A large-scale operational study of home-based therapy with ready-to-use therapeutic food in childhood malnutrition in Malawi

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Abstract

Home-based therapy with ready-to-use therapeutic food (RUTF) for the treatment of malnutrition has better outcomes in the *research* setting than standard therapy. This study examined outcomes of malnourished children aged 6–60 months enrolled in *operational* home-based therapy with RUTF. Children enrolled in 12 rural centres in southern Malawi were diagnosed with moderate or severe malnutrition according to the World Health Organization guidelines. They were treated with 733 kJ kg^{-1} day^{-1} of RUTF and followed fortnightly for up to 8 weeks. Staff at each centre followed one of three models: medical professionals administered treatment (5 centres), patients were referred by medical professionals and treated by community health aids (4 centres), or community health aids administered treatment (3 centres). The primary outcome of the study was clinical status, defined as recovered, failed, died or dropped out. Regression modelling was conducted to determine what aspects of the centre (formal training of staff, location along a main road) contributed to the outcome. Of 2131 severely malnourished children and 806 moderately malnourished, 89% and 85% recovered, respectively. Thirty-four (4%) of the moderately malnourished children failed, with 20 (2%) deaths, and 61 (3%) of the severely malnourished children failed, with 29 (1%) deaths. Centre location along a road was associated with a poor outcome. Outcomes for severely malnourished children were acceptable with respect to both the Sphere guidelines and the Prudhon case fatality index. Home-based therapy with RUTF yields acceptable results without requiring formally medically trained personnel; further implementation in comparable settings should be considered.

Keywords: malnutrition, Malawi, therapy, ready-to-use therapeutic food.

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Introduction

Childhood malnutrition is categorized into moderate and severe by the World Health Organization (WHO

1999). Moderate malnutrition is simple wasting, defined by a weight-for-height z-score (WHZ) > –3, but <–2 when compared with a reference population. Severe malnutrition is severe wasting, WHZ < –3 or the presence of oedema. The treatment of moderate malnutrition in Malawi involves distribution of corn/soy blend to families of affected individuals in accordance with standard international recommendations (The Sphere Project 2004). Treatment of severe malnutrition in Malawi requires hospital admission and feeding with milk-based formulas, such as F-75 and F-100 (WHO 1999). Standard therapy is given in two phases to all severely malnourished children. The first phase provides a modest amount of macronutrients, with the goal of stabilizing clinical condition and restoring appetite. The second phase of treatment provides a high-energy diet and promotes rapid catch-up growth. Outcomes achieved in operational programmes in Malawi are poor for both moderate and severe malnutrition, the recovery rate is 20–70% for moderate malnutrition, and it is 25–45% for severe malnutrition (Brewster *et al*. 1997; Patel *et al*. 2005).

Home-based therapy with ready-to-use therapeutic food (RUTF) for moderate and severe malnutrition has provided promising results in a research setting in Malawi (Manary *et al*. 2004; Sandige *et al*. 2004). RUTF contains powdered ingredients, such as sugar and milk, imbedded in a lipid paste, such as peanut butter (Manary 2006). RUTF is fortified with vitamins and minerals to provide the same amounts of all micronutrients as the standard WHO formula F-100. RUTF has a high energy density, about 23 KJ g^{-1} (5.5 kcal g^{-1}), and a very low water content. It does not support the growth of bacteria, even when directly contaminated, and can be stored safely in ambient tropical conditions without spoiling for many months (Briend 2001). In 2003, a controlled, comparative clinical effectiveness trial was conducted with home-based therapy with RUTF and standard therapy in 1178 children (Ciliberto *et al*. 2005). Outcomes were superior among those children receiving home-based therapy; recovery rate was 79% vs. 46%. Children with severe malnutrition and a good appetite achieved positive outcomes when they were treated exclusively as outpatients, foregoing the initial phase of treatment and proceeding directly to home-based therapy with RUTF. A research trial treating moderate malnutrition using RUTF in 372 children found that 56% recovered when they received RUTF, while only 22% recovered when they received corn/soy blend (Patel *et al*. 2005). In 2005, on the basis of this research and other clinical experiences from non-governmental organizations, the Ministry of Health in Malawi adopted home-based therapy with RUTF as an acceptable alternative to standard therapy. Home-based therapy with RUTF moved out of the realm of clinical research and into clinical practice.

