



Supplementary Feeding with Fortified Spreads Results in Higher Recovery Rates Than with Corn/Soy Blend in Moderately Wasted Children^{1,2}

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Abstract

Moderate childhood wasting is defined as having a weight-for-height Z-score (WHZ) < -2 , but ≥ -3 . These children are typically given fortified corn/soy blended flour (CSB), but this intervention has shown limited effectiveness. Fortified spreads (FS) can be used as supplementary foods instead; they are energy-dense, lipid-based pastes with added powdered micronutrients. In this randomized clinical effectiveness trial, the recovery rates were compared among children with moderate wasting who received either milk/peanut FS, soy/peanut FS, or CSB. Children received isoenergetic quantities of food, $314 \text{ kJ}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$, for up to 8 wk with biweekly follow-up. The primary outcome was recovery, defined as having a WHZ > -2 . Time-event analysis was used to compare the recovery rate. A total of 1362 children were enrolled in the study. Children receiving soy/peanut FS had a similar recovery rate to those receiving milk/peanut FS and children in either FS group were more likely to recover than those receiving CSB (80% in both FS groups vs. 72% in the CSB group; $P < 0.01$). The rate of weight gain in the first 2 wk was greater among children receiving milk/peanut FS ($2.6 \text{ g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$, $n = 465$) or children receiving soy/peanut FS ($2.4 \text{ g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$, $n = 450$) than among children receiving CSB ($2.0 \text{ g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$, $n = 447$; $P < 0.05$). Rates of length gain did not differ among the 3 groups. A total of 8% of children in each feeding group developed edema, indicative of severe malnutrition, while receiving supplemental feeding. We conclude that FS are superior supplementary foods to CSB for moderately wasted Malawian children. *J. Nutr.* 139: 1–6, 2009.

Introduction

Moderate wasting affects 11% of the world's children and these children have a risk of death 3 times greater than that of well-nourished children (1,2). Moderate wasting in childhood is defined as a weight-for-height Z-score (WHZ)⁷ < -2 but ≥ -3 without edema (3). Childhood nutritional status in Malawi is poor: 19% of children < 5 y of age are underweight (HZ < -2),

4% are wasted (WHZ < -2), and 2% are severely malnourished (WHZ < -3 or with edema) (1).

Typically, moderately wasted children in sub-Saharan Africa are treated with corn/soy blended flour (CSB) through targeted supplementary feeding programs. CSB is a low-cost combination of a cereal and a legume fortified with micronutrients. A supply of CSB provides $\sim 50\%$ of a child's daily energy requirement. There is limited evidence, however, to suggest that CSB is an effective choice for wasted children. A recent review of feeding programs involving $\sim 375,000$ children in whom CSB was used almost exclusively as the supplementary food found that the recovery rates ranged from 25–95%, the typical recovery rate was 65% (4). Although CSB is familiar and acceptable in the community, the inconsistency in outcomes in the treatment for moderate wasting raises questions about its effectiveness.

Ready-to-use therapeutic food (RUTF) is an energy-dense paste that does not require cooking, resists bacterial growth due to the low water content of the food, can be stored without spoiling for several months, and is nutritionally equivalent to the WHO's F-100 (5). RUTF was developed for management of

¹ Support provided to the Food and Nutrition Technical Assistance (FANTA) Project by the Office of HIV/AIDS (OHA) and the Office of Health, Infectious Diseases and Nutrition (HIDN) of the Bureau of Global Health at the Agency for International Development, under terms of Cooperative Agreement No. HRN-A-00-98-00046-00 awarded to the Academy for Educational Development (AED). The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

² Author disclosures: D. K. Matilsky, K. Maleta, T. Castleman, and M. J. Manary, no conflicts of interest.

⁷ Abbreviations used: CSB, corn/soy blended flour; FS, fortified spread; MSF, Médecins Sans Frontières; MUAC, mid-upper arm circumference; RUTF, ready-to-use therapeutic food; WHZ, weight-for-height Z-score.

