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Community-based management of acute malnutrition for infants under 6 months of age is safe and effective: analysis of operational data

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Abstract

Objective: To assess the effectiveness of outpatient management with ready-to-use and supplementary foods for infants under 6 months (u6m) of age who were unable to be treated as inpatients due to social and economic barriers.
Design: Review of operational acute malnutrition treatment records.
Setting: Twenty-one outpatient therapeutic feeding clinics in rural Malawi.
Participants: Infants u6m with acute malnutrition treated as outpatients because of barriers to inpatient treatment. The comparison group consisted of acutely malnourished children 6–9 months of age who were being treated at the same time in the same location in the context of two different randomised clinical trials.
Results: A total of 323 infants u6m were treated for acute malnutrition (130 severe and 193 moderate). A total of 357 infants 6–9 months old with acute malnutrition (seventy-four severe and 283 moderate) were included as contemporaneous controls. Among infants u6m with severe acute malnutrition, 98 (75·4 %) achieved nutritional recovery; in comparison, 56 (75·7 %) of those with severe acute malnutrition 6–9 months old recovered. Among infants u6m with moderate acute malnutrition, 157 (81·3 %) recovered; in comparison, 241 (85·2 %) of those aged 6–9 months recovered.
Conclusions: In a rural Malawian population of infants u6m who had generally already stopped exclusive breast-feeding and were now acutely malnourished, treatment with therapeutic or supplementary foods under the community management of acute malnutrition model was safe and effective. In settings where social and financial factors make hospital admission challenging, consideration should be given to lowering the recommended age of ready-to-use therapeutic and supplementary foods to infants u6m.

Keywords
Severe acute malnutrition
Moderate acute malnutrition
Ready-to-use therapeutic food
Ready-to-use supplementary food
Wasting
Kwashiorkor
Marasmus

Acute malnutrition (wasting) affects over 45 million children worldwide, with a disproportionately large burden of disease in sub-Saharan Africa and south Asia[1]. Both severe acute malnutrition (SAM) and moderate acute malnutrition (MAM) remain important contributors to childhood mortality and are also associated with an increased risk of infectious diseases[2], diminished child development[3,4] and increases in chronic disease later in life[5] among survivors.

The WHO has periodically published guidelines for the diagnosis and treatment of SAM in children 6–59 months of age in both the inpatient and outpatient settings[6,7]. The cornerstone of these guidelines is the community-based management of acute malnutrition (CMAM) model, a highly cost-effective[8] method centred on the identification and treatment of SAM at the village and household level using ready-to-use therapeutic food (RUTF)[6]. This treatment model has been extended in many places

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to include children 6–59 months old with MAM as well[9], using a variety of food products including RUTF, a variety of ready-to-use supplementary foods (RUSF), or a fortified-blended flour such as SuperCereal Plus[10–12]. Community-based identification and treatment of acute malnutrition have helped provide care to millions of acutely malnourished children who would not have otherwise presented to a healthcare facility. Home-based therapy for uncomplicated acute malnutrition leads to higher nutritional recovery and reduced relapse rates[9,13], when compared with the previous standard of care based on inpatient rehabilitation for cases of uncomplicated wasting, although these protocols have generally not been applied to children under 6 months of age.

The universally recommended optimal standard of care for infant nutrition under 6 months old (u6m) is exclusive breast-feeding[14]. Breastfed infants initially gain more weight than their formula fed counterparts and have decreased morbidity and mortality[15,16]. Many factors contribute to wasting among infants u6m, prominent among them being insufficient breast-feeding and inappropriate early introduction of complementary foods[17–19]. Globally, at most approximately 40 % of infants u6m are estimated to be exclusively breastfed[15,20]. Rates of exclusive breast-feeding for infants u6m of age in Africa are estimated to range from 5 % to 87 %[20]. In Malawi, recent estimates suggest that 43 %–71 % of infants u6m are exclusively breastfed[21–24]. However, these numbers reflect cross-sectional data for all infants u6m; in contrast, the percentage of children who reach 6 months of age still exclusively breast-feeding is necessarily lower. Data on exclusive breast-feeding rates at the age of 5–6 months are less easily available, but rates of 15 %–49 % have been reported recently in Malawi[21–24].

