about

A comprehensive report on community based management of children with severe acute malnutrition (CMAM). Findings from a systems-based implementation in Nandurbar, Maharashtra.



background

Globally, severely wasted children are, on average, 11 times more likely to die than their healthy counterparts. Moreover, the purpose and concern is not only to reduce mortality but children with severe acute malnutrition (SAM) are at exceptionally high risk of poor growth outcomes and are also thought to be at high risk for motor and cognitive delays, as brain development is further inhibited with increasing severity of malnutrition.

Severe wasting in children aged 6-59 months is defined as a mid-upper-arm circumference (MUAC) < 115 mm or a weight-for-height z-score (WHZ) < -3 of the median weight-for-height in the Child Growth Standards of the WHO.



In lakhs children under 5 , NFHS 4



The first priority of any program aiming to address malnutrition should focus on intensive community interventions to prevent malnutrition from setting in. however, when the prevention fails and the child develops sever acute malnutrition, the first priority should be to have a community based intervention in place so that the child continues to receive comprehensive nutrition intervention closer to the household.

According to WHO, the early detection and treatment of severe wasting is a proven, evidencebased intervention for child survival and nutrition. In past, in absence of the community based program, treatment and management of severe acute malnutrition has been restricted to the facility-based approaches, greatly limiting its coverage and impact. However, based on new evidences, WHO and UNICEF recommend that children with medically-complicated severe wasting be treated as in-patients in a facility while children with uncomplicated severe wasting should treated at home with the support of a community-based program for the management of acute malnutrition (CMAM).



The inpatient treatment in the health facility requires children with SAM and medical complications to be treated as per a medical protocol including antibiotics, other medicines, therapeutic milks, micronutrients supplementation as well as

structured play therapy and loving care environment for child stimulation.

The community based management of SAM, requires children (6-59 months) to be treated in a comprehensive manner with preventive nutrition interventions as well as using the energy dense nutrient rich therapeutic food suitable (soft, easy to eat for young children, and free from microorganisms that can harm children with SAM) for treatment of children with uncomplicated SAM.



The Lancet 2013 considers CMAM as a high impact intervention in spite of the relatively high cost of the therapeutic foods because it is highly effective in treating SAM and saving lives. Programmatic evidence supports the timely use of energy dense nutrient rich therapeutic foods along with the preventive approaches in CMAM programs. Globally, the shift to community-based decentralised care through CMAM combined with the preventive and therapeutic has allowed CMAM programs to treat large numbers of children cost-effectively. Moreover, managing children with SAM through CMAM allows cheaper and yet effective treatment closer to the household than the facility based treatment which should exclusively treat the medically complicated SAM cases and under 6 months children with SAM.

Maharashtra has been leading the country in its efforts for improved child nutrition and development outcomes. Maharashtra was the first State in India to set up a full time Nutrition Mission(Rajmata Jijau Mother child Health and Nutrition Mission-RJMCHN Mission) dedicated to improving nutrition of young children and their mothers through coordination among different government departments that provide direct nutrition interventions or nutrition-sensitive interventions with a focus on the youngest, the poorest and the most vulnerable.



Taking cognisance of the high prevalence of wasting among under 5 years children, its adverse impact on the survival, growth and development of children as well as the scientific evidence available, Government of Maharashtra, since the year 2008, initiated management of children with SAM at three different levels with support of NHM funds and later with state government funds. Malnourished children without any complications were managed at community level through Village Child Development Centre (VCDC) while children with complications were managed at facility through Child Treatment Centre (CTC) at rural hospital and Nutrition Rehabilitation Centre (NRC) at selected district / sub-district hospitals. The community based management of children with SAM in Maharashtra is being done through VCDCs using protocols adopted and locally developed. Since 2007, the community based management of children with SAM in Maharashtra is being implemented using locally developed recipes from the Amylase Rich Flour (ARF) by the Anganwadi workers.



The key purpose of treating children with SAM is to treat the severe underlying clinical condition that will contribute significantly in saving the lives of these children. Substantial programmatic evidence supports the use of energy dense nutrient rich therapeutic food suitable for CMAM. The shift from facility-based care to community-based decentralized care through CMAM combined with the effectiveness of the energy dense nutrient rich therapeutic food has allowed CMAM programs to grow rapidly and treat large numbers of children globally cost-effectively. After the child is fully stabilised and meets the requisite discharge criteria from the program, it is essential for the caregivers to provide nutritious foods and ensure appropriate care and hygiene practice at home. In the absence of appropriate feeding, care and hygiene, the child will likely become severely malnourished again.



key components

The components of a robust comprehensive CMAM include:

1) promotion of good infant and young child feeding practices, child stimulation for development, hygiene and other practices and services to prevent SAM,

2) Community level screening of children and identification and referral of children with SAM,

3) Facility based management of children with severe acute malnutrition with complications

4) community based or outpatient management of children with severe acute malnutrition without complications,

5) Follow up of children discharged from the CMAM program to avoid relapse



In 2014, from the data available from the Comprehensive Nutrition Survey Maharashtra-CNSM,(2012-2013), it was realised that that the prevalence of wasting as well as severe wasting among under 5 years children was very high among the tribals/adivasi. As a response to this, the Department of Women and Child Development, State Nutrition Mission and with technical clearance from Department of Public Health, jointly with Tata Trust and UNICEF decided to pilot the effectiveness of a comprehensive CMAM program through existing service delivery systems for children.

Given the high prevalence of wasting, difficult terrain and being a predominantly tribal district, Nandurbar with a population of 16.46 lakhs was chosen for the implementation of the effectiveness trial. There are a total of six blocks with 935 villages of which 131 villages and approximately 1400 hamlets are difficult to access. As per the latest available survey of NFHS 4 (2015-16); child nutrition indicators are as follows, 47.6 % are stunted, 39.8% of children under 5 years are wasted (WHZ< -2) and 15.1% are severely wasted (WHZ< -3). The assumption in the trial was that if the favourable results can be delivered in a difficult district of Nandurbar; they can be scaled up anywhere in Maharashtra and India.



strategies

- System Strengthening
- Counselling on IYCN
- Sensitisation of the community leaders and the ZP Members
- Linkages with existing nutrition programs like ICDS , Abdul Kalam Yojana etc.
- Capacity Building (>9000 functionary)
- Screening Active and Passive
- Supply and Logistics
- Data System and Management
- Community Interaction
- Social Mobilisation
- Community Volunteers
- Home based Counselling
- Special Screening Drives
- Linkages with NRCs/CTCs
- Policy, Advocacy and Partnership



the program

The major components of the CMAM program were as follows:

- 1. Bi-annual screening of all children age 6 72 months across all the 6 blocks of Nandurbar
- 2.Referring the SAM children with medical complication to the nearest Nutrition Rehabilitation Center (NRC)
- 3. Enrolling the SAM children without medical complications to the CMAM program from the children screened by ICDS



The identification of children with SAM was done by:

- 1) Active screening through screening drives usually conducted at 6 monthly intervals or less frequently in some of the blocks in Nandurbar District. When there was no standalone screening exercise,
- 2) frontline workers would screen children as part of the regular screening process in AWCs, during VHNDs and also for other programs and services as part of passive screening.

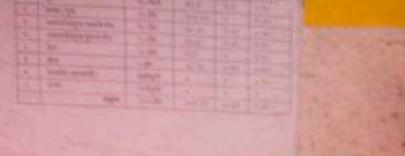
The screening was done using one of the three criteria – weight-for-height, mid-upper arm circumference and/or bilateral pitting oedema. The screening was done by team of Health and ICDS workers at the Anganwadi centres.



Early detection of children with SAM. The anganwadi worker (AWW), the communitybased frontline worker of the Integrated Child Development Services (ICDS) program screened children either in the context of monthly growth monitoring and promotion sessions at the Village Health and Nutrition Day (passive case finding) or through houseto-house community drives for the detection of children with SAM every three months (active case finding). The Auxiliary Nurse Midwife (ANM) and Medical Officer (MO) of the National Health Mission (NHM) programme screened sick children attending health facilities (passive case finding). In addition, families and communities referred children that they suspected to be severely undernourished.