Translating successful clinical research strategies into effective operational programmes is problematic in the developing world. It has been identified as one of the major barriers to improving health care and nutritional support among the world's 1 billion people who live in extreme poverty (Collins *et al*. 2006). Resource constraints, both human and material, create competition between a variety of services and interventions, and only the most robust strategies prove to be effective in operation.

To determine the operational effectiveness of home-based therapy with RUTF for moderate and severe childhood malnutrition, this strategy was implemented at 12 centres caring for a total of about 3000 malnourished children. These centres were representative of the resources available for nutritional support and care in Malawi. The hypothesis that was tested was that, in operation, home-based therapy with RUTF would achieve acceptable clinical outcomes when compared with international standards, and better outcomes than are reported by the institutions delivering standard therapy.

Methods

Participants

All children aged 6–60 months presenting to one of the 12 centres in southern Malawi during the period of May 2005 to May 2006 with either moderate or severe malnutrition and with a good appetite were eligible to participate in this operational study. The World Food Programme's (2004) criterion for categorization of malnutrition was used, because it is the local standard of care in Malawi and operationally simpler to implement. Children's weight, length and oedema were measured; the child's weight was then expressed as a fraction (%) of the WHO reference standard for weight-for-length (2006). The weight expressed as a fraction was determined by field workers from a laminated chart. Severe malnutrition was defined as being <70% of reference weight-for-height or presence of oedema; moderate malnutrition was defined as being 70–85% of reference weight-for-height. Appetite was determined to be good if the caretaker said that the child was consuming food when it was offered at home and the child consumed a test dose of 30 g of RUTF at the time of enrolment. Oedema was graded as mild or moderate if it was <1 cm of pitting on the dorsum of the foot, and severe if it was >1 cm. Children with severe oedema or anorexia were deemed too ill for enrolment into the study and treated as inpatients with standard therapy first.

This study was approved by the University of Malawi, College of Medicine's Research and Ethics Committee, and the Human Studies Committee of Washington University in St. Louis.

Setting

Malawi is a food-insecure nation where 86% families rely on subsistence farming of maize and beans as the main source of food. They typically live in mud huts, collect water from a well, and cook outside over open wood fires. Electricity is not available to most Malawians.

At each of the 12 centres, the nutritional care team was trained in the diagnosis and treatment of malnutrition using home-based therapy with RUTF by two senior, experienced nurses from the College of Medicine. The training included proper techniques to determine anthropometric measurements and the presence of oedema. The training occurred over a full month, and included working side-by-side with the nurse trainers for 4 days. Monthly problem-solving and retraining visits were made by the nurse trainers for the duration of the project. Centres were district hospitals, mission hospitals or rural health centres (Table 1). The staff caring for the malnourished children at the 12 centres were organized in one of three of the following ways: medical professionals (nurses or physician assistants) made the treatment decisions and administered the therapy, medical professionals referred children they suspected of malnutrition to community health aids for evaluation and treatment, or community health aids made the treatment decisions and administered therapy. Each of the 12 centres chose the organization structure which it felt was most appropriate given its resources.

Only one centre, Mwanza, was located in a town, defined as having a population >25 000. Mwanza and Montfort were located along a main road and thus had access to electricity, transportation and better public infrastructure.

Table 1. Summary of the characteristics of the 12 study centres

Treatment centre	Type of centre	Staff referring children for treatment	Staff caring for malnourished children
Domasi	Rural health centre	Medical professionals	Medical professionals
Kankao	Mission hospital		
Makwila	Rural health centre		
Mwanza	District hospital		
Pirimiti	Mission hospital		
Misomali	Rural health centre	Community health aids	Community health aids
Montfort	Mission hospital		
Neno Parish	Rural health centre		
Namandanje	Rural health centre	Medical professionals	Community health aids
Namitambo	Rural health centre		
Neno	Rural health centre		
Nsanama	Mission hospital		

Medical professionals are nurses or physicians' assistants.