The number of children u6m with acute malnutrition is unknown[25], with one decade-old estimate suggesting 8·5 million infants u6m being wasted at any given time[26]. Program-level care for these infants is also hindered by the lack of universal consensus on the anthropometric criteria that should be used to enroll children in treatment programmes for identifying those wasted children with the highest risk of morbidity and mortality in this age group[27–31]. However, there is increasing evidence that weight-for-age appears to perhaps be the best single anthropometric predictor of adverse outcomes[32].

The spectrum of acute malnutrition considered here ranges from MAM to one of the multiple forms of SAM, including kwashiorkor (oedematous malnutrition)[33]. The most commonly recommended approach to the treatment of acute malnutrition in infants u6m involves admission to an inpatient facility for the re-establishment of exclusive breast-feeding, with the use of F75, dilute F100 or commercial infant formula while breast-feeding is supported[34,35], followed by continued recovery at home with breastmilk or infant formula if needed[36–39]. Outpatient management for those with uncomplicated acute malnutrition has been suggested as well, but only with breastmilk or commercial infant formula. In 2013, WHO recognised that the use of RUTF and other such foods for infants u6m was occasionally practiced, but that their usage had not been systematically studied; this was recognised as a knowledge gap that warranted specific investigation[7].

Additional interventions such as antimicrobial therapy and micronutrient supplementation are often included as well, although the specific evidence base for these is relatively weak[40]. Outcomes from such resource-intensive inpatient programmes are variable[41,42], and there is certainly room to develop alternative treatment pathways for this population[43]. Meanwhile, there is no clear consensus for infants in whom adequate breast-feeding is impossible and formula feeding is infeasible due to financial cost or unsanitary drinking water. In resource-poor rural communities, families often find it impossible to bring their infants to hospital (and stay for a prolonged duration) for nutritional rehabilitation due to the financial, logistical and social barriers[44].

Innovative approaches to care for acutely malnourished infants who present for outpatient care is thus one of many neglected issues in infant malnutrition[45,46], despite admirable and vigorous new efforts to bring this vulnerable population to the forefront[47]. At the same time, CMAM programs are caring for children older than 6 months of age in many communities where these infants already live. These infants often present to CMAM programs for evaluation, where they may be identified as wasted but do not have any specific care available to them if hospitalisation is not possible due to health systems or family barriers[48]. When they do present and are recognised as malnourished, they may be turned away from care, or they may receive some minimal breast-feeding support and counselling, or they may even be treated using the same or similar protocols as older children. Whether treatment with ready-to-use foods in this population is safe and effective remains unexplored. The aim of the current study is to evaluate the outcomes of infants u6m with SAM and MAM who were treated as outpatients under the CMAM model using ready-to-use foods in an operational setting in rural Malawi in cases where hospital admission was not possible.

Methods

Setting and participants

Operational data for the current study were abstracted from twenty-one CMAM clinics in rural southern Malawi. The clinics are located in communities of subsistence farmers who predominantly lived in mud huts without electricity or running water. Clinic locations were specifically chosen to serve areas most isolated from advanced medical care. Many caretakers travelled 5–10 km on foot in order to

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reach these clinics. Clinics were staffed by community health workers, supported by experienced paediatric nutrition research nurses. These nurses had worked for 4–15 years specifically in community-based SAM and MAM management, in addition to extensive experience in clinical care in both inpatient and outpatient settings. They were also experienced in providing directed nutritional education regarding breast-feeding and complementary feeding practices based on recommended infant and young child feeding messaging. These clinics served acutely malnourished children 6–59 months of age with RUTF for uncomplicated SAM and one of several supplementary foods (RUSF or SuperCereal Plus) for uncomplicated MAM[37,49].

Infants were diagnosed with SAM based on a weight-for-length *Z*-score (WLZ) more than three standard deviations below the international median based on WHO growth standards or by the presence of bilateral pitting oedema of the feet; mid-upper-arm circumference was not used in these clinics at the time. Infants with WLZ between 2 and 3 standard deviations below the median and no oedema were diagnosed with MAM. Acutely malnourished infants u6m who were identified in these clinics received intensive counseling about breast-feeding and general health and hygiene and were referred for inpatient care. However, those infants whose caretakers were unable to take them hospitalisation and had no other options for nutritional rehabilitation were then managed as outpatients. No specific anti-infective therapy or micronutrient supplementation was provided. Catch-up vaccinations were encouraged, and HIV testing was encouraged if prenatal records did not indicate that testing had been performed recently.