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severe acute malnutrition, but recently RUTF and related products have been introduced as alternative supplementary foods for moderately wasted children. In Malawi, a milk/peanut fortified spread (FS) has been successfully used as a supplementary food for moderate wasting in conjunction with home-based therapy for severe malnutrition in children <5 y of age (6–8). Milk/peanut FS is an expensive product, but substituting locally produced soy, which is also high in protein content, for milk powder reduces the cost of FS without significantly changing the macronutrient content.

This study was conducted to determine the relative recovery and growth rates for moderately wasted children receiving either a soy/peanut FS, a milk/peanut FS, or CSB as a supplementary food. The study tested the hypothesis that children aged 6–60 mo with moderate wasting receiving 314 kJ·kg⁻¹·d⁻¹ of either milk/peanut FS or soy/peanut FS were more likely to recover during an 8-wk intervention than children receiving an isoenenergetic ration of CSB. The study also tested the hypothesis that children receiving milk/peanut FS and soy/peanut FS were equally likely to recover.

Subjects and Methods

Study area. Twelve rural study sites were identified in the southern region of Malawi based on census reports of moderately wasted children provided by the World Food Program.

Subjects. Children aged 6–60 mo present at 1 of 12 sites from July 2007 to February 2008 were screened for eligibility. Children with moderate wasting according to the WHO's current standards (WHZ < -2 but ≥ -3) and with a good appetite were eligible for the study. Children who had signs of severe malnutrition, including having a WHZ < -3 and/or edema, chronic illness, cardiac disease, congenital abnormalities, cancer, or those who had been discharged from the nutritional rehabilitation unit, were not eligible for the study. Informed consent was obtained from all participating caretakers. The study was approved by the College of Medicine Research and Ethics Committee, University of Malawi, and the Human Studies Committee of Washington University School of Medicine in St. Louis.

Study design. This was a randomized clinical effectiveness trial of 3 locally produced foods for the treatment of moderate childhood wasting.

Children were randomly assigned to 1 of the 3 diets: milk/peanut FS, soy/peanut FS, or CSB. Caretakers chose an envelope that contained 1 of 6 letters and this letter was recorded separately from the child's clinical measurements. Each of the 6 letters corresponded to 1 of the 3 diets. A research assistant not involved in the study implemented the randomization process. Field assistants who were aware of which letter corresponded to which food coordinated the food distribution process but did not assess the participants. Field workers and investigators remained unaware of the type of food each child received for the duration of the study.

Children participated in the study until they exceeded their target weight or after 8 wk of supplementation without recovery. Children were assessed biweekly. The target weight was any weight at least 0.1 kg greater than the weight corresponding to WHZ = -2. If the child remained wasted after 8 wk or developed edema during treatment, the child was enrolled in the standard therapy for severe malnutrition, home-based therapy with RUTF, and was referred for medical evaluation. No study food was given to children after 8 wk.

Recovery, defined as having a WHZ > -2, was the primary outcome. Secondary outcomes included the rates of gain in weight, stature, and mid-upper arm circumference (MUAC), and the development of adverse outcomes such as severe malnutrition or death.

The sample size was calculated to be 1200 children, 400 receiving milk/peanut FS, 400 receiving soy/peanut FS, and 400 receiving CSB. This sample size was chosen to detect a 10% difference in recovery rate between soy/peanut FS and CSB with 95% sensitivity and 90% power

and a 10% difference in recovery rate between milk/peanut FS and soy/peanut FS with 95% sensitivity and 80% power. The projected powers are different for the 2 comparisons, because the projected difference in recovery rates between the 2 FS products was lower than the projected difference between the soy/peanut FS and CSB. The trial was registered with Current Controlled Trials Ltd (9).