Nutritional management protocol

Upon enrolment, caretakers provided basic demographic and clinical information. Every child had his/her weight, length and mid-upper arm circumference (MUAC) measured. Weight was measured by placing the child in a harness and attaching the harness to a spring scale obtained from the UNICEF. MUAC was measured with a coloured, graduated plastic tape obtained from Teaching Aids at low cost. Height was measured with a locally made, wooden height/length board. Length was measured on children <2 years of age and standing height on children >2 years of age. Oedema was assessed by compressing the skin over both of the child's fourth metatarsal bones with a firm finger for 10 s and looking for evidence of pitting. History of fever, cough, diarrhoea, oedema, vomiting, skin sores, appetite, irritability and noticeable hair colour change were recorded.

Caretakers and children returned to the clinic for reassessment fortnightly. The child's weight, length and MUAC were measured, and an additional 2-week supply of RUTF, based on the child's weight at that visit, was distributed at each visit. Study participation lasted 8 weeks, after which children were discharged. Children were discharged from the study before 8 weeks if they reached WHZ > 0 based on their admission height, clinically relapsed (recurrence of oedema or systemic infection) requiring inpatient admission or died.

Study diet

The RUTF was produced locally by Project Peanut Butter in Blantyre, Malawi (Manary 2006). Locally produced RUTF consisted of 25% peanut butter, 28% sugar, 30% full-cream milk, 15% vegetable oil, and 1.4% imported vitamin and mineral supplement (CMV, Nutriset, Malaunay, France). RUTF contains a nutrient content similar to the standard, high-energy WHO formula F-100 (Table 2). RUTF was packed in plastic jars containing 260 g sealed with a plastic screw-top lid. The amount in each jar was approximately the amount consumed by the malnourished child in 1 day. The RUTF supplied to the caretaker provided the child with 733 kJ kg^{-1} day^{-1} (175 kcal kg^{-1} day^{-1}) and 5.3 g protein kg^{-1} day^{-1}. The micronutrient content of the RUTF was in accordance with WHO recommendations (1999) for catch-up growth. Typically, children ate the RUTF directly from the jar, without diluting it or mixing it with other foods.

Table 2. Nutrient content of ready-to-use therapeutic food (RUTF)

Constituent	Locally produced RUTF
Energy (J per 100 g food)	2190
Protein (g per 100 g food)	13
Lipid (g per 100 g food)	29

The micronutrient composition of RUTF included the following (per 100 g): 910 μg vitamin A, 16 μg vitamin D, 20 mg vitamin E, 53 mg vitamin C, 0.6 mg vitamin B_1, 1.8 mg vitamin B_2, 0.6 mg vitamin B_6, 0.5 μg vitamin B_{12}, 21 μg vitamin K, 65 μg biotin, 210 μg folic acid, 5.3 mg niacin, 320 mg calcium, 14 mg zinc, and 11.5 mg iron.

Quality control measures during production at Project Peanut Butter were stringent; samples of both raw materials and finished product are tested for bacterial contamination and presence of aflatoxins regularly. Project Peanut Butter is certified by the Malawi Bureau of Standards and produces food in accordance with WHO Codex Alimentarius.

Caretakers were instructed by our staff as to the proper administration of food. RUTF does not require any cooking or preparation, but caretakers must be sure that the food stays free of contamination from water. Upon follow-up, caretakers were asked whether the child was consuming the entire ration of food; if the child was not consuming the entire ration, the caretakers were advised to feed the child small amounts of RUTF 7–10 times per day with a spoon.

Data analyses

Data regarding the dates of participation, date of birth, anthropometric measurements and clinical status were abstracted from the patient management cards and entered into an Excel spreadsheet (Microsoft 2005). Weight-for-age *z*-score, stature-for-age *z*-score (HAZ) and WHZ were calculated using WHO Anthro 2005 (http://www.who.int/childgrowth/en), which uses the 2005 WHO growth standards. MUAC-for-age *z*-score was calculated using the method of de Onis *et al*. (1997). Children were categorized as having either moderate or severe malnutrition using the WHO criteria.