Anthropometry

At each visit, weight and the presence or absence of pitting oedema was recorded. Weights were obtained using a digital scale accurate to the nearest 5 g; length was recorded only during the initial visit, using a rigid height board accurate to the nearest 2 mm.

Nutritional therapy

Infants u6m were treated according to a weight-based protocol. Infants u6m with SAM were treated at 2-week intervals with locally manufactured RUTF (Project Peanut Butter, Blantyre, Malawi) at a dose of approximately 175 kcal/kg/d. Infants u6m with MAM were provided either RUTF, a soya-based RUSF, or Super Cereal Plus (CSB++)[10], depending on availability, at a dose of approximately 75 kcal/kg/d.

Study design

As with older children, the CMAM clinics kept routine records of anthropomorphic data for every child at each clinic visit. This retrospective operational study used data from the charts of children u6m outside one of the active research protocols. Records were abstracted for infants u6m at enrollment who met the criteria for uncomplicated MAM or SAM and who had a recorded outcome and outcome date. Participants were excluded if they failed a supervised appetite test and were referred to hospital for inpatient treatment (for SAM patients), had a chronic congenital condition (such as trisomy 21, but not HIV) or had irreconcilable inconsistencies within recorded data. Infants who failed an appetite test or had other clinic complications including hypothermia, lethargy, severe dehydration or clinical signs of severe infection were excluded.

Data recorded at the primary visit included gender, recumbent length, weight and the presence of pitting oedema. WLZ and the target weight needed to achieve WLZ > -2 was determined using standard field tables. Weight-for-age *Z*-score (WAZ) and height-for-age *Z*-score (HAZ) were computed subsequently. Demographic data recorded included whether the mother was the primary caretaker, whether the father was alive, whether the father was present in the home, if the infant was still being breastfed, if the infant was ever treated for TB, if the mother had TB or HIV and if the mother and child were on HIV treatment or *Pneumocystis jirovecii* prophylaxis. As this was an operational programme, the demographic information was often inconsistently collected; analysis was performed only on those with recorded data.

Children returned to clinic every 2 weeks for repeat anthropometry and evaluation of clinical progress. Outcomes included successful nutritional anthropometric recovery (WLZ ≥ -2 without oedema), failure to achieve nutritional recovery after 12 weeks, hospitalisation, death and loss to follow up. A patient was determined to have failed to achieve nutritional recovery if they had not reached their target weight by the end of 12 weeks or if they progressed from MAM to SAM. Additional variables evaluated included a number of days of treatment needed to achieve recovery and weight gain.

Contemporaneous controls

In order to provide some context for these operational results, the data for infants u6m were compared with infants 6–9 months of age who were being treated at the same time and in the same clinics by the same staff in the context a randomised clinical trial of antibiotics for SAM[50] or a randomised clinical of three different supplementary foods for MAM[10].

Statistical analyses

Continuous variables were compared using Student's *t* test, and categorical variables were compared using Fisher's exact test. WLZ, WAZ and HAZ were calculated using WHO Anthro software version 3.2.2 (WHO, Geneva). All analyses were done based on the intention-to-treat

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principle based on diagnoses and treatments made in the field (*e.g.* a child who was treated as MAM but who was actually SAM was considered MAM for the purposes of analysis).

Results

A total of 130 infants u6m with uncomplicated SAM and 193 with uncomplicated MAM who were treated as outpatients with ready-to-use or supplementary foods (Table 1). The median age of infants in both groups was just over 5 months. Infants in both groups were significantly stunted and underweight for age; birth information (gestational age, birth weight and length, etc.) was not available. Nearly half of the infants with SAM had nutritional oedema (kwashiorkor). Approximately 90 % of children in both groups were still breast-feeding; exclusive breast-feeding and the use of complementary foods were not specifically assessed, but clinical experience in this region of Malawi reflected the nearly universal introduction of maize-based porridge at 3–4 months of age. HIV testing was not universally or systematically performed but instead reflected a higher rate of testing among those with concerning symptoms and higher clinical suspicion; among those tested, a higher percentage of infants with SAM had mothers with HIV than those with MAM.