Children 6-35 months old with MUAC < 115 mm were referred to the anganwadi centre for triage and referral to the Nutrition Rehabilitation Centre (NRC) - or the Outpatient Therapeutic Programme (OTP). In children 6-35 months old with 115 mm \leq MUAC \leq 125 mm and children 36-72 months old with a weight-for-age z-score < -2, WHZ was assessed and all children with WHZ < -3 were referred to the ICDS centre for triage and referral to the NRC or the OTP. At the ICDS centre, the ANM assessed the presence/absence of bilateral pitting oedema and medical complications using the criteria for the Integrated Management of Neonatal and Childhood Illnesses (IMNCI)



In addition, the ANM assessed children's appetite. She ANM conducted the appetite test using the feeding option that would be tested in the respective block. The caregiver and her/his child were made to sit comfortably in a quiet room where the caregiver was briefed about the aim and methodology of the appetite test. If the child had consumed any food in the previous 2 hours, the caregiver was requested to wait until two-hours since the previous feed had elapsed and then the children's appetite was tested. The caregiver was counselled to take the child in her/his lap and encourage the child to eat the therapeutic food without forcing the child to eat. The child was observed for a maximum of one hour. If the child ate eagerly/on encouragement more than half of the dose assigned the test

was labelled as 'passed'.



In-patient therapeutic care. Children with a) bilateral pitting oedema; b) children with MUAC < 115 mm/WHZ < -3 and poor appetite (failed appetite test); and c) children with MUAC < 115 mm/WHZ < -3 and medical complications were referred to the NRC. In the NRC, children received therapeutic care as in-patients following protocols based on the guidelines for the management of SAM by WHO and the Indian Academy of Pediatrics. Once stabilized (oedema resolved, fever disappeared, medical complications were treated, age-appropriate immunizations were completed, appetite returned, weight gain started, children were active and alert, and caregiver was informed about follow up care) children were discharged for out-patient therapeutic care.



Out-patient therapeutic care. Children: a) who were been discharged from the NRC and b) with MUAC < 115 mm/WHZ < -3 with appetite and free of medical complications were admitted to the OTP where they received routine medication and therapeutic feeding. Treatment with ARF was the standard protocol for the treatment of SAM in Maharashtra at the time of the trial. ARF was prepared at the anganwadi centre (the village ICDS centre). Children in this group were fed ARF at the anganwadi centre in addition to home foods. L-RUTF was prepared at the anganwadi centre. Each child was assigned a daily quantity of L-RUTF on the basis of the child's weight

Children in this group were fed L-RUTF at the anganwadi centre in addition to home foods. If the child did not consume the assigned L-RUTF for the day at the center, the remaining portion was handed in a clean container to the caregiver, who was encouraged to feed it to the child at home before the end of the day. C-RUTF was produced by Compact India. Children in this group received a weekly allotment of C-RUTF to be consumed at home in addition to home foods. Children enrolled in this group were visited at home on alternate days by the village AWW or the accredited social health activist (ASHA), the community worker of the National Health Mission (NHM) to monitor the consumption of C-RUTF and solve any problems/question that caregivers may encounter with the feeding regimen.



Children attended the OTP for a maximum of 8 weeks and later based on midcourse corrections for a duration of 16 weeks. Children's progress was monitored weekly. At the weekly visit, children's MUAC (for those admitted with MUAC < 115 mm) and WHZ (for those admitted with WHZ < -3) were monitored and the child's mother/caregiver was counselled on optimal child feeding, hygiene and care.

Children were discharged from the OTP when they: a) reached a MUAC \geq 125 mm (for those admitted with MUAC<115 mm) or a WHZ \geq -2 (for those admitted with WHZ < -3) for two consecutive weekly follow-up visits; or b) had completed 8 weeks in the program, whichever happened first.

Children who were absent for two consecutive weekly follow-up visits were considered defaulters. Children who were discharged from out-patient therapeutic care were referred to the ICDS programme where they received fortified blended foods as a take home ration (children 6-35 months old) or as an on-site daily hot cooked meal (children 36-71 months old)



The report focuses on all children aged 6 to 72 months with uncomplicated SAM who were managed at the community level. In total, four cohorts of an average 120,000 children were screened in Nandurbar from the July 2014 to December, 2016.

Children 6-35 months old with MUAC < 115 mm and with medical complications were referred to Nutrition Rehabilitation Centre (NRC) - the stabilisation centre for children with medically-complicated SAM - or the Outpatient Therapeutic Programme (OTP). In children 6-35 months old with MUAC >115 mm, and MUAC \leq 125 mm and children 36-72 months old with a weight-for-age z-score < -2, WHZ was assessed and all children with WHZ < -3 were referred to NRC or the OTP.



three arm trial

Out of the total six blocks of Nandurbar, two block each were randomly assigned to each of the three feeding regimes as explained under. The three arm trial was initiated in July 2014 and was concluded in June, 2016. The trial assessed the effectiveness of three different feeding regimens for the management of uncomplicated SAM in children through CMAM



C-RUTF

Centrally-produced and packaged commercial energy dense nutrient rich ready-touse therapeutic food is a peanut-based energy dense nutrient rich therapeutic food produced in India containing powder milk, sugar, oil, and multiple micronutrients with a mean energy content of 520-550 kcal/100g (as per WHO formulation). Number of packets per children per day (being given as a weekly stock) was provided based on the weight of the child.





L-RUTF

Locally-prepared energy dense nutrient rich ready-to-use therapeutic food is a groundnut-based ready-to-use therapeutic food containing powder milk, sugar, oil and multiple micronutrients with a mean energy content of ~513 kcal/100 g. The ingredients were procured locally by the ICDS Anganwadi workers (for which dedicated funds were provided) and prepared by her at the AWC. Milk Powder and micronutrients were provided separately.





ARF

Amylase Rich Flour is a cereal-based energy food for children with SAM (was used in Maharashtra as an alternative to RUTF in VCDC) with a mean energy content of \sim 444 kcal/100 g. The ICDS Anganwadi workers procured the ingredients – wheat and green gram locally. Ingredients were soaked in water overnight, spouted (which takes few days), dried, roasted and finely grounded into an amylase rich four. Anganwadi workers prepared- the recipes at the Anganwadi centers, as well for home cooked foods, using the amylase rich flour, to which additional ingredients like milk, sugar and oil were added to make it energy dense. Funds were provided additionally.





capacity building

Training, Counselling and co-interventions : A team of Master Trainers, from the State Nutrition Mission, Department of Women and Child development, the Department of Public Health, Maharashtra University of Health Sciences, development partners (UNICEF and Tata trust), technical experts of repute, and field level staff designed and field tested the training module that was used to build the knowledge and skills of the frontline workers who delivered the programme interventions. In addition, a team of local tribal youth knowledgeable of the local language and culture were trained to provide counselling and support to caregivers in areas that were inaccessible to (not covered by) the ICDS and the NHM programmes and their frontline workers and help with the logistics of programme delivery.



