

## **Consensus Statement: National Consensus Workshop on Management of SAM Children through Medical Nutrition Therapy**

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**Justification:** Severe acute malnutrition (SAM) is an important preventable and treatable cause of morbidity and mortality in children below five years of age in India. The concerned stakeholders are not in agreement about the role of product based medical nutrition therapy in the management of this condition.

**Process:** In November 2009, a National Consensus Workshop was organized by the Department of Human Nutrition, All India Institute of Medical Sciences, New Delhi in collaboration with the Department of Pediatrics and Clinical Epidemiology, Sitaram Bhartia Institute of Science and Research, New Delhi, and the Sub-specialty Chapter on Nutrition, Indian Academy of Pediatrics. Presentations by eminent national and international scientists, the ensuing discussions, and opinions expressed by the participants provided the basic framework for drafting the consensus statement. The draft of the consensus statement was circulated to all the participants; it underwent two revisions after consideration of their comments.

**Objectives:** (i) Critically appraise the current global evidence on the utility of “Medical Nutrition Therapy” (MNT) for the management of SAM in under five children; (ii) Formulate a consensus amongst stakeholders regarding the need to introduce product based MNT for the management of SAM in under five children in India; (iii) Identify research priorities for MNT for the management of SAM in under five children in India; and (iv) Ascertain potential challenges for introducing product based MNT in India, if consensus opinion identifies such a need.

**Recommendations:** Guidelines related to the role of MNT in management of children suffering from SAM are presented. Global and regional data document the effectiveness of MNT using ready-to-use therapeutic foods (RUTF) and locally formulated products. Adequate caution should be exercised to ensure that MNT for SAM does not interfere with measures for the holistic prevention of childhood undernutrition. Indian manufacture of RUTF is feasible, and can be scaled up. Product-based nutrition therapy including RUTF can be introduced on a pilot basis when a delivery design and plan of action is developed and is in place as a part of the larger system to deal with childhood undernutrition. RUTF should be used only as therapeutic and not supplementary feeding, above six months of age, and for a limited time period (4-8 weeks) until the child recovers from SAM, which should be defined in explicit treatment protocols. An urgent research issue is comparison of RUTF with home-based and locally-formulated products.

**Keywords:** *Child malnutrition, Nutrition therapy, Ready-to-use therapeutic foods.*

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**S**evere acute malnutrition (SAM) is an important preventable and treatable cause of morbidity and mortality in children below five years of age in India. The concerned stakeholders are not in agreement about the role of product based medical nutrition therapy in management of children suffering from this condition. In an attempt to resolve this disagreement, the Department of Human Nutrition, All India

Institute of Medical Sciences, New Delhi in collaboration with the Department of Pediatrics and Clinical Epidemiology, Sitaram Bhartia Institute of Science and Research, New Delhi, and the Sub-specialty Chapter on Nutrition, Indian Academy of Pediatrics, organized a National Consensus Workshop on Management of SAM Children through Medical Nutrition Therapy. This Workshop was funded by the Department of Biotechnology,

Government of India and the Indian Council of Medical Research, Government of India. The Workshop was held from November 26 to 27, 2009 at the All India Institute of Medical Sciences, New Delhi with the following objectives: (i) critically appraise the current global evidence on the utility of “Medical Nutrition Therapy” (MNT) for the management of Severe Acute Malnutrition (SAM) in under five children; (ii) formulate a consensus amongst stakeholders regarding the need to introduce product based “Medical Nutrition Therapy” for the management of Severe Acute Malnutrition in under five children in India; (iii) identify research priorities for “Medical Nutrition Therapy” for the management of Severe Acute Malnutrition in under five children in India; and (iv) ascertain potential challenges for introducing product based “Medical Nutrition Therapy” in India, if consensus opinion identifies such a need.

