

Use of RUTF for Managing Severe Wasting /SAM: Key Concerns

This note has been developed to provide updated information on the issues/concerns related to Severe Acute Malnutrition /Severe wasting and its management with ready to use therapeutic foods (RUTF). Scientific evidence on the efficacy and related factors is shared with sources such as on cost, impact on life course, risks of contamination, risks of high sugars and replacement of breastmilk. Sustainability issues have been flagged in the end. We invite comments on this important public health intervention towards a more holistic approach that aims at reducing the number/percentage of children suffering from SAM . An issue that is there on the minds of policy makers, but unfortunately they get attracted to “quick fixes” rather than holistic approaches.

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Introduction

Childhood undernutrition is a deep rooted and multi-dimensional problem and requires matching action with a vision and objective to reduce the numbers resulting from mal-development over these years. The important ingredients for addressing this malady in a *sustainable* manner include food security; protecting, promoting and supporting breastfeeding and optimal complementary feeding; preventing early child bearing;ⁱ strengthening preventive and curative health systems, especially the capacity of frontline workers; enhancing literacy; and improving water supply and sanitation.ⁱⁱ

Despite this, there is a push for RUTF among the health sector for managing severe acute malnutrition. Some of the key concerns regarding this approach are discussed in this note.

1. **Scientific Evidence does not Support the use of RUTF:** Here is the most updated evidence on this subject:
 - a) **A Cochrane review (2013)** has concluded that data were inadequate to recommend the use of RUTF over a flour porridge-based treatment regime and either RUTF or flour porridge can be used to treat children at home depending on availability, affordability and practicality.ⁱⁱⁱ
 - b) **The Lancet series on maternal and child nutrition (2013)** reviewed interventions to treat SAM in community settings comparing ready-to-use therapeutic foods (RUTF) with standard care and identified no significant differences in mortality^{iv} in both the groups.
 - c) **The advantages, disadvantages and risks of ready-to-use food; Guest editor Ted Greiner(2014)^v**. This review concluded, "The introduction of RUTFs in the management of SAM has allowed health authorities to extend effective treatment beyond hospitals, i.e. in out-patient units or at home. As a consequence, the case fatality rates recorded in hospitals, usually less than 10%, can be achieved largely outside the hospital environment, thus greatly reducing cost and the burden on in-patient health care facilities, and allowing an increased coverage. This, however, is far from universal, and many cases, possibly the worst cases, are not yet reached by programmes. In addition, proof of the advantages of RUTFs over other products is weak. In addition, RUTFs have their downside. They are too expensive to be used for anything else besides treatment of SAM. Their provision depends often on short-term external funding for humanitarian or emergency programmes. They tend to be monopolized by a handful of manufacturers able to put in place strict quality control measures. Children treated with RUTFs require extra water; if clean water is not available, RUTF alone will not result in a healthy child. The product does not contribute to teaching the child to like the taste of the healthy local foods needed to avoid malnutrition in the future. Finally, they are only part of the solution: prevention and rehabilitation of SAM need much more than RUTFs. And SAM is only the tip of the malnutrition iceberg: 90% of malnutrition consists of forms other than SAM, and RUTFs are neither necessary nor appropriate in treating them."
 - d) **Efficacy of three feeding regimens for home-based management of children with uncomplicated severe acute malnutrition: a randomised trial in India (2016)^{vi,vii}**: This recently completed large,

multi-centric, robust efficacy trial' conducted at the instance of the Ministry of Health was essentially done to provide policy input. (Letter number P.13015/4/2008-Nut. & IDD sharing minutes of Expert group meeting). The results in Indian children with uncomplicated SAM, compared 3 groups, one, ready to use commercial therapeutic foods (RUTF), second, locally made ready to use therapeutic foods, (prepared locally using the same composition as in the first group), and third, home augmented foods(where the family was provided enough foods to prepare for the baby) , are published now.**Key findings of the trial are as under:**