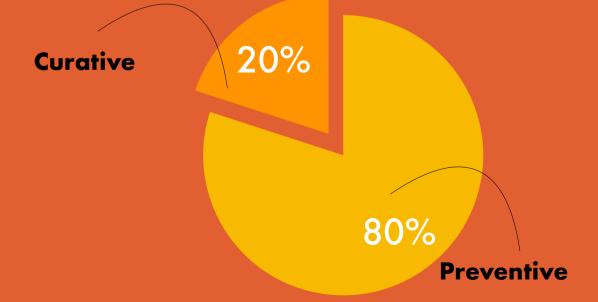
The training and capacity building strategy involved 1,249 supervisors and 10600 frontline workers of Health and ICDS spanning over 250 batches throughout the duration of CMAM. District resource groups involving Health and

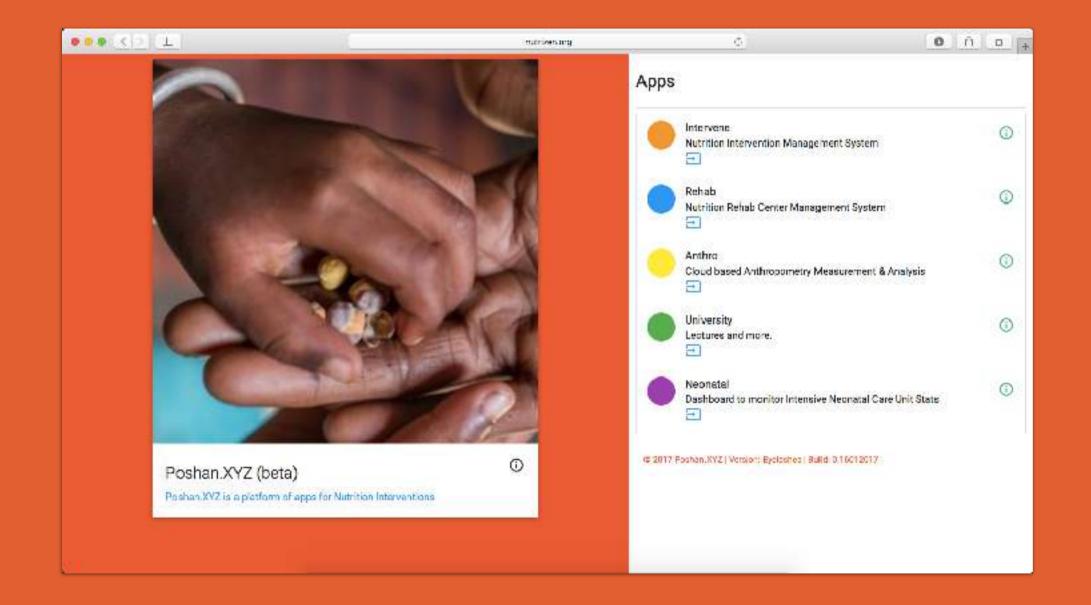
throughout the duration of CMAM. District resource groups involving Health and ICDS was created for rolling out of trainings for the frontline functionaries as well as to provide supportive supervision and monitoring the quality of implementation. It covered the following topics: causes and consequences of SAM; objectives of the CMAM programme; screening, detection, triage and referral of children with SAM; appetite test; hands-on training on anthropometry measurement, counselling of caregivers on therapeutic feeding, and delivery of co-interventions; counselling and problem-solving skills; record keeping and reporting skills.



The core component (almost 80%) of the training covered preventive aspects

and management /treatment of children with SAM (almost 20% of the training) using a community based approach. Along with the capacity building of the frontline workers; linkages with various existing programs (Take Home Ration under ICDS and growth monitoring and promotion, APJ Abdul Kalam Amrut Ahar Yojana for pregnant, breastfeeding mothers and under 3 years children; micronutrient supplementation program) for the preventive approach were established.





Counselling and support to caregivers in households and communities was provided by AWWs and ASHAs. They conducted home visits every alternate day to counsel and support mothers/caregivers to adhere to the feeding protocol and checked on potential medical complications that required referral. AWWs and ASHAs conducted mothers' meetings every fortnight to increase awareness on the prevention of child undernutrition and the interventions available for the management of SAM. Mothers' meetings placed emphasis on solving doubts and problems regarding the adherence to the feeding protocol and empowering mothers/caregivers to provide age-appropriate feeding and care for infants and young children. Once a week, caregivers of children admitted to the programme attended the OTP site with their child. At this weekly follow-up visit, AWWs and ASHAs gave caregivers the stock of therapeutic food needed for the following week.



In addition, AWWs and ASHAs reminded the mother/caregiver of the child a few key messages including: the impact of SAM on the on survival, growth and development of the child and the need to take remedial action; the need for special therapeutic foods for rapid and lasting recovery; the importance of adhering to the therapeutic feeding protocol, not sharing the therapeutic food with other members of the family, and encouraging the child to eat the therapeutic food completely while offering the child plenty of safe drinking water; the importance of appropriate food storage, hygiene practices before feeding the child and child stimulation; the importance of identifying danger signs and seeking help with the right person/service; and counselling to improve infant and young child feeding with focus on complementary feeding – frequency, quality and consistency.



Micronutrient supplementation and medicines: Co-interventions for children in the three groups included: deworming prophylaxis in the form of Albendazole (200 mg for children 12-23 months old and 400 mg for children 24-71 months old); vitamin A supplementation (100,000 IU for children 6-11 months and 200,000 IU for children 12-71 months old) except for children who had received a dose of vitamin A in the previous 6 months; and Amoxicillin (50mg/kg/day given in 3 divided doses during the first seven days after admission to the programme). In addition children in the ARF group were provided micronutrient supplements in the form of syrup as per national guidelines for the management of SAM. The experience of implementing and operationalising these three arms on field were different both in terms of feasibility of preparing, administering, time-taken as well as perception of mother after the child has consumed these ARF, L-RUTF and C-RUTF as well as children having suffered episodes of diarrhoea, fever, vomiting.



community ownership

The CMAM program invested in creating cadres of community resource groups from the blocks who were the linkage between the communities and the service providers. These were youth from the local communities who were familiar with local language, dialects and cultural practices. Their importance to the program can be quantified by the reduction of default rates by more than 50% over the duration of the program. These resource persons formed the last mile linkage reaching out the most vulnerable children who could have died due to severe conditions/complications. They contributed significantly to strengthening the capacities of the frontline functionaries in hard to reach hamlets/villages as well as followed up with the children discharged from CMAM as well as NRC. These resource persons are now being recognised as trusted counsellors by the communities and care givers. This community level advocacy resulted in ownership of the program by the community.



ethics approval

The study was approved by the Department of Public Health, Government of Maharashtra, Maharashtra University of Health Sciences and Haffkine Institute for Training, Research and Testing, Mumbai, India. The primary implementing bodies were the Department of Women and Child Development through the Integrated Child Development Services (ICDS) programme and the Department of Public Health through the National Health Mission (NHM) programme. Technical support was provided by the Rajmata Jijau Mother Child Health and Nutrition Mission (RJMCHNM) of the Government of Maharashtra and UNICEF. Tata Trusts provided the required financial support. Ethical clearance was granted by the Institutional Ethics Committee of the Haffkine Institute for Training, Research and Testing, Mumbai, India. The trial was registered at Clinical Trial Registry of India with identifier CTRI/2014/09/004958.



data analysis

Data from the six sites/blocks were pooled and analyzed using Stata Statistical Software, StataCorp©, 2012. Comparisons of means and proportions were used to check comparability among treatment groups. Linear models were used to compare the effectiveness of the three therapeutic feeding options. We adjusted for the baseline characteristics where significant differences at baseline existed. Mean values are provided as mean \pm SD; for all tests, p < 0.05 was considered significant. Records were anonymised and de-identified prior to analysis. The data has been presented phase wise.

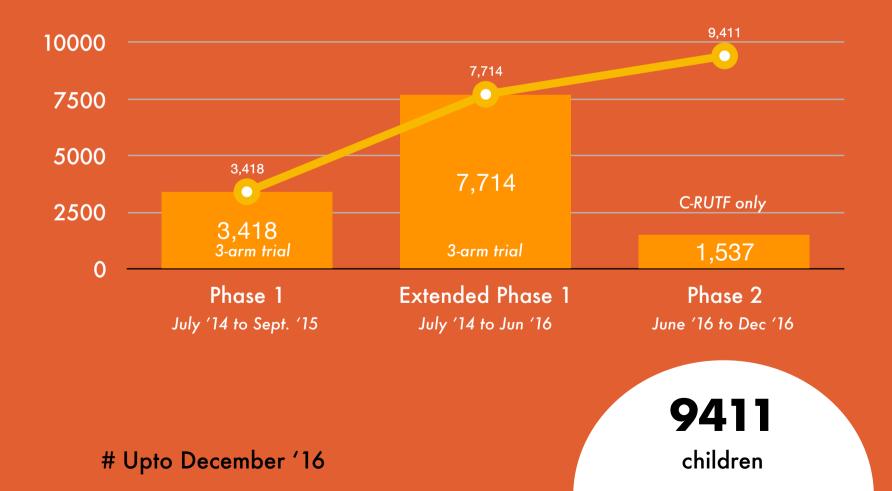


definitions

The important definitions used to define the indicators analysed are summarised as below.