Most infants u6m with acute malnutrition achieved nutritional recovery, with 75·4 % of children with SAM recovering and 81·3 % of children with MAM achieving anthropometric recovery criteria (WLZ ≥ -2 without oedema) (Tables 2 and 3). Of those who did not achieve documented recovery, most were due to being lost to follow up; it is unknown how many of these infants may have died at home as no home visits were conducted for these infants. When compared with infants 6–9 months of age enrolled contemporaneously in a randomised clinical trial[10,50], infants u6m had statistically similar recovery and failure rates, as well as similar durations of therapy needed until recovery and weight gain during treatment.

Given the heterogeneity of infants u6m, outcomes were stratified by age within this population as well (Tables 2 and 3). No clinically meaningful differences or trends were identified within these age strata (*P* values by χ^2 analysis were > 0·6 for both SAM and MAM), although the number of children included in the lowest strata (≤ 120 d old) was relatively small.

When comparing infants u6m with SAM who recovered with those who did not recover, those who were more severely malnourished (as identified by WLZ, WAZ and MUAC) at the time of diagnosis were less likely to recover (Table 4). There were also noticeable trends for other baseline characteristics which correlated with failure to recover, specifically recent illness symptoms, but only a recent history of diarrhoea proved statistically significant, likely due to the relatively small sample sizes evaluated. Infants who were still breast-feeding were more likely to recover.

Table 1 Baseline demographic and anthropometric characteristics for infants u6m with severe acute malnutrition (SAM) and moderate acute malnutrition (MAM) treated as outpatients

	SAM (*n* 130)		MAM (*n* 193)	
Demographics				
Median age in days	156		164	
Range	61–180		52–180	
Interquartile range	134·5–171·5		142–172	
Female	70	53·8 %	107	55·4 %
Infant is still breast-feeding	108/128	84·4 %	181/192	94·3 %
Anthropometry				
Oedema	60	46·2 %	–	
WLZ (infants with oedema)	−1·53	1·63	–	
WLZ (infants without oedema)	−3·68	0·72	−2·38	0·41
HAZ	−2·11	1·87	−1·89	1·96
WAZ (infants with oedema)	−2·33	1·56	–	
WAZ (infants without oedema)	−4·32	1·16	−3·08	1·41
MUAC (infants with oedema)	11·64	1·53	–	
MUAC (infants without oedema)	9·84	1·14	11·11	1·04
Days of illness in preceding 7 d				
Fever	2·1	2·5	2·0	2·2
Cough	2·8	2·7	2·2	2·4
Diarrhoea	1·9	2·5	1·8	3·0
Vomiting	1·0	1·8	0·8	1·5
Family demographics				
Biological mother is primary caregiver	115	90·6 %	185	97·4 %
Biological mother is alive	117/121	96·7 %	168/173	97·1 %
Biological father is alive	58/59	98·3 %	122/125	97·6 %
Biological father lives in the home	43/59	72·9 %	98/121	81·0 %
Mother has had HIV test	81/99	81·8 %	147/191	77·0 %
Mother has had positive HIV test	24/79	30·4 %	17/146	11·6 %

SAM, severe acute malnutrition; MAM, moderate acute malnutrition; WLZ, weight-for-length *Z*-score; HAZ, height-for-age *Z*-score; WAZ, weight-for-age *Z*-score.

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Table 2 Outcomes stratified by age for infants u6m with severe acute malnutrition (SAM) treated as outpatients, with contemporaneous comparison to infants older than 6 months, stratified by age at enrollment