- i. 1.1% of over 1, 00,000 screened children between 6 months and 5 years of age had severe acute malnutrition (SAM).
 - ii. After few weeks ver lowe recovery rates were found. The 'Data monitoring board for the study' recommended paid health workers for services to help feed the child 8 times/day. They also extend the treatment to 16 weeks rather than keep it 8 weeks. ***This means that severe acute malnutrition cannot be sufficiently countered in the field without supporting care-givers in practical ways.***
 - iii. The results also show that the differences between home augmented foods group and commercial RUTFgroup were not significant. The locally created ready to use therapeutic foodgroup (this being different from commercial RUTF only in texture) was little better as there was 57% recovery rate as compared to 43%. ***The trial suggests that the choice of dietary product is largely irrelevant for sustained recovery following community management of acute malnutrition.***
 - iv. ***The study further looked at what happens to children after you stop treatment. However, 16 weeks after the intervention, the overall proportion of children cured had dwindled to 15%.*** Thus, the data clearly shows that the overall impact in all three groups is low, with over 40% children remaining in SAM even after a prolonged period of intervention. Even these gains are temporary with cure rates declining to 15% after 4 months of stopping treatment.
- e) **Survival and Recovery in Severely Wasted Under-five Children Without Community Management of Acute Malnutrition Programme(2017)^{viii}** study has been published recently in the 'Indian Pediatrics' on "Survival and recovery in severe malnutrition ". It is done with the objective to evaluate recovery and survival of severely wasted children in two rural blocks of Uttar Pradesh. Out of 18463 children under five who were clinically examined; prevalence of severe wasting (weight height <-3Z) was found to be 2.2%. These 409 children with severe wasting were followed up for survival and repeat anthropometry. Parents and caregivers of severely wasted children were given appropriate nutrition counseling by the project staff and referred to nearest PHC. There was no special CMAM programme for these children. In this study on 409 children only 11 children died during 1 to 7.4 months follow up. This resulted in a low case fatality rate. In this study, 1.2% children died within one month of follow up and 2.7% within 7.4 months. The earlier perception is that these mortality rates are very high (30-50%).According to the authors, such perceptions of mortality risks of untreated severely wasted children have been drawn from studies that are 2 to 4 decades old. Among survivors, spontaneous recovery occurred with only 30% remaining severely wasted.

f) **Day-care management of children with severe malnutrition in an urban health clinic in Dhaka, Bangladesh (2007):**A study from Dhaka, Bangladesh was one of the first to highlight successful recovery of severely malnourished children treated at home with home cooked foods such as *khichuri* and *halwa*.^{ix}

g) **Evidence that has been used by the World Bank in their costing study on malnutrition, An Investment Framework for Nutrition^x.** It is estimated that an additional \$7 billion per year over the next ten years is needed to reach the global targets for stunting, anemia in women, and exclusive breastfeeding and to mitigate the impact of wasting. However the evidence that has been used by them to justify a focus on treatment of SAM children in order to save lives does not suggest so, and is interpreted differently.

The WB report cites, “WHO recommends outpatient treatment of children with uncomplicated severe acute malnutrition (85–90 percent of cases) using ready-to-use therapeutic food and a seven-day preventive course of antibiotics (WHO 2013). This treatment has been shown to reduce mortality and lead to recovery in about 80 percent of cases (Hossain et al. 2009; Khanum, Ashworth, and Huttly 1994, 1998; Lenters et al. 2013).”

Exploration of cited studies doesn't substantiate this statement. What can we say ?

Hossain MM, Hassan MQ, Rahman MH, Kabir AR, Hannan AH, Rahman AK. Hospital management of severely malnourished children: comparison of locally adapted protocol with WHO protocol. Indian Pediatr. 2009 Mar;46(3):213-7.

This is a Hospital based study (not a community treatment of SAM) and has a Small sample size (30 in each arm). It compares WHO protocol using F-75, F-100 AND ICMH protocol using food prepared (100 kcal/100 ml) from locally available ingredients like cow's milk, micronutrients etc. **Both protocols were equally effective.**

Lenters LM, Wazny K, Webb P, Ahmed T, Bhutta ZA. Treatment of severe and moderate acute malnutrition in low- and middle-income settings: a systematic review, meta-analysis and Delphi process. BMC Public Health. 2013;13Suppl 3:S23. doi: 10.1186/1471-2458-13-S3-S23. This is a systematic review and meta-analysis that in Conclusions: Gaps in our ability to estimate effectiveness of overall treatment approaches for SAM and MAM persist. In addition to further impact studies conducted in a wider range of settings, more high quality program evaluations need to be conducted and the results disseminated.