Outcome was categorized as: *recovered* if children's oedema resolved and they gained weight such that their final weight-for-height was >85% of their ideal weight-for-height; *failed* if they did not achieve a weight-for-height > 85% of their ideal weight-for-height or relapsed requiring inpatient treatment; *died*; or *dropped out* if they simply missed two follow-up visits. Weight gain and the growth in MUAC were determined by calculating the change per day during the first 4 weeks of the study, the time interval when the maximum growth velocity is expected. The statural growth rate was calculated as change in stature per day over 8 weeks.

The demographic and anthropometric characteristics of children that dropped out of the therapy were compared to those that did not using a chi-square test for dichotomous parameters and a Student's *t*-test for continuous parameters. Binary logistic regression modelling (enter mode) was used to determine whether the treatment centre was predictive of dropping out (SPSS version 10.0.0, Chicago, 1999). Covariates included in the model were sex, age, presence of oedema, HAZ, WHZ, MUAC and whether child started treatment as inpatient. A probability of <0.05 for any one predictor was considered to be statistically significant for the regression analyses. Logistic regression modelling (enter mode) was used to account for the effect of treatment centre. Covariates included in the model were: sex, age, presence of oedema, HAZ, WHZ, MUAC, whether child started treatment as an inpatient, and centre. Deaths were treated as failures. Three separate models were created, one that treated dropouts as successes, one that treated dropouts as failures and one that omitted dropouts from the regression model. Interactions between covariates were not formally assessed, although an interaction was expected between the anthropometric indices and MUAC. A probability of <0.05 for any one predictor was considered to be statistically significant for the regression analyses.

To compare the outcomes with international standards, the Sphere Project guidelines (2004) for good care of the malnourished child were used. To compare the case fatality rate of home-based therapy with RUTF vs. international standards, an estimate of the predicted case fatality rate was made using the method of Prudhon *et al*. (1997), and was compared with the actual case fatality rate.

Table 3. The demographic and anthropomorphic characteristics of the study children

Characteristic	Severe Male = 1046 Female = 1085	Moderate Male = 444 Female = 362
Age (months)	25 (13)	20 (11)
Presence of oedema	2090 (98%)	0 (0%)
Weight-for-height *z*-score	−1.5 (1.4)	−2.7 (0.56)
Height-for-age *z*-score	−3.1 (1.8)	−3.3 (1.9)
Weight-for-age *z*-score	−2.7 (1.4)	−3.7 (1.2)
Mid-upper arm circumference (cm)	12 (1.4)	11 (1.2)
Mid-upper arm circumference-for-age *z*-score	−2.8 (1.0)	−3.4 (1.1)
Started treatment as an inpatient	484 (23%)	57 (7%)

Data expressed as number (%) for dichotomous characteristics and mean (SD) for continuous characteristics.

Results

Of the children treated from May 2005 to May 2006, 2131 were severely malnourished and 806 were moderately malnourished (Table 3). Of the severely malnourished children, 2090/2131 (98%) had kwashiorkor. There were no adverse events attributed to the use of RUTF, and no child developed anaphylaxis or a rash suggestive of allergy.

In total, 1887/2131 (89%) of the severely malnourished children (Table 4), and 686/806 (85%) of moderately malnourished (Table 5), recovered. On average, children with severe malnutrition gained 3.5 g kg^{-1} day^{-1} (SD = 4.1) and children with moderate malnutrition gained 4.6 g kg^{-1} day^{-1} (SD = 4.1) (Table 6).

Of the severely malnourished children, 29/2131 (1.4%) died. The severely malnourished children who died had a mean age of 18 months (SD = 8), 24/29 (83%) had oedema, and their mean WHZ was −2.5 (SD = 1.7). When compared with severely malnourished children who recovered, those who died were younger, less likely to have oedema and more wasted