	SAM ≤ 180 d (*n* 130)		SAM 181–270 d (*n* 74)*		Difference	95 % CI	OR	95 % CI	*P* value	SAM ≤ 120 d (*n* 19)		SAM 121–150 d (*n* 31)		SAM 151–180 d (*n* 80)	
Recovered	98	75·4 %	56	75·7 %			0·98	0·50, 1·91	1·00	16	84·2 %	21	67·7 %	61	76·3 %
Duration of therapy until recovery (d)	31·5	17·8	36·9	23·4	−5·5	−12·2, 1·3			0·11	31·1	16·2	35·6	17·8	30·2	18·0
Weight gain among infants that recover (g/kg/d)	4·7	4·4	3·7	4·1	0·9	−0·4, 2·3			0·18	4·6	6·6	5·3	2·6	4·4	4·1
Failed to recover	32	24·6 %	18	24·3 %						3	15·8 %	10	32·3 %	19	23·8 %
Remained malnourished after 12 weeks	7	5·4 %	4	5·4 %						1	5·3 %	3	9·7 %	3	3·8 %
Hospitalised	4	3·1 %	3	4·1 %						0	0·0 %	1	3·2 %	3	3·8 %
Died	4	3·1 %	10	13·5 %						0	0·0 %	1	3·2 %	3	3·8 %
Lost to follow-up	17	13·1 %	1	1·4 %						2	10·5 %	5	16·1 %	10	12·5 %

SAM, severe acute malnutrition.
*Placebo arm from contemporaneous SAM clinical trial[50].

Table 3 Outcomes stratified by age for infants u6m with moderate acute malnutrition (MAM) treated as outpatients, with contemporaneous comparison to infants older than 6 months, stratified by age at enrollment

	MAM ≤ 180 d (*n* 193)		MAM 181–270 d (*n* 283)*		Difference	95 % CI	OR	95 % CI	*P* value	MAM ≤ 120 d (*n* 18)		MAM 121–150 d (*n* 45)		MAM 151–180 d (*n* 130)	
Recovered	157	81·3 %	241	85·2 %			0·76	0·46, 1·22	0·31	15	83·3 %	35	77·8 %	107	82·3 %
Duration of therapy until recovery (d)	20·8	11·8	22·2	13·9	−1·4	−4·0, 1·3			0·31	17·7	6·2	20·6	13·6	21·3	11·7
Weight gain among infants that recover (g/kg/d)	4·6	2·6	3·7	2·5	0·9	0·4, 1·4			0·0010	4·6	1·5	4·9	3·1	4·5	2·5
Failed to recover	36	18·7 %	42	14·8 %						3	16·7 %	10	22·2 %	23	17·7 %
Remained malnourished after 12 weeks	4	2·1 %	1	0·4 %						1	5·6 %	0	0·0 %	3	2·3 %
Hospitalised	0	0·0 %	0	0·0 %						0	0·0 %	0	0·0 %	0	0·0 %
Died	3	1·6 %	3	1·1 %						0	0·0 %	0	0·0 %	3	2·3 %
Lost to follow-up	17	8·8 %	3	1·1 %						2	11·1 %	6	13·3 %	9	6·9 %
Transferred to care for SAM	12	6·2 %	35	12·4 %						0	0·0 %	4	8·9 %	8	6·2 %

MAM, moderate acute malnutrition.
*All infants from contemporaneous MAM clinical trial[10].

Table 4 Comparison of infants u6m with severe acute malnutrition (SAM) with and without nutritional recovery treated as outpatients with ready-to-use therapeutic food (RUTF)

	SAM with recovery (*n* 98)		SAM without recovery (*n* 32)		Difference	95 % CI	OR	95 % CI	*P* value
Demographics									
Median age in days (range)	157·5	61–180	155	66–179	3·1	−8·6, 14·8			0·60
Female	49	50·0 %	21	65·6 %			0·52	0·24, 1·23	0·15
Infant is still breast-feeding	85/96	88·5 %	23/32	71·9 %			3·02	1·16, 7·82	0·045
Anthropometry									
Oedema	49	50·0 %	11	34·4 %			1·91	0·82, 4·19	0·15
WLZ (infants with oedema)	−1·23	1·55	−2·88	1·28	1·65	0·63, −2·68			0·0020
WLZ (infants without oedema)	−3·52	0·53	−4·05	0·94	0·53	0·17, −0·89			0·0044
HAZ	−2·07	1·83	−2·23	1·96	0·17	−0·59, 0·92			0·67
WAZ (infants with oedema)	−2·14	1·53	−3·21	1·40	1·07	0·05, 2·10			0·040
WAZ (infants without oedema)	−4·19	1·15	−4·63	1·12	0·45	−0·15, 1·05			0·14
MUAC (infants with oedema)	11·87	1·58	10·65	0·73	1·21	0·55, 1·87			<0·001
MUAC (infants without oedema)	10·14	1·04	9·11	1·02	1·03	0·48, 1·58			<0·001
Days of illness in preceding 7 d									
Fever	1·51	2·06	2·28	3·22	−0·77	−1·75, 0·20			0·12
Cough	1·97	2·58	2·97	2·78	−1·00	−2·07, 0·07			0·066
Diarrhoea	1·24	2·10	2·25	2·88	−1·01	−1·95, −0·06			0·037
Vomiting	0·57	1·53	0·38	0·93	0·20	−0·37, 0·77			0·50
Family demographics									
Biological mother is primary caregiver	88	91·7 %	27	87·1 %			1·63	0·51, 5·24	0·49
Biological mother is alive	88/92	95·7 %	29/29	100·0 %			*		0·57
Biological father is alive	47/48	97·9 %	11/11	100·0 %			*		1·00
Biological father lives in the home	35/48	72·9 %	8/11	72·7 %			1·01	0·26, 4·46	1·00
Mother has had HIV test	58/72	80·6 %	23/27	85·2 %			0·72	0·24, 2·23	0·77
Mother has had positive HIV test	11/56	19·6 %	13/23	56·5 %			0·19	0·28, 0·65	0·0025