Study participation. Caretakers brought their children for screening, at which time each child was checked for edema and had his/her weight, height, and MUAC measured by a trained study staff member. Weight was measured using an electronic scale (SECA model 334; precision, 5 g). Length was measured in triplicate using a canvas measure mat and the mean value was used as the length (SECA model 210; precision, 0.25 cm). MUAC was measured with a standard insertion tape (TALC). The scale was checked for accuracy with a known weight every 2 wk and recalibrated if necessary. Upon enrollment, the caretaker of the participating child was interviewed to obtain basic demographic information, including the child's date of birth, sex, history of physical illness, and family background. Caretakers and children returned to the clinic for reassessment every 2 wk. At each visit, measurements of the child's weight, length, and MUAC were taken. Children were checked for edema and any other adverse events were noted; adverse events included any untoward reactions to the food, such as the development of a rash or vomiting.

In-depth focus group discussions were conducted with 106 caretakers (10,11), 39 with children who received milk/peanut FS, 39 who received soy/peanut FS, and 28 who received CSB. A qualified independent interviewer led focus group discussions. Caretakers were divided by the food type received and asked questions as a collective group. Each discussion lasted ~20 min and caretakers were asked about their perception of the food, whether food was shared in the home, how often the child was fed, whether they encountered any resistance from the community, and if they observed any problems with the feeding.

Food products. The 3 food products were a micronutrient-fortified CSB (80% corn/20% soy), a soy/peanut FS (27% peanut paste/26% soy flour), and a milk/peanut FS (26% peanut paste/25% dry skimmed milk). Vegetable oil and sugar comprised the remainder of the FS, added in palatable ratios. Concentrated minerals and vitamins were added to both types of FS (Nutraset); soy/peanut FS also had vitamin B-12 added. Children in all 3 groups received rations of 314 kJ·kg⁻¹·d⁻¹. The quantity of food provided was determined by the child's body weight and was based on meeting ~50% of the estimated energy requirement of the moderately wasted child (12). The cost of the foods in Malawi at the time of the study for locally manufactured milk/peanut FS was US\$ 0.16/1000 kJ, soy/peanut FS was US\$ 0.08/1000 kJ, and CSB was US\$ 0.04/1000 kJ.

The micronutrient and protein content of the 3 foods is shown for comparison for a 10-kg child (Table 1). The micronutrient content of the milk/peanut FS and the soy/peanut FS were made identical by specially formulating the micronutrient mixture. The 3 food products provided at least 1 RDA of most micronutrients (at 3135 kJ/d) for children aged 1–3 y. CSB has <1 RDA of vitamin D and both FS have <1 RDA of calcium, phosphorous, potassium, and vitamin B-6. Milk/peanut FS and soy/peanut FS were packaged in 245-g plastic jars and CSB was packaged in 1-kg bags. The CSB and FS were procured from local production facilities: CSB from RAB Processors and both FS from Project Peanut Butter. All food production facilities are certified by the Malawi Bureau of Standards and produce the foods in accordance with the WHO Codex Alimentarius. The ingredients are available locally, except for the micronutrient mix, which was imported from Nutraset.

Senior research nurses instructed caretakers on how much of the supplementary food to feed the enrolled child each day and to increase the feeding frequency by giving 2 additional meals during the day. Emphasis was placed on not sharing the supplementary food with other members of the household. Caretakers were told that the supplements should be treated as a medical therapy and that the children would not recover unless their dietary intakes increased. The research nurses also advised caretakers on healthy feeding practices for their children. Caretakers were given a 2-wk supply of food for the enrolled child, based on the child's weight. If a subject was a twin, an additional ration of the supplementary food was given to the caretaker to limit sharing between twins.

TABLE 1 Nutrient intake of the supplementary foods per 3135-kJ supplement

	RDA for 1- to 3-y-old child ¹	CSB	Milk/peanut FS Soy/peanut FS
Mass of supplemental food, g		200	136
Protein, g	16	34.4	18.9
Calcium, mg/d	800	1660	442
Phosphorus, mg/d	800	412	545
Magnesium, mg/d	80	348	129
Potassium, mg/d	3000	1280	1530
Zinc, mg/d	10	10.0	19.3
Copper, mg/d	0.34	1.8	2.45
Iron, mg/d	10	35.0	15.9
Vitamin A, µg/d	400	1560	378
Vitamin C, mg/d	40	80	72.9
Vitamin D, µg/d	10	5.0	21.9
Niacin, mg/d	9	12.5	7.29
Folic acid, µg/d	50	600	287
Thiamine, mg/d	0.7	1.06	0.81
Riboflavin, mg/d	0.8	0.98	2.49
Vitamin B-6, mg/d	1.0	1.0	0.81
Vitamin B-12, µg/d	0.7	2.0	0.73

¹ From (25).