- Recovery Those who achieved the discharge Criteria by end of 8/16 weeks
- Default Those who did not complete the 8/16 weeks of treatment for various reasons like migration etc.
- Non Responders Those who did not reach the discharge criteria
- Mortality Those who died while enrolled in the program

program reach*

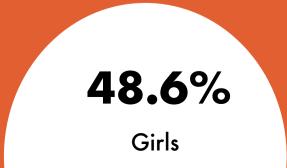


phase 1

The first phase of the trial having findings from the 3418 children aged 6 – 72 months who received either of the three feeding regime (ARF,L-RUTF and C-RUTF) for standard 8 weeks have been presented in detail. While the analysis was going on for the phase 1; the trial also continued and by the end of the extended phase 1, a total of 7714 children received either of the three feeding regime for 8 weeks. The initial findings, formed the basis of the recommendation from the ethics committee. Hence it was decided to continue the trial with only C-RUTF and discontinue the ARF and L-RUTF arm. The duration of the treatment was also increased from 8 weeks to standard 16 weeks.

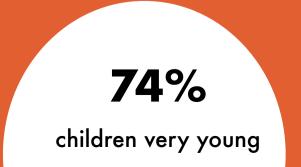


Admission											
	ARF		L-RUTF		C-RUTF		ALL				
	n	%	n	%	n	%	n	%			
Gender wise distribution of children admitted in the program											
Girls	245	45.3	193	43.6	1222	50.2	1660	48.6			
Boys	296	54.7	250	56.4	1212	49.8	1758	51.4			
Total	541	100	443	100	2434	1000	3418	100			
Admission based on MUAC and WHZ criteria											
MUAC	137	25.3	159	35.9	1069	43.9	1365	39.9			
WHZ	404	74.7	284	64.1	1365	56.1	2053	60.1			



During this period, children were treated for a maximum duration of 8 weeks on either of three feeding regime that is ARF, L-RUTF and C-RUTF.

3,418 children aged 6-59 months old with uncomplicated SAM were admitted to the program. The proportion of boys and girls was similar (51.4% vs. 48.6% respectively). 1,365 (39.9%) were admitted on the basis of MUAC < 115 mm while 2,053 (60.1%) were admitted on the basis of WHZ < -3. Children were very young 74% (n=2,521) were in the age group 6-35 months. 18 children (0.5%) with severe congenital/pathological conditions were transferred to the district hospital and were not transferred back to the CMAM program as their clinical management required highly specialised skills. The remaining 3,400 children (99.5%) are the exits - deaths, defaulters and discharged – of the CMAM program.



	ARF		L-RUTF		C-RUTF		ALL				
	n	%	n	%	n	%	n	%	p-value		
Discharged											
Recovered	112	26.3	119	31.3	825	40.0	1056	36.8	0.0		
Non recovered	314	73.7	261	68.7	1240	60.1	1815	63.2	0.0		
Total	426	100	380	100	2065	100.1	2871	100	0.0		
Exits											
Death	0	0	2	0.5	5	0.2	7	0.2	0.298		
Defaulter	115	21.3	60	13.6	347	14.4	522	15.4	0.0		
Discharged	426	78.7	380	86.0	2065	85.4	2871	84.4	0.0		
Total	541	100	442	100	2417	100	3400	100	0.0		

Of the 3,418 children who participated in the trial, 541 (15.8%) were enrolled in the ARF group, 443 (13.0%) in the L-RUTF group and 2,434 (71.2%) in the C-RUTF group.

The recovery rates in C-RUTF group (n=825) were significantly higher (40.0%) in comparison to the L-RUTF (n=119; 31.3%) and ARF (n=112; 26.3%) groups (p<0.001). Moreover, the recovery rates in all groups were significantly higher among children with MUAC \geq 110 mm or WHZ \geq -4 at admission while weight gain was significantly higher among children with MUAC < 110 mm or WHZ < -4 at admission.

Further analysis showed that the mean weight gain was significantly higher in children admitted to the C-RUTF group ($3.06 \pm 3.20 \text{ g/kg/day}$) than in the L-RUTF ($2.26 \pm 1.89 \text{ g/kg/day}$) and ARF ($2.39 \pm 1.66 \text{ g/kg/day}$) groups (p<0.001). However, there was no significant difference in MUAC at admission between the three groups.



There was a significant increase in the MUAC of the children of each of the three groups (p<0.001) during the duration of the program. However, at discharge, children's mean MUAC was significantly higher in the two RUTF groups (L-RUTF: 119.1 \pm 6.1 and C-RUTF 119.8 \pm 7.0) than in the ARF group (115.8 \pm 6.4) (p<0.0001).

Seven (0.2%) of these 3,400 children died while being the programme that is within 8 weeks. All of them were in the age group 6-35 months old and six were in the age group 6-23 months old. A total of 15.4% children (n=522) defaulted from the program before discharge after a mean 25.8 ± 14.3 days in the programme.

While default rates were significantly higher in the ARF group (21.3%) than in the C-RUTF (14.4%) and L-RUTF (13.6%) groups (p<0.001) but the death rates in the ARF, L-RUTF and C-RUTF groups were not significantly different (p=0.298). the findings clearly highlighted that the survival rates were equally high (\geq 99%) in the three groups, comparing favourably with national (\geq 97% survival rate) and international (\geq 90% survival rate) standards of care.



18 children (0.5%) diagnosed with severe congenital/pathological conditions were transferred to the district hospital but were not transferred back to the CMAM program. It is postulated that in a 'worst case scenario' analysis (i.e. if these 18 children had stayed in the CMAM program and died), still then the death rate in the CMAM program (0.7%) would still be below the national standard of care (<3%). Death rates in Nandurbar's CMAM program are comparable to those reported by CMAM programs in India and lower than those observed in CMAM programs in other countries.

After correcting for baseline characteristics, the adjusted difference in recovery rates between the C-RUTF and the ARF group was 11.8% (95% CI 6.8% to 16.9%; p=0.000) while recovery rates in the L-RUTF and ARF groups were not significantly different (p=0.268). Also, the C-RUTF was found to be significantly more effective than L-RUTF or ARF in supporting children's recovery (40.0% vs. 31.3% and 26.3% respectively).

Similarly, the higher recovery rate in the C-RUTF was also found to be associated with the significantly higher weight gain in this group than in the L-RUTF and ARF groups $(3.06 \pm 3.20 \text{ g/kg/day vs.} 2.26 \pm 1.89 \text{ g/kg/day} \text{ and } 2.39 \pm 1.66 \text{ g/kg/day} \text{ respectively})$. This remained statistically significant after adjusting for baseline characteristics.



The higher mean weight gain in the C-RUTF group was also associated with a significantly shorter length of stay in the programme compared to children in the ARF group while the mean length of stay in the L-RUTF and ARF groups were not significantly different.

Therefore, C-RUTF was more effective than the other feeding regimens in achieving significantly higher recovery rates in children with uncomplicated SAM but not in preventing death. The findings of the first phase of the effectiveness trial are in line with those of the efficacy trial by Dr. Nita Bhandari (2016) and colleagues in India confirming the higher efficacy of RUTF compared to standard home management of SAM.

Bhandari N, Mohan SB, Bose A, et al. Efficacy of three feeding regimens for home-based management of children with uncomplicated severe acute malnutrition: a randomized trial in India. BMJ Global Health 2016; 1:e000144. doi:10.1136/bmjgh-2016-000144





field insights

In the ARF arm, the locally prepared recipes using the amylase rich flour, prepared from wheat and green gram were given to children with uncomplicated SAM. However, the time required for preparing the amylase rich flour is more as it requires overnight soaking in water, sprouting which takes few days, drying, roasting and then finely grinding. Further, while preparing the recipes at the Anganwadi centres as well for home cooked foods using the amylase rich flour, additional ingredients like milk, sugar and oil is required to be added.