WLZ, weight-for-length *Z*-score; HAZ, height-for-age *Z*-score; WAZ, weight-for-age *Z*-score.
*OR cannot be computed due to non-zero values.

Table 5 Comparison of infants u6m with moderate acute malnutrition (MAM) with and without nutritional recovery treated as outpatients with supplementary food

	MAM with recovery (*n* 157)		MAM without recovery (*n* 36)		Difference	95 % CI	OR	95 % CI	*P* value
Demographics									
Median age in days (range)	163	85–180	165·5	52–180	−1·23	−9·39, 6·93			0·77
Female	84	53·5 %	23	63·9 %			0·67	0·33, 1·44	0·35
Infant is still breast-feeding	149/156	95·5 %	32/36	88·9 %			2·66	0·83, 9·13	0·13
Anthropometry									
WLZ	−2·39	0·41	−2·31	0·41	−0·08	−0·24, 0·07			0·27
HAZ	−1·91	1·96	−1·82	1·93	−0·09	−0·80, 0·63			0·81
WAZ	−3·10	1·41	−2·98	1·42	−0·12	−0·64, 0·39			0·64
MUAC	10·97	1·60	11·11	1·11	−0·14	−0·59, 0·32			0·54
Days of illness in preceding 7 d									
Fever	1·72	1·99	2·81	2·62	−1·09	−1·86, −0·31			0·0064
Cough	1·68	2·24	2·50	2·54	−0·82	−1·67, 0·02			0·055
Diarrhoea	1·62	3·10	2·17	2·35	−0·55	−1·64, 0·54			0·32
Vomiting	0·49	1·15	1·33	1·94	−0·84	−1·33, −0·35			0·0008
Family demographics									
Biological mother is primary caregiver	152	98·7 %	33	91·7 %			6·91	1·35, 39·5	0·048
Biological mother is alive	139/142	97·9 %	29/31	93·5 %			3·20	0·54, 16·07	0·22
Biological father is alive	101/103	98·1 %	21/22	95·5 %			2·40	0·16, 21·22	0·44
Biological father lives in the home	83/100	83·0 %	15/21	71·4 %			1·95	0·64, 5·98	0·23
Mother has had HIV test	119/155	76·8 %	28/36	77·8 %			0·94	0·41, 2·24	1·00
Mother has had positive HIV test	13/118	11·0 %	4/28	14·3 %			0·68	0·22, 2·04	0·51

WLZ, weight-for-length *Z*-score; HAZ, height-for-age *Z*-score; WAZ, weight-for-age *Z*-score.

A maternal history of a positive HIV test was also correlated with failure to recover.

Among infants u6m with MAM, anthropometric variables were not correlated with recovery. A recent history of fever and vomiting were significantly correlated with failure to recover (Table 5). Household factors such as continued breast-feeding and the presence of both biological parents showed generally non-significant trends towards correlating with recovery.