Table 4. Outcomes of severely malnourished children by centre

Treatment centre	*n*	Recovered	Failed	Died	Dropped out
Domasi	132	113 (86%)	8 (6%)	1 (1%)	10 (8%)
Kankao	164	143 (87%)	4 (2%)	2 (1%)	15 (9%)
Makwila	377	334 (89%)	13 (3%)	10 (3%)	20 (5%)
Misomali	184	174 (95%)	3 (2%)	2 (1%)	5 (3%)
Montfort	44	37 (84%)	1 (2%)	0 (0%)	6 (14%)
Mwanza	264	214 (81%)	5 (2%)	2 (1%)	43 (16%)
Namandaje	126	116 (92%)	1 (1%)	0 (0%)	9 (7%)
Namitambo	380	339 (89%)	17 (4%)	4 (1%)	20 (5%)
Neno	50	41 (82%)	1 (2%)	3 (6%)	5 (10%)
Neno Parish	64	53 (83%)	5 (8%)	2 (3%)	4 (6%)
Nsanama	182	174 (95%)	2 (1%)	3 (2%)	3 (2%)
Pirimiti	164	151 (92%)	1 (1%)	0 (0%)	12 (7%)
Total	2131	1889 (89%)	61 (3%)	29 (1%)	152 (7%)

Values expressed as number (%).

Table 5. Outcomes of moderately malnourished children by centre

Treatment centre	*n*	Recovered	Failed	Died	Dropped out
Domasi	15	10 (67%)	2 (13%)	1 (7%)	2 (13%)
Kankao	15	10 (67%)	4 (27%)	0 (0%)	1 (7%)
Makwila	154	134 (87%)	8 (5%)	2 (1%)	10 (6%)
Misomali	176	174 (99%)	0 (0%)	2 (1%)	0 (0%)
Montfort	56	40 (71%)	5 (9%)	3 (5%)	8 (14%)
Mwanza	120	89 (74%)	6 (5%)	4 (3%)	21 (18%)
Namandaje	13	9 (69%)	1 (8%)	1 (8%)	2 (15%)
Namitambo	47	41 (87%)	0 (0%)	2 (4%)	4 (9%)
Neno	31	23 (74%)	3 (10%)	3 (10%)	2 (6%)
Neno Parish	98	82 (84%)	2 (2%)	0 (0%)	14 (14%)
Nsanama	56	54 (96%)	0 (0%)	2 (4%)	0 (0%)
Pirimiti	25	20 (80%)	3 (12%)	0 (0%)	2 (8%)
Total	806	686 (85%)	34 (4%)	20 (2%)	66 (8%)

Values expressed as number (%).

Table 6. Growth rates of children in study

	Severe malnutrition $n = 2131$	Moderate malnutrition $n = 806$
Weight gain (g kg^{-1} day^{-1})	3.5 (4.1)	4.6 (4.1)
Stature gain (mm day^{-1})	0.39 (0.54)	0.29 (0.29)
MUAC gain (mm day^{-1})	0.24 (0.35)	0.21 (0.31)

Data expressed as mean (SD). MUAC, mid-upper arm circumference.

(all P-values < 0.01). Of the moderately malnourished children, 20/806 (2.5%) died. The moderately malnourished children who died had a mean age of 18 months (SD = 8), their mean WHZ was –3.0 (SD = 0.7), and their HAZ was –4.4 (SD = 2.1). When compared with moderately malnourished children who recovered, those who died were more stunted and wasted (all P-values < 0.01).

Of the severely malnourished children, 152/2131 (7%) dropped out, and of the moderately malnourished children, 65/806 (8%) dropped out (Table 7). Regression modelling to predict the outcome of dropping out of therapy found that children with lower

Table 7. Comparison of children that were lost to follow-up with those that recovered or failed

Characteristic	Children lost to follow-up n = 218	Children that recovered, failed or died n = 2719	Children that recovered n = 2575	Children that failed or died n = 144
Age (months)	25 (15)	24 (12)	24 (12)	18 (9)**
Presence of Oedema	142 (66%)	1946 (71%)	1865 (72%)	81 (55%)**
Weight-for-height, *z*-score	–2.1 (1.5)*	–1.8 (1.3)	–1.7 (1.3)	–2.7 (1.4)**
Height-for-age, *z*-score	–3.3 (2.0)*	–3.1 (1.8)	–3.1 (1.8)	–3.4 (2.1)**
Weight-for-age, *z*-score	–3.4 (1.5)*	–2.9 (1.4)	–2.9 (1.4)	–3.7 (1.4)**
Mid-upper arm circumference (cm)	11.8 (1.9)*	12.1 (1.9)	12.2 (1.9)	11.0 (1.9)**
Started treatment as an inpatient	44 (20%)	501 (18%)	467 (18%)	34 (23%)

Data expressed as number (%) for dichotomous characteristics and mean (SD) for continuous characteristics.
* Significantly < children that recovered, failed or died, $P < 0.05$, Student's *t*-test.
** Significantly < children that recovered or those that were lost to follow-up, $P < 0.05$, Chi-square test used for dichotomous parameters and Student's *t*-test used for continuous parameters.