The invited participants are listed in the **Appendix**. Eminent national and international scientists were requested to prepare evidence based state of the art presentations on relevant issues identified by the Organizing Committee. These presentations, the ensuing discussions, and opinions expressed by the participants provided the basic input for drafting the consensus statement. The first draft of the consensus statement was circulated to all the participants for their comments. A second draft was developed after receiving their comments. The second draft was again circulated for comments to all participants. Following this, the finalized third version of the consensus statement was developed, which was approved by the majority of the participants.<sup>1</sup>

#### CONSENSUS STATEMENT

- In India, 8.1 million children are estimated to suffer from severe acute malnutrition (SAM).<sup>2</sup> In a nation marching ahead on the economic front, the magnitude and serious consequences of SAM among children makes it unethical not to urgently initiate measures to prevent and treat SAM. Protecting lives and promoting optimum

<sup>1</sup> Dr Arun Gupta participated in the workshop. He provided inputs till the second draft stage but did not want to be listed as a signatory for the finalized third version of the Consensus Statement.

development of SAM children is also a human rights issue.

- Up to 15% under-5 children with SAM require inpatient management because of medical complications. The remaining 85% (without medical complications) can be managed through a community- and/or home-based care approach.
- There is an urgent need to update both facility- and home-based care recommendations for the management of SAM among children in India, on the basis of latest evidence.
- Medical Nutrition Therapy (MNT) is only a component of the entire process of managing SAM children and being a time-limited therapeutic intervention, it should not be viewed as being in conflict with the objective and accepted process of attaining food and nutrition security or promoting appropriate Infant and Young Child Feeding (IYCF) practices for children with or without SAM. However, adequate caution should be exercised to ensure that MNT for SAM does not interfere with measures for the holistic prevention of childhood undernutrition.
- Ready to Use Therapeutic Food (RUTF) as per WHO and UNICEF specifications<sup>3</sup> is a Medical Nutrition Therapy based on sound scientific principles with a balanced composition of type I and type II nutrients. Apart from anthropometric recovery, RUTF results in physiological and

<sup>2</sup> The World Health Organization (WHO) and United Nations Children’s Fund proposed diagnostic criteria for severe acute malnutrition in children aged 6 to 60 months are weight for height below -3 SD (based on 2006 WHO reference) and/or presence of bipedal edema or mid upper arm circumference below 115 mm (WHO Child Growth Standards and the Identification of Severe Acute Malnutrition in Infants and Children. A Joint Statement by the World Health Organization and the United Nations Children’s Fund, 2009). The Indian Academy of Pediatrics recommended diagnostic criteria (2007), adapted from the earlier WHO guidelines, are weight for height/length below 70% or  $\leq 3SD$  of NCHS median and/or visible severe wasting and/or bipedal edema; mid upper arm circumference criteria may also be used for identifying severe wasting (Bhatnagar S, Lodha R, Choudhury P, Sachdev HPS, Shah N, Narayan S, Wadhwa N, Makhija P, Kunnekel K, Ugra D. IAP Guidelines on Hospital Based Management of Severely Malnourished Children [adapted from WHO guidelines]. *Indian Pediatr* 2007; 44: 443-61).

functional (including immunological) recovery. It has a specific composition which has been tested and proved effective in functional recovery of SAM children. RUTF should not be confused with ready to use food (RTUF) or any other products or preparations.