Data analysis. Baseline characteristics were tabulated as means ± SD for continuous measures and as *n* (%) for dichotomous measures. Anthropometric indices were calculated using WHO 2005 standards (Anthro 2005 Beta) (13). The rate of weight gain was expressed as $\text{g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$, normalized to the initial body weight and the duration of treatment. Rates of length and MUAC gain were normalized to the duration of treatment. Intention-to-treat analysis was used.

Rates of reaching WHZ > -2 over the 8-wk study duration were compared using time-event analysis (Kaplan-Meier survival analysis) (SPSS 15.0 for Windows). $P < 0.05$ was considered significant. The rates of growth were compared by ANOVA at each 2-wk interval. The duration of therapy in each food group was compared using the Wilcoxon's Signed Rank test.

The association between the development of edema and demographic and anthropometric characteristics on enrollment of the subjects was assessed by binary logistic regression modeling (SPSS 15.0 for Windows). Covariates were age, sex, WHZ, HAZ, caretaker, mother alive, father alive, food group, breast-feeding status on enrollment, and weight gain after 2 wk of supplementary feeding. A $P < 0.01$ was considered to be a significant predictor for any one covariate, because multiple covariates were considered.

To compare the case fatality rate of soy/peanut FS to international standards for the treatment of malnutrition, an estimate of the predicted case fatality rate was made using the method of Prudhon et al. (14) and compared with the actual case fatality rate.

Results

A total of 1362 children were recruited into the study and 1302 children completed the study (Fig. 1; Table 2). No caretaker of an eligible child refused enrolment and no adverse reactions to either FS or to CSB were observed. Nine pairs of twins were enrolled in the study; there were no households with 2 children of differing ages enrolled.

A larger fraction of children who received milk/peanut FS or soy/peanut FS recovered than those children who received CSB (Fig. 2; $P < 0.01$ by time event analysis). Children receiving either milk/peanut FS or soy/peanut FS gained weight and MUAC faster than children given CSB, with the exception of

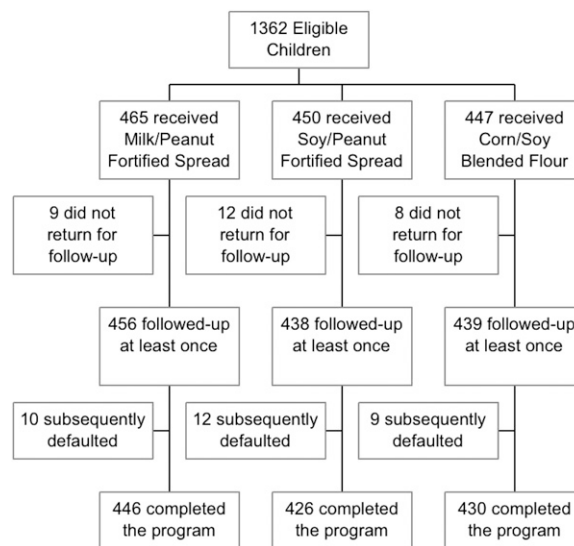


FIGURE 1 Subject enrollment flow chart.

weight after 6 wk (Fig. 3; growth rates at each 2-wk interval compared by ANOVA). The rate of statural growth did not differ among the 3 food groups.

The outcomes after 8 wk of supplementary feeding indicate that children receiving CSB remained in the program longer and were less likely to recover (Table 3). Considering the length of stays of the entire population of children that were in each food group, the mean period of food supplementation for children receiving CSB was 4.0 wk and the mean period for children receiving soy/peanut FS or milk/peanut FS was 3.3 wk.