The micronutrient requirement of these children are met by micronutrient supplementation as per the government norms. It is noticed that there is also some improvement in the children using these protocols but with a few disadvantages such as, preparation of nutrition protocol is cumbersome needing long hours of efforts by the Anganwadi workers and difficult especially in monsoon, as there are chances of contamination and fungus growth due to humidity.

It is likely to contain anti-nutritional factors, less energy dense and poor quality of proteins. The particle size remains big for the stomach capacity of a child with SAM and compliance to micronutrient syrups becomes an issue. Although not confirmed, these associated issues might have contributed to high rates of default among the children in the ARF arm.



Although encouraging results were noticed in the group on L-RUTF (or also referred as the Special Feed on the field) which was prepared using groundnut powder, milk powder, sugar, the L-RUTF also needs to be freshly prepared every day for the use though less cumbersome than the amylase rich foods but required the children to remain in AWC for longer duration. Additionally, micronutrients and associated issues still remained to be addressed. The composition closely resembles globally acceptable protocol as the same ingredients are used except micronutrients. The challenge was contamination of milk powder and quality of peanuts maintaining right combinations and also the proportions of these ingredients.

The Medical Nutrition Therapy (MNT)/RUTF is manufactured using groundnut powder milk powder, sugar, and oil with a composition globally endorsed protocols using micronutrients. The experiences from field for the MNT or RUTF were found to be extremely encouraging in terms of feasibility to administer even in a difficult situation and can monitor the compliance by the children.



The major challenges experienced by the functionaries and local administration in the ARF and Local-RUTF arm were:

- 1) delays in procurement of local ingredients;
- 2) delays and difficulties in timely fund transfer,
- 3) ensuring consistency of the food,
- 4) potential risk of contamination,
- 5) procurement of low quality ingredients at local level (e.g. groundnut with high aflatoxin not properly processed and removed),
- 6) ensuring supply and consumption of micronutrient syrup. In ARF the additional challenges was to ensure preparation during the monsoon season when it was difficult to ensure germination/sprouting and thereafter drying of the same. Similarly in the Local-RUTF arm, there was added challenge of procurement, storage, distribution of milk powder and micronutrients sachets.



In this context, C-RUTF, in-spite of the procurement and distribution challenge, was a viable option to scale up across varied topographies and demographics and hence was decided by the local administration to scale-up the C-SAM program with C-RUTF only. Similarly, there are challenges in the C-RUTF arm as well like handling the supply chain management of the C-RUTF to ensure timely delivery of the stocks at the Anganwadi centres as well as to avoid any stock outs was very difficult. Considering the remoteness of the parents due to mountain terrain, long distance, heavy rains, ensuring continuous supply is a huge challenge especially when it has to be delivered

through routine government systems.



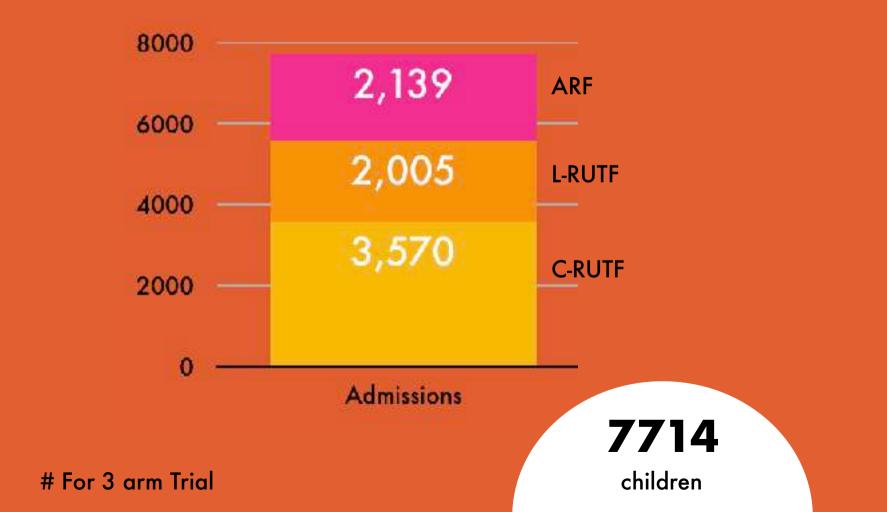
midcourse correction

In the 8 weeks duration trial of phase 1, larger number of children having MUAC < 10.5 cm and weight for height < - 4SD were not recovering. Based on the evidence of the three arm trial which demonstrated that C-RUTF had better recovery rates in children with SAM, this was presented to the ethics committee for programmatic mid-course correction. The ethics committee recommended below changes in the protocol of the trial in Nandurbar.

- 1. All the children receiving C-RUTF instead of the earlier phase of three arms with ARF, SF and C-RUTF
- 2. Change in the duration which was increased from 8 weeks to 16 weeks wherein children received the treatment for standard 16 weeks and were discharged thereafter.

Based on the recommendations, the two arms ARF and L-RUTF was discontinued in the trial and only C-RUTF was continued to be given to the children with SAM for a duration of standard 16 weeks.

feeding regimes*

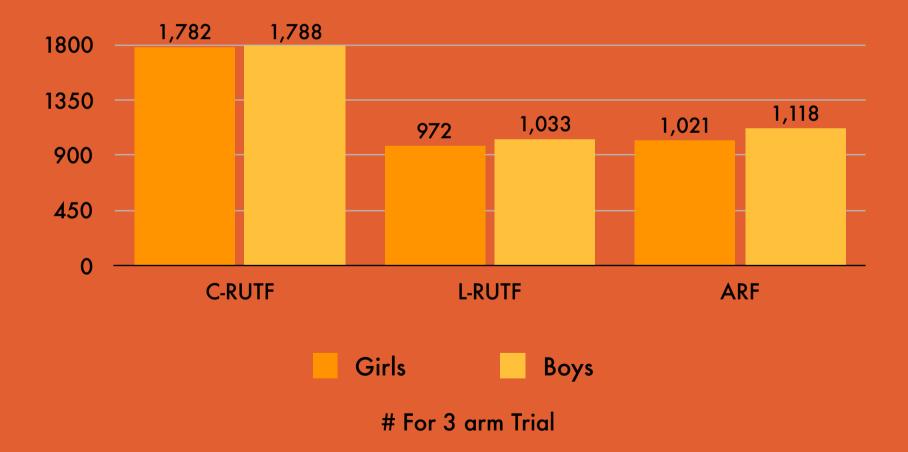


extended phase 1

While the analysis of the phase 1 was on-going and being presented to the ethics committee for recommendations, the trial continued as an extended phase and covered a total of 7714 children (including the 3418 children of phase 1). While the data analysis and findings presented for 7714 children is limited in comparison to the detailed analysis of findings of data from 3418 children of phase 1