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Discussion

Very little data exist on the community treatment of acute malnutrition in infants u6m, as nearly all research has focused on infants and children older than 6 months of age, for which several international and regional clinical practice guidelines have been formulated[37]. Nevertheless, these younger infants represent a large and highly vulnerable population[26] who often live in rural areas without access to effective nutritional rehabilitation care available in inpatient facilities[19]. Several risk factors have been identified for their wasting, including poor intrauterine growth, premature birth, maternal malnutrition, small for gestational age birth and insufficient duration of breast-feeding with the early introduction of complementary feeding[18,19]. The global scale-up of CMAM provides an opportunity to consider whether the foods and protocols used for the treatment of older children might be applied to wasted infants u6m as well in circumstances when hospital admission is not realistic and a return to exclusive breast-feeding may take precious time and may not be possible[51].

Our study demonstrates that the majority (78·9 %) of infants u6m with uncomplicated SAM or MAM achieved anthropometric resolution of their acute malnutrition when provided with therapeutic or supplementary foods based on the existing CMAM model. Infants u6m with MAM had higher recovery rates than those with SAM (81·3 % *v.* 75·4 %) and lower documented mortality (1·6 % *v.* 3·1 %). Importantly, recovery rates for infants u6m were similar to the recovery rates of infants aged 181–270 d for infants with both SAM (75·7 %) and MAM (85·2 %). This indicates that those infants u6m who pass a supervised appetite test and demonstrate no clinical complications can be considered for outpatient therapy similar to those older than 6 months of age who have been treated as such for many years. RUTF, RUSF and SuperCereal Plus appear to serve as adequate nutritional substitutes in children with uncomplicated SAM and MAM when other sources are not available.

While inpatient care is the most widely recommended standard treatment in u6m with acute malnutrition, inability to access care remains a significant barrier for families. This challenge was demonstrated in a prospective cohort study in Bangladesh which found that the vast majority of infants u6m with SAM referred for inpatient care did not actually report for treatment[19]. This is likely due to the significant social and economic burden placed on caregivers, particularly mothers, who are unable to spend long periods with their infants in the hospital due to these logistical challenges.

Outpatient treatment for acute malnutrition in infants is acceptable, even preferable, to beneficiaries and communities[37,49]. In Senegal, a qualitative study found that community-based care for infants u6m facilitated access to treatment and influenced health-seeking behaviour, provided an appropriate breast milk supplement was available[44]. Another qualitative study based in Bangladesh showed that caregivers reported outpatient treatment would be a welcome addition to the treatment options for acute malnutrition[46]. The current study also recognised that caregivers of infants may not be as adept at identifying acute malnutrition in u6m as with older children and thus it may be advisable to encourage systematic anthropometric evaluation of infants u6m, as this would also help identify malnourished infants earlier. The community viewed hospitalisation as providing higher quality treatment, but that they would still prefer an outpatient treatment option for uncomplicated acute malnutrition. Thus, even if there were resources in place to treat u6m as outpatients, it would not necessarily make families more unwilling to bring their infants to the hospital for treatment if complications were identified.

Preventive efforts to decrease the risk of low birth weight and early growth faltering such as antenatal nutritional and anti-infective measures may help decrease the risk of acute malnutrition in infants u6m[52], and thus ideally make measures such as those described here unnecessary. Given the limitations in the retrospective study design, we did not assess whether HIV-positive mothers were receiving antiretroviral therapy (or the timing of such therapy), how severe their HIV disease was (viral load, CD4 count, WHO staging, etc.) or whether any of the infants in the study were indeed infected.

The lack of exclusive breast-feeding is likely the most common risk factor for SAM in infants u6m[17]. This certainly indicates a call for increased support and counseling on the importance of exclusive breast-feeding, which should remain at the centre of all nutritional care for infants u6m, even those with acute malnutrition. Indeed, we found that those infants who were still breast-feeding were generally more likely to recover. However, in many populations, *exclusive* breast-feeding has already stopped and the introduction of the supplementary foods provided here for these small and vulnerable infants for therapeutic purposes is worth considering, and in fact is already acknowledged to be happening in daily practice in many locations[7]. Ultimately, relying on improving breast-feeding alone is inadequate and may not lead to rapid nutritional recovery during this vulnerable period of acute malnutrition as there may not be enough time to wait without continued stunting of these infants' development and further time at risk for mortality and further morbidity[51]. In our patient population, 84·4 % of those with SAM and 94·3 % of those with MAM were still breast-feeding, although very few exclusively. This demonstrates that even among infants who are breast-feeding, acute malnutrition is a significant problem. Breast-feeding did seem to have some positive association with recovery in both SAM and MAM groups. Among children with acute malnutrition, breast-feeding support and education remains an important – essential – component of

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addressing and treating malnutrition in infants, yet is unlikely to be sufficient on its own.