Of 1362 children, 109 (8%) developed edema, diagnostic of severe malnutrition, during the course of their supplementary feeding. The proportion of children developing edema was the same in all 3 food groups. To assess for risk factors for this unexpected finding, logistic regression modeling of the development of edema found that younger age, lower WHZ, and no weight gain after 2 wk were associated with the development of edema (model $r = 0.29$; chi-square for model 45 with 10 df; $P < 0.001$).

Among the children who did not gain weight in the first 2 wk of treatment, 201/365 (55%) recovered, whereas among the

TABLE 2 Enrollment characteristics of children treated for moderate malnutrition¹

Characteristic	Milk/peanut FS	Soy/peanut FS	CSB
<i>n</i>	465	450	447
Male, <i>n</i> (%)	162 (35)	169 (38)	162 (36)
Age, mo	20.1 ± 12.4	19.6 ± 12.6	19.6 ± 13.1
Weight, kg	7.56 ± 1.68	7.55 ± 1.77	7.46 ± 1.80
Height, cm	74.0 ± 9.1	74.1 ± 9.7	73.4 ± 9.6
MUAC, cm	12.1 ± 0.9	12.1 ± 1.0	12.2 ± 1.0
WHZ	-2.2 ± 0.4	-2.2 ± 0.4	-2.2 ± 0.4
Weight-for-age, <i>Z</i> -score	-3.0 ± 0.9	-3.0 ± 0.9	-3.0 ± 0.9
Height-for-age, <i>Z</i> -score	-2.5 ± 1.5	-2.5 ± 1.6	-2.6 ± 1.5
Mother alive, <i>n</i> (%)	450/458 (98) ²	445/449 (99)	440/443 (99)
Father alive, <i>n</i> (%)	435/454 (96)	431/447 (96)	429/441 (97)
Breast-feeding, <i>n</i> (%)	310/445 (70)	306/436 (70)	310/427 (73)

¹ Values are means ± SD or *n* (%).

² The denominator is different from the number of children enrolled in the food group for some demographic characteristics, because these data were missing.

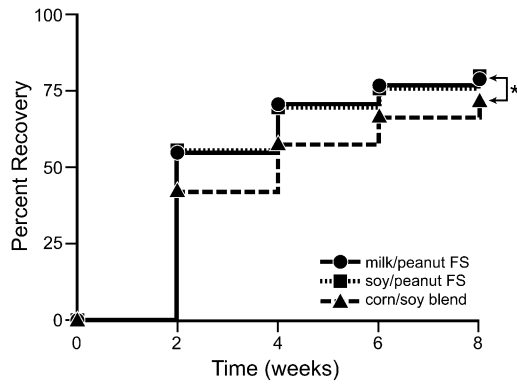


FIGURE 2 Recovery rates for moderately wasted Malawian children who received milk/peanut FS, soy/peanut FS, or a CSB as a supplementary food for up to 8 wk. Recovery was defined as reaching WHZ > -2. *CSB differs from both FS, $P < 0.01$ (time event analyses at each 2-wk interval).

children who did gain weight in the first 2 wk of treatment, 827/971 (85%) recovered ($P < 0.001$; 2×2 Fisher's exact test).

A total of 10 deaths occurred in the program; 3 children who received milk/peanut FS, 2 who received soy/peanut FS and 5 who received CSB. These children were 11.9 ± 5.4 mo old and had a WHZ of -2.1 ± 0.5 (nonsignificant differences when compared with the entire subject population by Student's t test).