- Global evidence, primarily from Africa, indicates that RUTF-based nutrition therapy is effective for facility- and home-based management of SAM children who do not have medical complications, and can be scaled up for community or home-based management for children over six months of age.
- Pilot experience from India (Bihar and Madhya Pradesh) suggests that RUTF is effective for nutritional therapy of SAM children and can also be scaled up. Similar experience from Maharashtra has been reported with other locally formulated products. Other models from West Bengal and Gujarat, on a smaller scale, have also showed similar weight gains with locally formulated products. There is a suggestion from observational data in Madhya Pradesh that RUTF may be superior to standard treatment with F-100 and IAP formulations. However, there is no head to head comparison of effectiveness of RUTF with locally formulated products. Further, all of these experiences from India relate to weight gain and not to height gain or physiological or functional recovery.
- A qualitative study undertaken in mid 2009 from six states of India suggests that against the backdrop of fragile food security and faulty feeding practices, mothers who are time constrained tend to reach out to market foods to feed their children, which may be of sub-optimal nutrition quality. Further, the families do not recognize the signs of undernutrition until children develop severe malnutrition and medical complications.
- Considerable sensitivities exist regarding the possibility of commercial exploitation of undernutrition through aggressive marketing and supply of international product-based nutrition therapy and erosion of: (i) exclusive breastfeeding during the first six months of life, and (ii) continued breastfeeding between 6 and 24 months of life. Further, any action has to be in consonance with the Infant Milk Substitutes Feeding Bottles, and Infant Foods (Regulation of Production, Supply and Distribution) Act 1992 as amended in 2003 (IMS Act) (<http://www.bpni.org/documents/IMS-act.pdf>) and the Supreme Court orders on the Right to Food Act ([www.righttofoodindia.org](http://www.righttofoodindia.org) and [www.sccommissioners.org](http://www.sccommissioners.org)).
- Indian manufacture of RUTF is feasible, can be scaled up and even industrial production for export has been started by at least a couple of units. The fear of commercialization can be obviated by following principles of: (i) non-proprietary product; (ii) partially decentralized manufacture with public sector involvement; (iii) public health system being the sole procurement agency with a specific strategy that ensures purchase from multiple producers; and (iv) prescribed product, which is not freely available.
- Product-based nutrition therapy including RUTF can be introduced on a pilot basis at scale (district or state level) utilizing existing systems for sustainability. The pilot project should be introduced when a delivery design and plan of action is developed and is in place as a part of the larger system to deal with childhood undernutrition. RUTF should be used only:
  - As therapeutic and not supplementary feeding
  - Above six months of age
  - For a limited time period (4-8 weeks) until the child recovers from SAM, which should be defined in explicit treatment protocols
- MNT could be operationalized by the Health Ministry through the Integrated Management of Newborn and Childhood Illnesses (IMNCI)

<sup>3</sup>Community-based management of severe acute malnutrition. A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007. ISBN 978-92-806-4147-9. Accessed on January 16, 2010 from <http://www.unicef.org/search/search.php?querystring=Management+of+Severe+Acute+Malnutrition&hits=&isNews=>

module, which also has a component for the management of SAM. The Integrated Child Development Services (ICDS) system could converge for the identification and referral of children with SAM and the follow up of these children after their discharge from therapeutic feeding.

- To aid the evaluation process in an observational manner, outcome measures should be recorded after some time of operationalization of intervention program and include follow-up of rehabilitated children.
- Regulatory issues would need to be resolved between the two nodal authorities (Drug Controller General of India and Food Safety and Standards Authority of India) before MNT can be operationalized. The feasibility of manufacturing, regulation and registration as a food and use and distribution as a drug should be explored.
- Food and nutrition security and preventive aspects should be ensured during treatment for and after recovery from SAM to prevent relapses.
- Urgent research issues include:
  - Comparison of RUTF with home-based and locally-formulated products
  - Physiological recovery and longer benefits of the above treatments
  - Effect of introduction of RUTF on breast feeding
  - Operationalization and economic analysis in different settings

*Contributors:* HPSS, UK and SV were the designated writing committee members for this workshop. HPSS composed the first draft of this statement, which after input from UK and SV was circulated to all the participants. A similar process was followed for the second and final drafts for circulation to all participants.

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*Competing interests:* None stated.

