU** | 3 drops (1/2 capsule) | |
| | | > = 1 year, adolescent (>8kg) | **200 000 IU** | 6 drops (one capsule) | |
| **FOLIC ACID** | YES | All beneficiaries | **5 mg** | Single dose | Single dose at admission |
| **AMOXYCILLIN** | YES | All beneficiaries **EXCEPT under 2 kg** | **60 mg/kg/day** | 3 times / day | 7 days (or 10 days if needed) |
| **FANSIDAR** | YES | All beneficiaries **EXCEPT less than 4 kg** | **25 mg/kg** | Single dose | Single dose at admission |
| **ALBENDAZOLE*** | YES | < 1 year | **DO NOT USE** | NOTHING | XXX |
| | | 1 to < 2 years | **200 mg** | Single dose | Single dose at discharge from NRU or immediately on admission if OTP direct |
| | | > = 2 years | **400 mg** | Single dose | |

**Do not repeat the dosage of vitamin A if the child is readmitted or has already received curative dose of Vitamin A during the LAST 30 days**

*** IF USING MEBENDAZOLE: <1 year: nothing 1 - <2 years: 250mg >=2 years: 500mg unique dose**

**IRON:** **This should NOT be given immediately as contained in RUTF.**

**If child is diagnosed with anaemia then treat from week 3 of admission according to the MoH protocol for the treatment of anaemia.**

## 14.9 Appendix 9: Action protocol, OTP Dowa

| RAPID EXAMINATION | Action | REFERAL CRITERIA to NRU | CAUTION: arrange home visit if possible | OKAY: CONTINUE CTC |
|---|---|---|---|---|
| CRITERIA OF ADMISSION | GRADE OEDEMA | grade +++ or ++ | grade + | No oedema |
| | AGE | <6 months | | |
| APPETITE / ANOREXIC | OBSERVE CHILD EATING TRIAL DOSE RUTF | Refuses to eat or has difficulty taking/swallowing the RUTF | Eats with encouragement | Tries and asks for more |
| TEMPERATURE | AXILLIARY TEMPERATURE | Fever: >= 39°C<br>Hypothermia: < 35°C (under-arm) | Between (36.5°C and 39°C)<br>Between (35°C and 35.5°C) | Normal range (35.5 - 36.5°C) |
| RESPIRATION RATE (rr) | RR FOR ONE MINUTE | > 60 respirations/minute for under 2-months<br>> 50 respirations/minute from 2 to 12 months<br>> 40 respirations/minute from 1 to 5 years<br>> 30 respirations/minute for over 5 year-olds | | Normal range |
| HYDRATION STATUS | CHECK URINE OUTPUT, RECENT D&V, FONTANELLE, MOUTH DRY, RECENT EYE CHANGES | No urine output, no tears<br>Fontanelle depressed<br>Mouth dry, Eyes recently sunken<br>History of acute diarrhoea & vomiting | mouth a little dry | Normal urine, mouth not dry |
| ANAEMIA | Hb READING<br>CHECK NAILS, EYES | < 7 g/100ml<br>Very pale, difficulty breathing | Between 7 and 9 g/100ml<br>Slightly pale - prescribe ferrous-folate | >9 g/100ml<br>Colouration |
| SUPERFICIAL INFECTION | CHECK EARS, BODY FOR DISCHARGE/PUS, INFECTION, ABCESS | Discharges from ears, extensive absesses, extensive sores | Slight skin irritations eg scabies, small abcess easy to drain, small sores not associated wth oedema | No infections |
| WEIGHT CHANGES | CONSIDER LAST 3 WEIGHTS | weight loss for 3 consecutive weeks or static weight for 5 consecutive weeks | Static weight or weight fluctuating bewteen small gains and loss | Weight gained |
| ALERTNESS | REGARD BEHAVIOUR | Very weak, apathetic, unconscious<br>Fitting/convulsions | Drowsy, quiet | Alert, conscious |

## *14.10 Appendix 10: Education message sheet for OTP, Dowa*

EDUCATION MESSAGE SHEET FOR COMMUNITY THERAPEUTIC CARE *

1. Thin/sick child + RUTF = Fat/healthy child – RUTF is a medicine for sick children.

2. Sick children don't like to eat. Give small regular meals of RUTF and encourage the child to eat often and during the night.

3. For young children continue breast feeding on demand.

4. Always offer plenty of water (boiled) to drink, while eating RUTF.

5. Always use soap for child's hands and face before feeding. Keep food clean and covered.

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

7. With diarrhoea NEVER stop feeding. Give EXTRA food and EXTRA water.

* This sheet includes the basic essential messages only and should be expanded to include more detail and more messages if time/capacity allows.