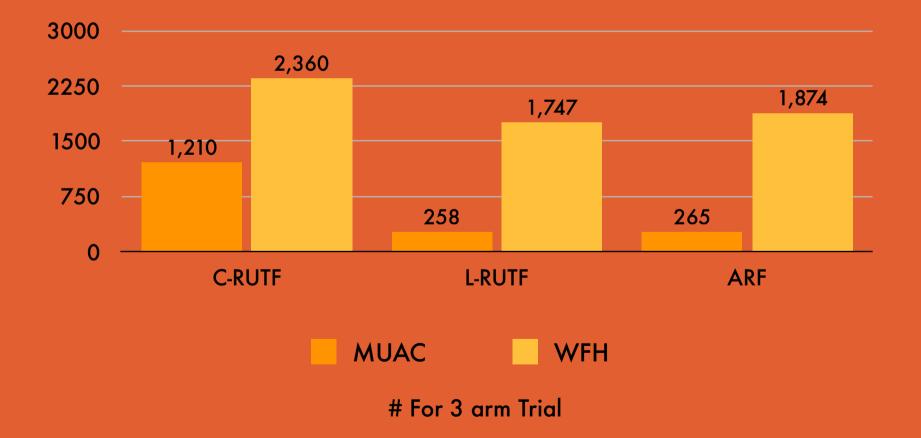
gender distribution*



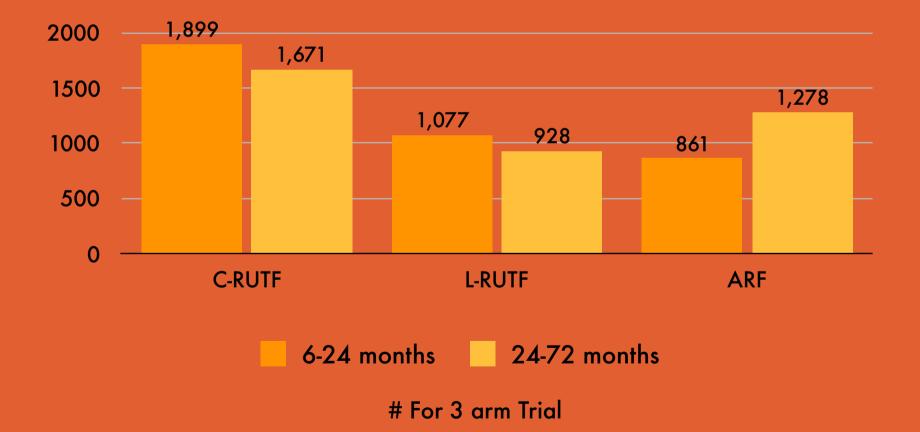
In the first phase (July 2014 to September 2015), a total of 3418 children were enrolled in the 3 arms trials. The findings of the same has already been summarised above. The trial with 8 weeks of intervention was further extended after September, 2015 and additionally bi-annual rounds of screening drives were conducted and eligible children as per admission criteria were included. Including the 3418 children of the phase 1; a total of 7714 children were admitted in the extended phase of the trial. (July 2014 to June 2016).

50% of the children enrolled in the C-RUTF arm recovered after 8 weeks while 37% of the SAM children recovered respectively for each L-RUTF/SF and ARF arm. Default rates were not significantly different across the three regime of C-RUTF, L-RUTF/SF and ARF (15% and 12% vs. 16% respectively). Eleven children died while in the programme (total phase 1 and 2). A total of 1121 children (14.34%) defaulted the program before discharge. Around half of the children were younger aged below two years and approximately half (48%) were girls.

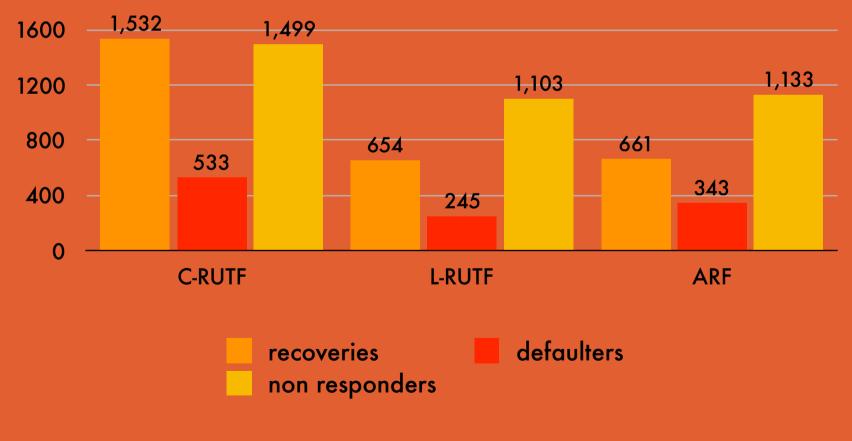
admission criterion*



age-wise distribution



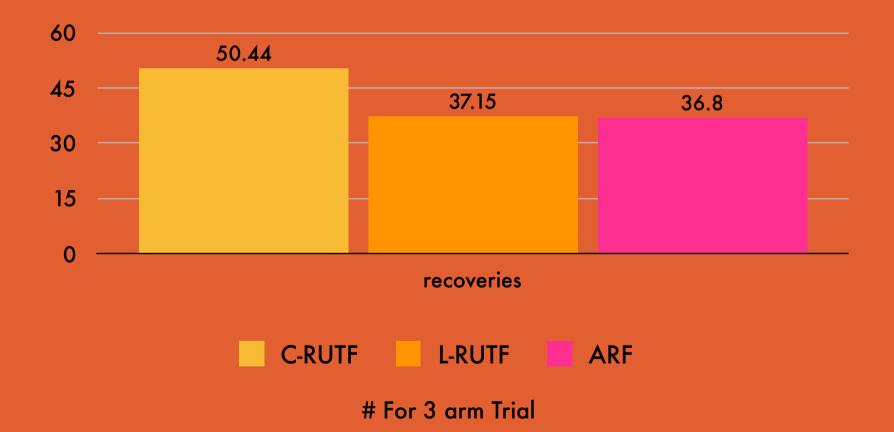
treatment outcomes



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For 3 arm Trial

recovery rates (%)*



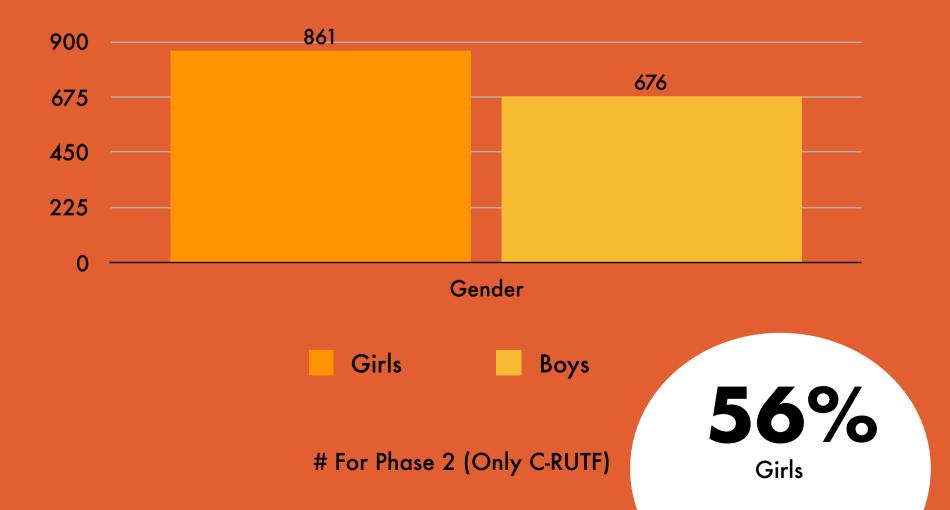


phase 2

Based on the encouraging results and recommendation of the ethics committee to increase the treatment duration, he duration of treatment using C-RUTF along with preventive components was increased to 16 weeks. Along with C-RUTF, children were consuming the home-food as well. Since June 2016, when the decision was implemented to increase the treatment duration, a total of 1537 SAM children in Nandurbar received C-RUTF for 16 weeks.



gender distribution*



A total of 861 (56%) and 676 (44%) girls and boys respectively were identified with SAM and were enrolled. More number of younger children of below 2 years (58%) and younger females (60%) were identified and received the C-RUTF for 16 weeks. Larger proportion of all females (61%) were admitted to SAM management through MUAC as a criteria while 49.5 % of admissions using weight for height criteria (WFH)

were girls. Moreover, 60% of the total admissions were young girls (6-24 months) and 50% were girls aged 24-72 months. Thus predominantly younger females with SAM were admitted to the CMAM program through MUAC criteria.