2. Government of India does not support the use of RUTF: In a recent response to NAPI on 18th August 2017 the Honorable Union Minister J P Nadda said that RUTF is a temporary solution and may not benefit a common household in developing appropriate food habits and as against home augmented foods. The Ministry of Women and Child Development has also issued a notification on 28th August 2017 to Principle Secretaries of all states that RUTF has no evidence in management of SAM and can replace best practices and family foods; therefore the states

have been asked to comply with Ministry of Health and Family Welfare's position of not using RUTF for management of SAM children.^{xi xii}

- 3. It is expensive to use RUTF and it diverts resources:** One study from West Africa has estimated the cost of CMAM using therapeutic food as approximately 150 Euro per child^{xiii}. Another study estimated the cost from use of RUTF at US \$70-200 per child cured which is very expensive and about half of which, is only for the product itself.^{xiv} For example, if 0.3 million <5 children in Odisha were to require RUTF, the total annual expense will be USD 60 Million or INR 390 Crore. There needs to be some strong scientific justification for such costs, especially since they are likely to divert funds away from the meager budgets for the existing nutrition programmes. *Prudent, cost-effective and sustainable strategies to address SAM should follow the holistic preventive route instead of diverting funds towards distributing nutrient-products with evanescent benefits for the mere tip of the iceberg.*
- 4. Risk of high fats and sugars:** RUTF produced by Valid Nutrition is a high energy, high fat and high-sugar product. A 92 gm. sachet of the product contains 500 calories, source of calories being fats 45-60%, sugar 28-45% and proteins 10-12%.^{xv} For an infant, such a high-energy, high fat, high sugar diet is not scientifically sound. WHO recommends that total dietary fat should not exceed 30% of total energy intake and intake of free sugars should be limited to less than 10% of total energy intake in children^{xvi}. In Rajasthan, RUTF has been used for community based management of SAM and it is manufactured in India but it carries the same amounts of sugar and fats^{xvii}. Ingredients composition given is Peanut (30%), Sugar (29%), Milk Solid (20%), Vegetable Oils (18%), Emulsifier (E471), Minerals, Vitamins, Antioxidant (E304, E306, E472c). There may be a risk of metabolic perturbations (adiposity and hypercholesterolemia) due to high fat content of RUTF, and harmful contents of sugar.
- 5. Potential Impact of RUTF use on life course health and nutrition:** A recent review article^{xviii} in 2017 has highlighted potential long-term health risks of RUTF use. Increased consumption of RUTF may cause result in permanent alteration of the epigenome and associated metabolic functions. Exposure of the young child to sweet and fatty single food, RUTF, may shape young children's taste preferences and could be detrimental to future preferences and eating habits.
- 6. Potential replacement of breastmilk in the diet:** Consumption of such a high-energy product by a child suffering with SAM would seriously compromise the intake of breastmilk, which is very important from immunological and nutritional point of view. This is important to note that between 6 – 23 months of age breastmilk provides a sizable proportion of energy, high quality protein and other nutrients and a breastfed child needs only 200 -500 extra calories from complementary sources.^{xix}
- 7. Risk of contamination:** Peanuts/groundnuts, a major ingredient of the RUTF, are at inherent risk of being contaminated with moulds like *Aspergillus flavus* and *Aspergillus parasiticus*, which produce cancer-causing chemicals Aflatoxin^{xx} and bacteria like *Salmonella* and *Enterobacteriaceae* which may cause life threatening illness in immune-compromised malnourished children.^{xxi}

8. Use of RUTF is not sustainable:The use of RUTFs does nothing to contribute to sustained nutritional rehabilitation. It defeats all the arguments of sustainability.

- Children fed a single treatment food are unlikely to develop a taste for normal, local, bio-diverse, nutritious family foods essential for their recovery and long-term rehabilitation.
- RUTF can quickly deposit fat in the body to distort the normal growth of the child and may be a reason for reported high relapse rates of SAM in various studies. Once the RUTF is stopped, the growth and development of these children are severely affected and faltered.

Providing food secure environment is necessary to retain benefits of any treatment of SAM. A study from India has reported a high default rate of 38% and with higher relapse and non-recovery from SAM in food insecure environment^{xxii}. These 38% enrolled children abandoned the programme before completing the treatment, suggesting poor acceptance of the treatment modality.

Conclusion

Preventive approaches are the hallmark of the NitiAayog's recently launched 3- year Action Agenda^{xxiii}; which states that "Over the course of next three years, the healthcare system in the country must prioritise public health and shift from being curative to preventive." Given this principle, using RUTF for treatment of SAM is a short -sighted approach to tackling child undernutrition. It is a potential risky approach to infant health and one that creates dependency. Instead of a one stop curative approach, focus should be on long term holistic measures that are preventive in nature, such as enough diverse food to eat for children, supporting women to breastfeed, safe water supply, and good health care made available for all children.