MUAC, lower WHZ or those receiving care from either Mwanza or Montfort Treatment Centres were more likely to drop out. No other centre was associated with dropping out in this model.

To determine if the centre at which the malnourished child was treated was a significant predictor of their outcome, three binary logistic regression models were created; one where dropouts were included as failures, one where dropouts were included as successes and one where dropouts were excluded from the analyses. In all three models malnourished children with lower MUAC, lower WHZ and children who had been initially treated as inpatients were more likely to have a worse outcome, but centre was not a predictor of outcome in any of the models.

For severely malnourished children, there were no differences in recovery rate based on the organization or formal medical training of the staff; 955/1101 (87%) of children cared by medical professionals recovered, 670/738 (91%) referred by medical professionals but cared for by community health aids recovered, and 264/292 (90%) cared for by community health aids recovered.

The Sphere guidelines for good care of moderate or severe malnutrition state that 75% of children should recover, and no more than 15% should dropout and 10% should die (fail), and our outcomes fall within these guidelines. For the severely malnourished children, the Prudhon index predicted that 64 children in our population were likely to die; the 29 observed deaths (95% CI 20–42 deaths) is significantly less. For the moderately malnourished children, the Prudhon index predicted that there would be 12 deaths; the 20 observed deaths (95% CI 13–31) is significantly greater.

Discussion

This operational project in Malawi demonstrates on a large scale that children with severe and moderate malnutrition can be successfully treated in a resource-limited setting with no medically trained personnel, with outcomes that are acceptable when compared with the Sphere guidelines. The case fatality rate, when compared with predicted case-fatality rate using the Prudhon index, was about half of what would be expected for severely malnourished children, and greater than expected for moderately malnourished children.

The primary limitation of the current study is that it does not directly compare home-based therapy with RUTF vs. any alternative in a controlled manner. This is because home-based therapy is already considered to be an acceptable alternative therapy in Malawi; in operational work in resource-poor settings, parallel therapeutic options are not offered. The current study was conducted in rural sub-Saharan Africa, where extreme poverty creates a chronic food shortage. Malawians rely heavily on maize as their staple food, and kwashiorkor constitutes the vast majority of the severely malnourished children. While RUTF will certainly be efficacious in any setting, caution should be exercised in applying the home-based therapy management protocol to populations that are different from rural Malawi, such as urban populations, populations enduring political crises, and populations with high rates of chronic illness that contribute to their malnutrition, such as HIV infection.

Of the severely malnourished children treated in this setting, 77% did not need inpatient care because at the time of presentation they still had a good appetite. The community was well informed of the home-based therapy protocol used at these 12 centres. Mothers became aware that their children were not likely to be hospitalized and thus would not incur the huge opportunity costs of being removed from their farms and family, allowing them to seek treatment before their children's condition had deteriorated to an advanced stage. It is in the advanced stages of severe malnutrition, when overwhelming infection and marked electrolyte derangements are seen, that death is more likely.

The outcomes of children referred or cared for by medical professionals were similar to those in children who were cared for solely by community health aids. This indicates that the assessment and management protocol used in home-based therapy with RUTF was easy to understand and implement for workers with a very modest level of healthcare training. Thus, the implementation of malnutrition treatment programmes utilizing home-based therapy with RUTF is less likely to be limited by health worker resource constraints than traditional inpatient treatment schemes, and thus better suited for sub-Saharan Africa.