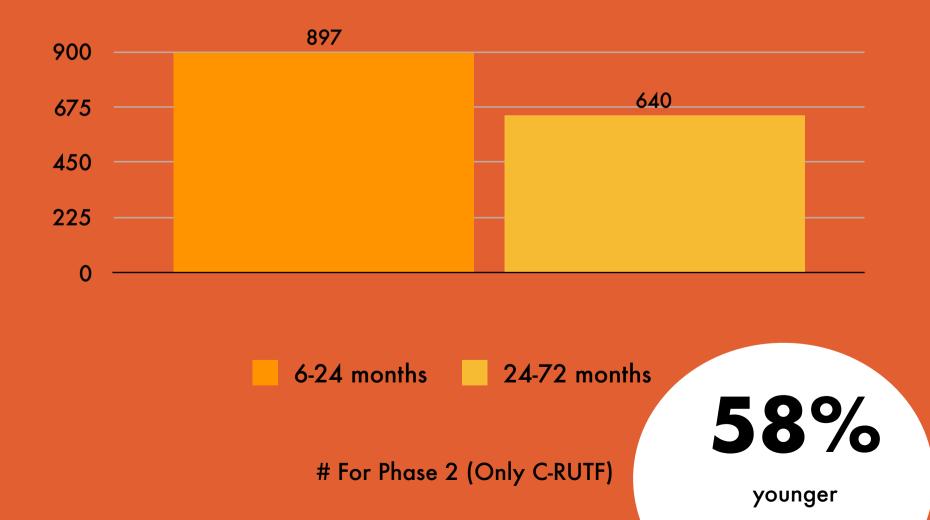
admission criterion[#]



66% (939 SAM children out of 1537 SAM children) of the SAM children enrolled in CSAM program recovered and achieved the discharge criteria. In the first phase with treatment for 8 weeks, in total 43% of the children recovered and achieved the discharge criteria. This rose drastically to 66% of children recovering when the duration of treatment was increased from 8 weeks to 16 weeks.

Although, 33.68 % (477 SAM children) were non-responders as per the global definition of not reaching the discharge criteria, one third of them did show significant improvement in the nutrition parameters and graduated from SAM to MAM in their nutritional status. While there was no mortality reported, as timely referral was done of the complicated cases to NRC. 7.9 % children defaulted from the C-RUTF regime and the major reason for default was migration. As the CMAM program got institutionalised over the duration of the program the non-responders and defaulters reduced.

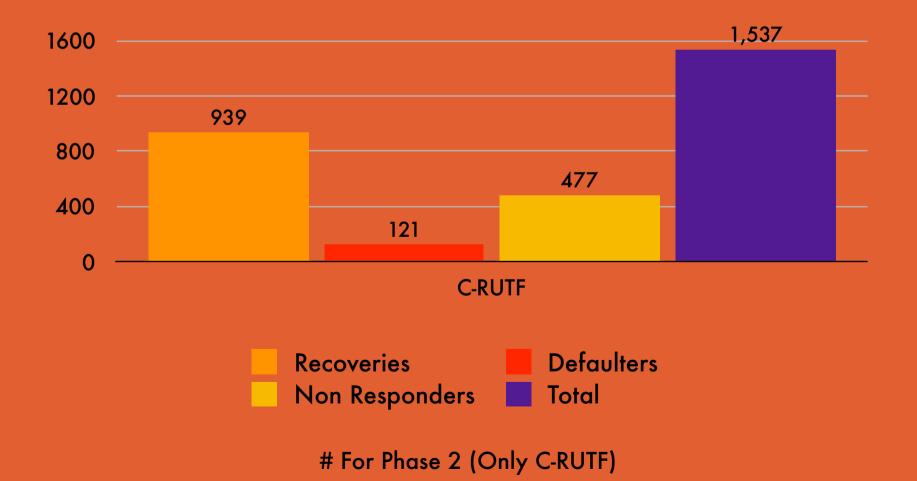
age-wise distribution[#]



Our study had several strengths. It was an effectiveness trial delivered by the community workers and supervisors of Government of Maharashtra's ICDS and NHM programs supported by community resource persons. The sample size across the different phases was large enough to ensure adequate statistical power. Regular supervision of the delivery of interventions, using the existing health and ICDS systems, ensured system driven sustainability, timely availability of food and medical supplies in the three groups. Refresher training including both preventive and therapeutic interventions ensured that implementation by community workers, supervisors and data collectors was standardised with regularity to ensure consistency in the delivery of intervention, reporting and analysis.

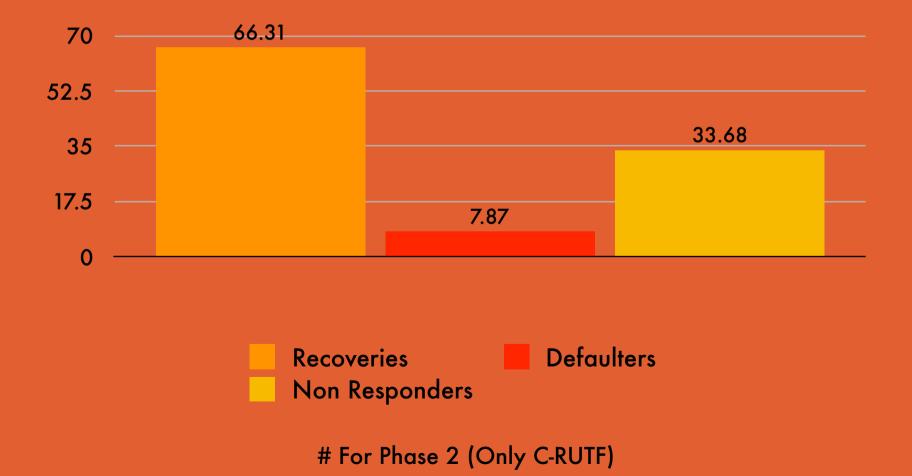
The study had a few limitations. There were visible differences between the three feeding regimens of the program which did not allow the effectiveness trial to be blinded but the teams in each trial involved in the implementation were unaware of the potential benefits of the three feeding regimens. It is also important to note that the training and supportive supervision on the preventive approach and effective feeding and care protocol was strengthened across the arms and blocks.

treatment outcomes



#

outcomes (%)*



reaching out to more girls[#]



For Phase 2 (Only C-RUTF)