## Appendix

### List of Invited Participants

Agarwal Vandana, *Nutrition Specialist, UNICEF*; \*Agarwal KN, *Ex-Professor of Pediatrics, New Delhi*; Agnani Manohar, *Commissioner Health, Madhya Pradesh*; Aguayo Victor, *Chief, Child Nutrition & Development, UNICEF*; Aiyer Sheila, *Govt. Medical College, Baroda*; \*Anand VK, *WHO, New Delhi*; Arora Narendra, *Executive Director, INCLEN, New Delhi*; \*Arora Mahesh, *Director, Ministry of Women and Child Health, New Delhi*; Ayoya Mohamed Ag, *Nutrition Specialist, UNICEF*; \*Bagchi Kunal, *Advisor, WHO SEAR, New Delhi*; \*Banapurmath CR, *Professor of Pediatrics, Davangere*; Bavdekar Sandeep, *Professor of Paediatrics, GS Medical Collge, Mumbai*; Bhan MK, *Secretary, Department of Biotechnology; New Delhi*; Bhandari Nita, *Joint Director, Society for Applied Studies, New Delhi*; Bhatnagar Shinjini, *Senior Research Scientist, AIIMS, New Delhi*; Bose Anuradha, *Professor, Department of Pediatrics, CMC, Vellore*; Briend André, *Former Medical Officer, World Health Organization*, \*Chakravarty Indira, *Member, Food Safety and Standards Authority, Govt. of India*; Chandola Tamsunaro Rongsen, *Senior Scientist, Society for Applied Studies, New Delhi*; Chaudhary Nidhi, *National Professional Officer, WHO, New Delhi*; \*Chellani Harish, *Pediatrician, Safdarjung Hospital, New Delhi*; Choudhury Panna, *Consultant Pediatrician, New Delhi*; Collins Steve, *Director, Valid International, Oxford*; Dalwai Samir, *Consulting Paediatrician, Mumbai*; Doyon Stéphane, *Nutrition - Access Campaign (CAME), Médecins Sans Frontières*; Dubey AP, *President, IAP- Sub-Specialty Chapter on Nutrition, New Delhi*; Gera Tarun, *Pediatrician, New Delhi*; Gite Naresh, *Director(Monitoring), Government of Maharashtra*; Golden Mike, *Emeritus Prof. of Pediatrics, Ireland*; Gupta Arun, *Regional Co-ordinator, IBFAN Asia, New Delhi*; \*Gupta Piyush, *Editor-in-chief, Indian Pediatrics, New Delhi*; Hariprasad Deepali, *Sr. Program Officer, Maternal & Child Health/Nutrition, New Delhi*; Heldal Jan Are, *Technical Advisor, Compact AS, Norway*; Jarrett Stephen, *Principal Adviser, UNICEF, New York*; Kapil Umesh, *Professor, Department of*

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*the Commissioner to the Supreme Court, New Delhi; Patwari Ashok K, MCH- STAR Initiative, New Delhi; Prakash V, Director, Central Food Technological Research Institute, Mysore; \*Prakash Vijoy, Principal Secretary, Rural Development, Patna, Bihar; Raj Kamal, Nutrition Specialist, UNICEF-India, New Delhi; Ramji Siddarth, Professor of Pediatrics, New Delhi; Rasaily Reeta, Deputy Director General, ICMR, New Delhi; Roy D, Deputy Drugs Controller (India), New Delhi; Sachdev HPS, Senior Consultant Pediatrics, New Delhi; \*Sethi NK, Senior Advisor (Health), Planning Commission, India; Shah Dheeraj, University College of Medical Sciences, Delhi; Shreeranjana, Joint Secretary Ministry of Women and Child Development, Government of India, New Delhi; Srivastava RK; Director General Health Services, New Delhi; Tamamura Mihoko, Country Director and Representative, UN-World Food Programme, New Delhi; Tandon Rajiv, Chief-MCH, USAID, New Delhi; \*Tiwari BK, Advisor (Food and Nutrition), DGHS, New Delhi; Toteja GS, ICMR, New Delhi; Vir Sheila, Public Nutrition and Development Center, New Delhi; Yadav Birendra Prasad, District Magistrate, Madhepura; and \*Yunus Shariqua, World Food Program, New Delhi.*

*\*could not participate.*