One curious aspect of this operational data set is that there were fewer moderately malnourished children treated than severely malnourished children, and the moderately malnourished children had a lower WHZ and a higher case fatality rate than those classified as severe. This may in part be due to the very high prevalence of nutritional oedema in Malawi, less frequently associated with wasting, estimated to be 2.5% among all 1- to 3-year-old children (Courtright & Canner 1995). Table 5 indicates that five of the centres treated <50 moderately malnourished children with simple wasting. In these locales there were supplementary feeding programmes distributing corn/soy blend, and children were not eligible to receive both home-based therapy with RUTF and corn/soy blend. The common understanding within the medical community in Malawi is that home-based therapy with RUTF is for malnourished children at risk for development of complications and death, while supplementary feeding is for families with food insecurity. Four of the centres that treated very few moderately malnourished children were places where medical professionals referred children for home-based therapy. We speculate that children who appeared more severe to the medical professionals were preferentially referred for the home-based therapy, and mothers themselves may have sought home-based therapy when they believed their child was at greater risk of complications.

Our operational findings are similar to reports of research studies using home-based therapy with RUTF for severely malnourished children in Malawi, where the recovery rate was 79–95% (Manary *et al.* 2004; Sandige *et al.* 2004; Ciliberto *et al.* 2006). In addition, our findings are in concordance with a report from Malawi, Sudan and Ethiopia where 23 511 children were treated with community therapeutic care (which uses home-based therapy with RUTF as the cornerstone of its management), which found that 79% of children recovered, 10% failed to recover and 11% dropped out (Khara & Collins 2004).

A total of 7.4% of malnourished children dropped out of the operational study before reaching a definitive outcome. If dropouts are excluded from the outcome analyses, 96% of children recovered. While the age and type of malnutrition among children that dropped out was not different from children that reached a definitive outcome, the children that dropped out did have lower anthropometric indices than those that reached a definitive outcome. This may well indicate that the fraction of these dropouts that failed therapy was >4%. Regression modelling identified that dropout rates were particularly high at the two centres located near border towns along a truck route connecting South Africa to other Southern African Development Community nations. We speculate that these centres were probably seeing more children with undiagnosed HIV infection, and that this contributed to the higher dropout rate. Perhaps such centres should consider interventions to improve patient follow-up such as an initial follow-up visit after 1 week instead of after 2 weeks, routine HIV testing or have village health aids attempt to make a home visit to those children newly enrolled in home-based therapy for malnutrition.

During the 2005–2006 hungry season in Malawi at 48 inpatient treatment facilities, 3932 severely malnourished children were treated; 67% of these children recovered, 20% failed to recover and 13% dropped out (Action Against Hunger 2006). All of these treatment facilities received F-75 and F-100, the standard milk-based foods for treating malnutrition, hospital medications and supplies, and had regular training of their staff in the standards for care prescribed by the WHO. Treatment of moderate malnutrition at supplementary feeding centres in Malawi during that time period showed that about 12 500 children were treated, and 72% recovered, 8% failed to recover and 20% dropped out (Action Against Hunger 2006). Direct comparisons between severely malnourished children treated with home-based therapy and these admitted for standard inpatient therapy cannot be made because we have no way of accounting for differences in case severity. It is possible that the operational outcomes with home-based therapy may in fact be better than those with standard inpatient therapy or supplemental feeding programmes, when a consistent supply of RUTF is available.

Comparison of the case fatality rate seen in this study can be made with a historical database of malnourished children receiving standard therapy in Malawi, because information about severity of malnutrition and child's appetite was available (Brewster *et al*. 1997). Among 505 children matched for severity, the case fatality rate was 11%, compared with 1.4% in this study, and the recovery rate was 25% compared with 89% in this study.

Operational home-based therapy with its locally produced food and successful implementation by community health aids is more practical than inpatient therapy for severely malnourished children with a good appetite. In resource-constrained circumstances such as Malawi, it is challenging to provide the medical staff, routine monitoring, specialized milk-based foods and hygienic facilities needed for adequate inpatient care. The robust nature of home-based therapy with RUTF demonstrated by these operational data suggests that it should be considered for nationwide implementation in Malawi and for operational trial in sub-Saharan Africa regions, where extreme poverty creates a chronic burden of severe malnutrition.

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