faces behind the numbers



Palak Padvi



Pintu Pawara



Manisha Pawara



C-RUTF Saches transported
SUPPly & logistics

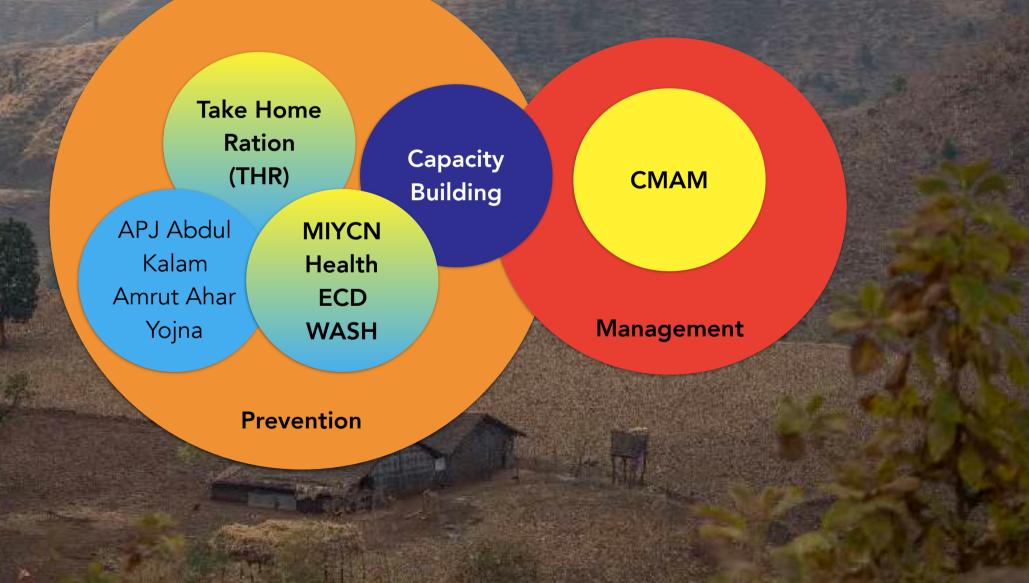
20 tonnes

inaccesible pockets

anganwadi centres



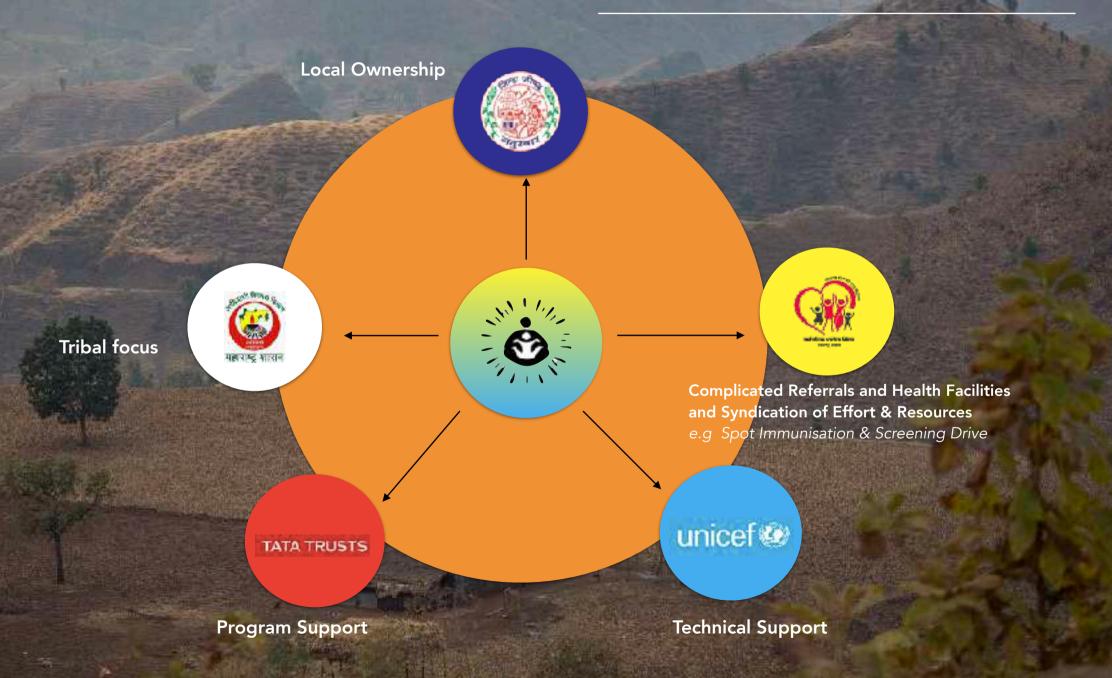
Prevention to Management



conclusion

CMAM program brings the services for management of Severe Acute Malnutrition (SAM) closer to the community by making services available at the anganwadi centre, communities and primary health care settings. This is provided through adopting preventive approaches to improve IYCN, WASH,ECD, child stimulation along with the use of centrally manufactured ready-to-use therapeutic foods (complying global standards), community outreach and mobilisation.

Symbiotic Partnerships



66% of the children with SAM who consumed C-RUTF (produced in India) along with receiving preventive nutrition interventions for 16 weeks successfully achieved their discharge criteria and recovered in the program positively. The cure rates increased from 43 % to 66% when the treatment duration was increased from 8 to 16 weeks. However, it is important to note that even after 16 weeks of intervention, one third of the children didn't recover and were referred to NRCs/CTCs for appropriate treatment.

In total 11 deaths were reported in the first phase of the CMAM program which could be due to delay in screening and/or enrolment to the program, while no mortality was reported in the last phase of the program which was the most intensive phase of the program. Subjective evidences especially from the local administration and officials reported that the media reporting deaths of children in Nandurbar which was very rampant earlier reduced drastically after the CMAM program matured on the field indicating a positive impact of the program on the field.

This large scale systems implemented CMAM program in the highly vulnerable district Nandurbar ,Maharashtra is first to establish that timely and effective CMAM services for children with uncomplicated SAM can be delivered through public programme and government systems (esp. ICDS and Health) for children in India using the existing infrastructure.



The trial clearly underlines the credibility of the existing Government system that can positively implement the community based management of acute malnutrition. The current systems if augmented with timely and quality skill based capacity building can effectively use standard global protocols in the facility and at the community. The trial clearly emphasised that prevention (focusing on care, nutrition-health-WASH counselling and ECD) and therapeutic interventions go hand-in-hand and when implemented in conjunction can impact the nutritional status of uncomplicated SAM children positively.

The trial findings indicate that centrally manufactured energy dense nutrient rich therapeutic food is superior to enriched home foods for the recovery of children with uncomplicated SAM. However, there was no clear difference in mortality between the three arms when it comes to death as an outcome findings. The trial also confirm that energy dense nutrient rich therapeutic foods (as per WHO formulation) can be safely used in CMAM programs using existing systems in Maharashtra and are effective in supporting weight-gain in children with uncomplicated SAM and is feasible to administer.



The duration of the trial with C-RUTF was increased from 8 weeks to 16 week as the most important predictor of recovery within eight weeks of treatment was anthropometry at admission. Children with poorer anthropometry at admission (MUAC < 110 mm or WHZ < -4) were 2-3 times less likely to recover within eight weeks of treatment despite the fact that they were gaining weight at a higher rate than children with better anthropometry at admission (MUAC \geq 115 mm or WHZ \geq -3). This provided opportunity for longer duration of counselling, home visits, micronutrient supplementation and other preventive approaches as well as provision of therapeutic foods till 16 weeks when compared with earlier 8 weeks regime. Longer duration also provided opportunities for improving longer follow-ups, establishing synergies with other programs, setting up linkage of NRC and CTC with CSAM, and improvements in monitoring and data quality. The trial was successful in reaching to the youngest children and especially younger girls who are more vulnerable.

However, it is important to note that while the treatment duration was increased from 8 weeks to 16 weeks; the extension period didn't include ARF and L-RUTF arm. Besides, the CMAM intervention, program supported in strengthening the existing health and ICDS infrastructure and massive screening drives (both active and passive), as a starting point for management of SAM among children, it also helped to identify the complication cases which were referred to the Nutrition Rehabilitation Centres (NRCs).



Our trial establishes that CMAM services for children with uncomplicated SAM can be delivered through public programme platforms for child health, nutrition and development in India. This is the first trial to document the effectiveness of ready-to-use therapeutic foods for the recovery of children with uncomplicated SAM in India. Our findings confirm that ready-to-use therapeutic food is superior to enriched home foods for the recovery of children with uncomplicated SAM.

To improve its population level impact on survival and recovery, we recommend that the CMAM programme give priority to the early detection and treatment of SAM in children 6-35 months old using MUAC < 115 mm as the admission criteria. In Nandurbar three-quarters of the admissions and all deaths concerned children aged 0-35 months. Global evidence indicates that when children with SAM are identified on the basis of both MUAC < 115 mm or WHZ < -3, the two populations of children identified by these two criteria do not overlap uniformly.



In most populations, children identified as severely wasted by MUAC will generally be at higher risk of death than those identified by WHZ. Thus, where resources are limited, it is preferable to screen by MUAC than by WHZ. Children admitted with MUAC < 115 mm must be discharged with MUAC \geq 125 mm. The use of appropriate ready-to-use therapeutic foods – in line with the composition recommended by WHO is key to ensure adequate weight gain and full recovery. Appropriate ready-to-use therapeutic foods produced from locally available ingredients are now manufactured in India as per international quality standards can be provided to children with SAM along with strong counselling on prevention of SAM.



key lessons

program implementation

- Energy Dense foods or Ready to Use Therapeutic foods can improve the recovery rates faster than other feeding protocols for children with SAM
- MUAC facilitates in identifying the youngest and the most vulnerable children with SAM who are at highest risk of deaths.
- CMAM program quality improves over the period of at least 2-3 years resulting in quality screening and timely referral and follow up.
- Ensuring prepositioning of supplies and logistics for effective implementation of CMAM.
- Establishment of robust data monitoring systems will contribute to better program outcomes

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key lessons

service delivery

- Convergence of Health and ICDS is key to the success for CMAM.
- Existing government platforms to be linked with CMAM for scale.
- Capacity building focusing on skills and counselling can enhance the capacities of the Health and ICDS workers to provide timely and quality care.
- CMAM contributes to improving the efficiency and credibility of the Service delivery.
- CMAM implemented at scale with quality can contribute to reduction in morbidity and mortality.



Mascots of Hope

key lessons

community

- Existing government systems can deliver timely and quality care for children with Severe Acute Malnutrition.
- Engaging local community youth as champions of change increases program ownership by the community.
- Involvement of district authorities and communities are core to quality implementation of CMAM.