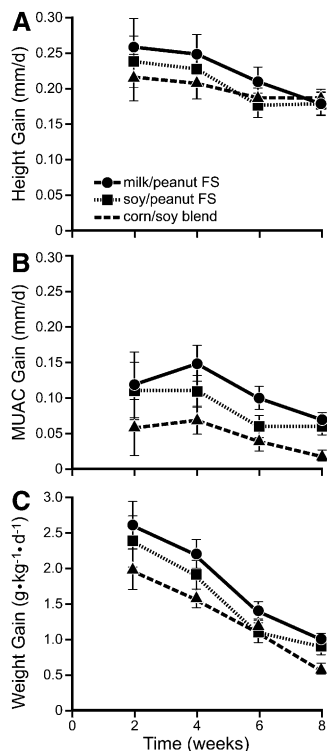


FIGURE 3 Rates of gain in stature (A), MUAC (B), and weight (C) for moderately wasted Malawian children who received milk/peanut FS, soy/peanut FS, or CSB as a supplementary food for up to 8 wk. Values are means, whiskers are 95% CI, $n = 1362$. Rates of weight gain and MUAC gain were greater ($P < 0.05$) for children who received either FS compared with children who received the CSB, except children who received the soy/peanut FS at 6 wk. Growth rates at each 2-wk interval compared by ANOVA.

TABLE 3 Outcomes of moderately wasted Malawian children who received milk/peanut FS, soy/peanut FS, or a CSB as a supplementary food for up to 8 wk¹

Outcome	Milk/peanut FS	Soy/peanut FS	CSB
<i>n</i>	465	450	447
Recovered, <i>n</i> (%)	369 (79)	360 (80)	323 (72)*
Remained wasted, <i>n</i> (%)	35 (8)	29 (7)	67 (15)
Developed edema, <i>n</i> (%)	39 (8)	35 (8)	35 (8)
Death, <i>n</i> (%)	3 (0.6)	2 (0.5)	5 (1.1)
Lost to follow-up, <i>n</i> (%)	19 (4)	24 (5)	17 (4)
WHZ at discharge	$\sim 1.6 \pm 0.7$	$\sim 1.7 \pm 0.7$	$\sim 1.8 \pm 0.8$
Height-for-age at discharge, <i>Z</i> -score	$\sim 2.7 \pm 1.3$	$\sim 2.6 \pm 1.5$	$\sim 2.8 \pm 1.9$
Duration of supplementary feeding, <i>d</i> expressed as median (25%tile-75%tile)	14 (14, 42)	14 (14, 42)	28 (14, 56)**

¹ Values are means \pm SD, *n* (%), or median (25th, 75th percentile). Asterisks indicate different from both FS groups, $P < 0.01$: *time event analysis; **Wilcoxon's Signed Rank test.

Six of the children did not return for follow-up after enrollment and 2 children had edema when they returned for follow-up after 2 wk of treatment. All 10 of these children were reported to have died when a field worker visited their homes 1 mo after they did not return for follow-up and all were reported to have had an acute illness, such as malaria or pneumonia. The mathematical model of Prudhon et al. (14) predicted 13 deaths among the 1362 enrolled children.

In the focus groups discussions, caretakers unanimously stated that they were pleased with the supplementary foods that they received. Caretakers receiving any supplement believed that the foods were a medical treatment and only 4 caretakers reported sharing the food with others. Most caretakers compared the food to a medication, stating that medicine cannot be given to well children and, similarly, that the food they received could not be shared.

Discussion

Home-based therapy using either milk/peanut FS or soy/peanut FS was more effective in treating moderate wasting than the standard CSB treatment.

One limitation of this trial is that it was conducted in agrarian, rural Malawi where corn is the staple food. Results may differ in urban settings or in non-African populations. Because this was not a strict efficacy trial, there was no provision for assessment of compliance with consumption of the food, nor was the dietary intake from habitual sources assessed. It was assumed that some sharing took place in the home. Only 4.3% of enrolled children were lost to follow-up; default rates < 10% are considered acceptable by international standards (15).

