

NUTRITION ADVOCACY IN PUBLIC INTEREST-India (NAP*i*)

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October 24, 2019

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Email Id- pksinha.pmo@gov.in

Sub: Severe Malnutrition Regarding

Dear Mr. Sinha

We write to you as you are overseeing policy issues and matters relating to all ministries/departments/agencies/bodies.

We are part of a national think tank on nutrition, the Nutrition Advocacy in Public Interest in India (NAP*i*). It consists of independent experts in epidemiology, human nutrition, community nutrition and pediatrics, medical education, social work, communication, administration and management. We have decades of experience in respective fields and have come together to advocate on nutrition policy in public interest since 2015.

We understand that the Government of India is going to soon finalise the guidelines for the management of severe acute malnutrition (SAM), which is a good step indeed.

We are pleased to submit our "Position Statement on Managing Severe Acute Malnutrition/ Severe Wasting" for your kind perusal and consideration for inputs into the new policy. This statement is based on contextual scientific evidence during the past decade. Several people including medical, public health, public policy, academic, economics, legal, research, and administrative experts have endorsed the statement. (List Annexed)

We conclude in the Statement:

"A broad approach is required as the focus on RUTF diverts the attention from real prevention solutions and food. This will be prudent to focus on implementation of known health and nutrition interventions for pregnant women and children 0-2 years to prevent the SAM. Long-term holistic measures those are preventive in nature, such as, optimal maternal nutrition during pregnancy, supporting women to practice optimal breastfeeding,

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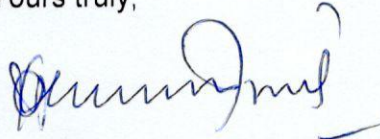
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enough diverse food to eat for children after 6 months of age, safe water supply, and good health care is made available for all children. Children with SAM should receive comprehensive care, which includes supervised feeding using local foods with focus on protein-sufficiency and calorie- density. Therefore, to reduce the number of malnourished children requires a clear policy and plan from the Government of India, one that includes sustainable strategies to reduce the burden of the SAM".

We request your kind attention. Should you require us to brief you, our team shall be happy to do so.

We look forward to a positive response from you,

Yours truly,



Dr. Arun Gupta MD
On behalf Nutrition Advocacy in Public Interest (NAP*i*)

Copy for information and necessary action

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- Dr. Vinod Paul, Member, NITI Aayog.
- Shri Ratan P. Watal, Member Secretary EAC-PM
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October 2019

Position Statement on Managing Severe Acute Malnutrition/Severe Wasting

Nutrition Advocacy in Public Interest (NAPI) has developed this statement to provide updated information on the key issues/concerns related to Severe Acute Malnutrition /Severe wasting, its contribution to child mortality and its prevention and management with ready to use therapeutic foods (RUTF). Scientific evidence on the efficacy of RUTF 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 also been flagged. We believe that a more holistic preventive and curative strategy that aims at reducing the prevalence of children suffering from SAM should be adopted. The focus is needed on a 'care model' that includes prevention, treatment of infections, and food, rather than "quick fixes" for treating it.

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A national think tank on nutrition –consisting of independent experts in epidemiology, human nutrition, community nutrition and pediatrics, medical education, administration and management; having decades of experience in respective fields; has come together to advocate on nutrition policy in public interest.

Position Statement on Managing Severe Acute Malnutrition/Severe Wasting

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 maldevelopment 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' in both the groups.^{iv}
- 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 very low 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 RUTF group were not significant. The locally created ready to use therapeutic food group (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 counselling 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) **Cochrane review 2019^x.** The review has been published in May 2019. Its key findings are “Compared to alternative dietary approaches, standard RUTF probably improves recovery (moderate-quality evidence) and may increase the rate of weight gain slightly (low-quality evidence), but the effects on relapse and death are unknown (very low-quality evidence). With ‘quality of evidence’ we mean how confident we are that the particular finding represents the true effect. For example, ‘very low quality’ means we are very uncertain about the finding, ‘low-quality evidence’ means the future research is very likely to change the finding, ‘moderate-quality evidence’ means that future studies may change this finding, and ‘high-quality evidence’ means that it is unlikely that future studies will change the finding.” Authors go on to recommend “well-designed, randomised controlled trials (experimental studies where participants meeting the inclusion criteria have an equal chance of being allocated to any of the intervention or control groups) in which analyses have been performed separately for children with and without HIV, and that also measure and report on diarrhoea occurrence, are needed.”
- h) A recent Indian study^{xi} conducted by the business organisation FICCI has compared RUTF with pre-cooked and packed foods to treat SAM children. The study has many limitations, which may require careful attention before using its findings to support use of RUTF in the management of SAM. The study duration was only for 8 weeks and the patients were not followed up. This is not possible to know the proportion of SAM children sustaining the gains achieved during the intervention. Secondly, The number of participants was small, and this question warrants a larger prospective study. Thirdly, the RUTF preparation contained 53 gram Sugar per 100-gram product. This is an unhealthy product according to WHO standards of sugar contents in the foods. High sugar also explains the high acceptability of these products. The study authors have an explicit conflict of interest as they received financial support from the Nuflower Food Private Limited, manufacturer of the RUTF product used in this study. It is intriguing to note that authors took ‘ethical clearance’ for the study from FSSAI. Authors say, “Regarding the use of nutreal as a nutrient energy paste for the management of SAM, the ethical clearance was taken from Food Safety and Standards Authority of India