As an operational study, there are a number of limitations in our data that should be considered when interpreting the outcomes. Foremost is potentially incomplete data collection as patient records were not consistently kept with the intention of answering the specific questions addressed here. This was particularly true for the inconsistent collection of demographic data. Since infants with incomplete data collection were excluded, this also may have introduced some bias into our findings. As with all operational studies, we have no objective measurement of compliance; while the infants received a standardised amount of therapeutic or supplementary food in clinic, we do not know what quantity they ate while at home. Nevertheless, the results do reflect the reality of what may be expected to occur when this intervention is applied in a real-world field setting.

Indeed, even if the foods provided were shared among others in the household, this overall increase in food availability may have sufficiently decreased the overall household food insecurity enough to allow increased nutrition for the malnourished infant to recover. This may especially be true if the supplement helped the infant's mother improve her own nutritional status, although the quantities provided were based on a small infant's weight and are unlikely to provide a significant amount of energy for an adult. Even if the family was selling the therapeutic food, the small extra income may have ameliorated some household food insecurity.

A consensus on the optimal anthropometric criterion used to identify and treat acute malnutrition in infants u6m with the highest risk of mortality remains an ongoing challenge in the community[27,31]. While MUAC is an accepted standard of determining nutrition status for children from 6 to 59 months, specific thresholds in infants u6m are not yet universally accepted[28]. Although WAZ has emerged as perhaps the best single anthropometric indicator[28,32], we used WHZ as our marker of wasting as this was what was being used operationally during this time in rural Malawi. Indeed, it would almost certainly be better in the future to include clinical factors in addition to anthropometry to develop a 'cluster' or 'complex' of signs and symptoms that would help identify the infants at highest risk[53,54].

Because the operational clinical practice was to only treat acutely malnourished children (including u6m infants) with uncomplicated malnutrition who successfully passed a supervised appetite test, 88·5 % (286/323) of the patients in the current study were over 4 months of age. Thus, these results do not necessarily apply to infants younger than this age, as our sample size was relatively small and they may not be developmentally mature enough to eat semi-solid foods at younger ages.

Further, without an untreated control group, it is impossible to determine whether a similar number of patients would have recovered even without specific nutritional supplements. We also cannot determine whether inpatient treatment or other food formulations would have led to higher recovery rates. We were unable to identify any historical controls to determine 'expected' recovery or mortality rates in infants u6m. However, we did compare results with contemporaneous controls in infants 180–270 d old and outcomes were quite similar. This data were collected over similar time periods and from the same patient population.

We do not necessarily disagree with the current guidelines for the treatment of acute malnutrition in u6m. The re-establishment of exclusive breast-feeding should still remain the gold standard to achieve for infants u6m with acute malnutrition, including hospitalisation for nutritional rehabilitation whenever possible. However, a large number of infants who live in rural areas and are not able to be hospitalised are not being served by current guidelines. In our experience in rural southern Malawi, approximately 50–75 % of 4–6 months old infants with acute malnutrition who present to our clinics have uncomplicated cases and are able to be managed using the protocols and foods described here.

Our study showed that the CMAM model for u6m was associated with resolution of acute malnutrition in nearly 80 % of infants, rates similar to comparable children 6–9 months old. We propose that RUTF, RUSF and SuperCereal Plus should be considered as treatment options for those infants 4–6 months old with uncomplicated acute malnutrition who pass a supervised feeding test and who cannot be hospitalised for more thorough nutritional rehabilitation. We did not enroll enough infants under 4 months of age to make a recommendation at that age; it would be reasonable to expect that infants that young would have different nutritional needs and chances of recovery using this approach. As the current study was based on operational data, randomised prospective studies comparing this outpatient approach with therapeutic or supplementary foods with other strategies as part of outpatient or inpatient management are warranted.

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