Our results are consistent with other reports of using a ready-to-use food in supplementary feeding programs for moderately wasted children. A controlled comparative trial among moderately wasted children found that 58% of children recovered when given RUTF, whereas only 22% recovered when given CSB (16). Médecins Sans Frontières (MSF) in Niger reported that of 59,698 moderately wasted children treated with RUTF, the recovery rate was 95% (17). Niger was suffering from a famine precipitated by one failed harvest and MSF, a well-resourced international relief agency, administered the feeding; both the temporary famine and the response of MSF are factors associated with a better outcome

than treatment of moderate wasting in the context of chronic poverty, as in Malawi. Also, a larger food supplement (4180 kJ/d) was given in Niger. Finally, different populations are likely to have different prevalences of HIV, malaria, and other endemic illnesses. The program in Niger offered curative services for some of these complicating illnesses, whereas the Malawi trial did not. These differences between the Malawi and Niger programs likely contributed to the higher recovery rate in Niger.

Ready-to-use foods require no cooking and are distinct from the habitual cereal staples in their organoleptic characteristics; the dissimilarity may discourage sharing. The greater energy density of ready-to-use foods requires consumption of smaller food volumes by the malnourished child. These characteristics may contribute to the effectiveness of ready-to-use foods.

The 72% recovery rate among children receiving CSB was greater than expected (5,18). During a food crisis in Malawi in 2006, supplementary feeding programs with CSB for children with moderate wasting reported recovery rates of 35–67% (19). We speculate that the high recovery rate in this study may be due in part to mothers' increased compliance and vigilance, prompted by the health professionals delivering the care. The presence of health professionals may have communicated a sense of urgency and importance of the feeding.

The lack of a positive response to feeding (weight gain) in the first 2 wk was a predictive marker for children who were at greater risk of not recovering. These children may benefit from more thorough medical evaluation or frequent follow-up.

It is intriguing that 8% of all children receiving supplementary food developed nutritional edema (kwashiorkor) (Table 3). This indicates that the provision of a high-quality supplementary food does not prevent kwashiorkor in vulnerable children. The etiology of kwashiorkor is unknown. Classically, kwashiorkor was thought to be the result of protein deficiency; however, prospective dietary surveys of children who subsequently developed kwashiorkor did not indicate that they consumed less protein than children who did not develop kwashiorkor (20). More recently, kwashiorkor has been hypothesized to be the result of excessive oxidative stress (21), yet antioxidant supplementation was not shown to prevent kwashiorkor (22). It is possible that some other factor in the environment, in conjunction with the habitual corn diet, is causing the edema in children with moderate wasting.

Foods containing animal products are associated with better linear growth and development among children in observational studies (23,24). This study offers an opportunity to compare the benefits to moderately wasted children of 2 different FS with very similar nutrient contents. Although one contained milk and the other soy, the groups did not differ in recovery rate, weight gain, statural growth, or MUAC gain, which represents gain in lean body mass. Both FS provided similar amounts of protein, zinc, and iron, nutrients used for the accumulation of lean tissue. These children recovering from wasting gained stature at a rate similar to the normal growth rate of well-nourished children. These data suggest that the inclusion of milk in supplementary foods for wasted children does not result in better linear growth. This finding, however, should be regarded as preliminary, given that the period of supplementation was relatively short. No information about the effect of FS with milk for the treatment of stunting can be inferred from this study.

Although FS may be more effective food supplements than CSB, their major limitation is their high cost. The relative costs of the foods in Malawi at the time of the study were such that locally manufactured soy/peanut FS cost half that of milk/peanut FS and twice that of CSB. Children treated with CSB required 20% more

food, lessening the difference in costs of the foodstuffs. Some supplementary feeding programs operate without medical personnel and focus on community food distribution, whereas others employ health professionals to treat moderate wasting in the context of other types of malnutrition and illnesses. Cost effectiveness analyses of each type of program would help identify the best food products and delivery mechanisms for different settings.

This study suggests that outcomes in supplementary feeding programs could be improved by using FS and that soy/peanut FS leads to the same recovery rates as milk/peanut FS for children with moderate wasting. Incorporating the management of moderate wasting into the health care service system may also help to increase dietary compliance and optimize outcomes. Future research is needed to determine whether soy/peanut FS is effective in other settings and operational contexts.

Acknowledgments

We thank Johanna Mayer, Laurel Barrett, and Lacey LaGrone for their help with enrolling children in the study.

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