(FSSAI) Ministry of Health and Family Welfare, Government of India.” The study has reported a mean weight gain in both the groups, namely, RUTF group and Defined foods group and concluded that weight gain is more in the RUTF group. However, the comparison in weight gain should have been done g/kg/d as children included in the study were of a wide age group (8 months–45 months) and each child’s caloric and nutritional requirements and intake may have been different.

- i) A cohort study from India published in October 2019 has looked into mortality and recovery following moderate and severe acute malnutrition in more than 2800 children aged 6-18 months in rural Jharkhand and Odisha.^{xii} The study found that SAM carried a lower case fatality rate (1.2%) than expected from WHO estimates of 10%–20%. The study concluded that “.....in India, high rates of acute malnutrition in children over 6 months old are accompanied by lower case fatality rates than those reported in older, largely African studies.”

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 Principal 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.^{xixiv}

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^{xv}. 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.^{xvi} 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 in RUTF: 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%.^{xvii} 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^{xviii}. 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.^{xix} 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^{xxi} 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.^{xxi}
7. **Risk of contamination in RUTF:** 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^{xxii} and bacteria like *Salmonella* and *Enterobacteriaceae* which may cause life threatening illness in immune-compromised malnourished children.^{xxiii}
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.
 - a) 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.
 - b) 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.
 - c) 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^{xxiv}. These 38% enrolled children abandoned the programme before completing the treatment, suggesting poor acceptance of the treatment modality.
 - d) **Care, nutrition and health interventions:** An observational longitudinal study from the tribal area of India looked into effect of a comprehensive package of care, nutrition and health interventions on the nutritional status of children < 3 years. Children received day-care by trained local women, comprehensive early childhood care development; supervised feeding using local foods with inputs for protein-sufficiency

and calorie- density (Eggs, Adapted SAT mix / Nutrimix / Sattu; 70% caloric requirement and 15 g of protein per day), building capacities of family and community for behaviour change through participatory learning and action(PLA), growth monitoring and early community-level action triggered by growth faltering, promotion and prevention, focus on hand- washing, hygiene, safe water, oral rehydration salt (ORS) solution for treatment of diarrhea, smoke-free environment, referral to NRC (as per government protocols) and PHC. The study documented good improvement in the WHZ category of SAM children with this comprehensive approach.^{xxv}

Conclusion

The available scientific evidence, which includes a cohort study from India in 2019, states that mortality from SAM is not very high as it was assumed to be, spontaneous recovery also occurs in the absence of CMAM programme, recovery rate is low after treatment with RUTF is stopped, choice of a particular product is irrelevant to recovery, and India has under nutrition that is far more chronic than acute. Evidence to use RUTF against home-based foods is not sufficient and persuasive. Use of RUTF has potential risks associated like high sugar and fat content with long-term use. Giving RUTF is an expensive strategy, as it may cost equivalent to entire PoshanAbhiyan budget or 1/4th of NHM^{xxvi}.

A broad approach is required as the focus on RUTF diverts the attention from real prevention solutions and food. This will be prudent to focus on implementation of known health and nutrition interventions for pregnant women and children 0-2 years to prevent the SAM. Long-term holistic measures those are preventive in nature, such as, optimal maternal nutrition during pregnancy, supporting women to practice optimal breastfeeding, enough diverse food to eat for children after 6 months of age, safe water supply, and good health care be made available for all children. Children with SAM should receive comprehensive care, which includes supervised feeding using local foods with focus on protein-sufficiency and calorie-density. Therefore, to reduce the number of malnourished children requires a clear policy and plan from the Government of India, one that includes sustainable strategies to reduce the burden of the SAM.

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