Therefore, to reduce the number of malnourished children requires a clear policy from the Government of India, one that includes sustainable strategies to address SAM.

ⁱFall CH, Sachdev HS, Osmond C, Restrepo-Mendez MC, Victora C, Martorell R, Stein AD, Sinha S, Tandon N, Adair L, Bas I, Norris S, Richter LM; COHORTS investigators. Association between maternal age at childbirth and child and adult outcomes in the offspring: a prospective study in five low-income and middle-income countries (COHORTS collaboration). *Lancet Glob Health*. 2015 Jul;3(7):e366-77.

ⁱⁱDangour AD, Watson L, Cumming O, Boisson S, Che Y, Velleman Y, Cavill S, Allen E, Uauy R. Interventions to improve water quality and supply, sanitation and hygiene practices, and their effects on the nutritional status of children. *Cochrane Database Syst Rev*. 2013 Aug 1;8:CD009382. doi:10.1002/14651858.CD009382.pub2.

ⁱⁱⁱSchoonees A, Lombard M, Musekiwa A et al. Ready-to-use therapeutic food for home- based treatment of severe acute malnutrition in children from six months to five years of age. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD009000. DOI: 10.1002/14651858.CD009000.pub2 <https://www.ncbi.nlm.nih.gov/labs/articles/23744450/>

^{iv}Bhutta ZA, Das JK, Rizvi A, Gaffey MF, Walker N, Horton S, Webb P, Lartey A, Black RE; Lancet Nutrition Interventions Review Group.; Maternal and Child Nutrition Study Group.. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? *Lancet*. 2013 Aug 3;382(9890):452-77.

^v<http://ibfan.org/breastfeedingbreafs/BB%2056-57-The%20advantages-disadvantages-and-risks-of-ready-to-use%20foods.pdf> (accessed May 9, 2017)

^{vi}<http://gh.bmj.com/content/1/4/e000144>

^{vii}<http://gh.bmj.com/content/1/4/e000144.e-letters>

^{viii} [http://napiindia.in/docs/SAM-Survival-\(3\).pdf](http://napiindia.in/docs/SAM-Survival-(3).pdf)

^{ix}Ashraf H, Ahmed T, Hossain MI, Alam NH, Mahmud R, Kamal SM, Salam MA, Fuchs GJ. Day-care management of children with severe malnutrition in an urban health clinic in Dhaka, Bangladesh. *J Trop Pediatr*. 2007 Jun;53(3):171-8.

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- ^x<https://openknowledge.worldbank.org/handle/10986/26069>
- ^{xi} <http://www.wcd.nic.in/sites/default/files/RUTF.PDF>
- ^{xii} <http://napiindia.in/docs/JP-Nadda's-response-on-RUTF.pdf>
- ^{xiii} Isanaka S, Menzies NA, Sayyad J, Ayoola M, Grais RF, Doyon S. Cost analysis of the treatment of severe acute malnutrition in West Africa. *Matern Child Nutr.* 2016 Dec 5.
- ^{xiv} Emergency Nutrition Network (ENN). Managing acute malnutrition at scale: A review of donor and government financing arrangements. In: Coverage Monitoring Network. What do we know now: A decade of community based treatment of SAM. Conference Report 17-18 Oct 2013, page 7.
- ^{xv} http://www.validnutrition.org/wp-content/uploads/2015/09/Valid_Nutrition_Fact_Sheet-final-300915.pdf
- ^{xvi} WHO. Guidelines: Sugar intake for adults and children. See: http://apps.who.int/iris/bitstream/10665/149782/1/9789241549028_eng.pdf
- ^{xvii} <http://nrhmrajasthan.nic.in/POSHAN.asp>
- ^{xviii} Bazzano AN, Potts KS, Bazzano LA, Mason JB. The Life Course Implications of Ready to Use Therapeutic Food for Children in Low-Income Countries. *Int J Environ Res Public Health.* 2017 Apr 11;14(4) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409604/>
- ^{xix} http://www.fao.org/fao-who-codexalimentarius/sh-proxy/zh/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-37%252FCRD%252FCRD_08.pdf
- ^{xx} <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/aflatoxins>
- ^{xxi} https://www.unicef.org/supply/files/Ready-to-use_Therapeutic_Food_Current_Outlook.pdf
- ^{xxii} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4381773/>
- ^{xxiii} <http://niti.gov.in/writereaddata/files/coop/ActionPlan.pdf>