Wasting Reset

Wasting prevention, early detection and treatment to catalyse action and accountability



5 Nutritional products

Solutions from the products for treating wasting working group

August 2021









considered priorities:



Stock medical facilities of all kinds with the supplies needed to treat according to national priorities and protocols – children and pregnant and lactating women (PLW) affected by wasting. Improving the availability of wasting products at country level can be achieved through increased domestic resource allocation for wasting products, including key commodities in national essential medicines/commodities lists, strengthening supply chains, and increasing and improving local production capacity where it can improve product availability.



Improve the cost-effectiveness of wasting product production and programmes through the development, scale-up and use of new, more costeffective ready-to-use food (RUF) formulations, improving the visibility of demand for suppliers, as well as the efficiency of quality testing and price adjustment. The adoption of simplified programmes that treat wasting, with dosage tailored to risk, will also support this change.



Strengthen the supply chain management of wasting products, particularly over the 'last mile', through integrating (including capacity-building actions) the procurement, distribution and general management of wasting products into national supply chain systems where appropriate, and developing mechanisms to better understand pipeline breaks and stockouts.



Fill knowledge and guidance gaps, particularly on the effectiveness of products for PLW, and on the dietary treatment of moderate wasting.

Background

Wasting products, such as therapeutic milks, RUFs and specific fortified blended foods (FBFs) (e.g. Supercereal Plus and BP-100), are the cornerstone of dietary treatment for wasting, both for children and PLW.

The influential Lancet Nutrition series in 2013 presented the treatment of uncomplicated severe wasting with ready-to-use therapeutic food (RUTF), in the context of community-based management of acute malnutrition (CMAM), as an evidence-based and cost-effective targeted intervention that could considerably reduce child mortality globally if scaled up appropriately with adequate investment.^{1,2}

In 2020 about 5 million children with severe wasting were treated worldwide, which means that only one out of

three children in need had access to treatment (UNICEF Nutridash data, 2020). This is a missed opportunity to reduce the large burden of mortality and morbidity linked to wasting and to increase the economic potential of individuals, communities and countries.3 While the burden of moderate wasting is higher, and 6 million children with moderate wasting were treated in 2020, the coverage of treatment is considerably lower. This is because of the lack of guidance, the scale of the problem relative to funding and operational logistics, and the heterogeneity of risk within this group of children. Balanced-energy protein supplementation in pregnancy for undernourished women has also been recognised as an evidence-based intervention to improve birth outcomes and reduce the risk of wasting in infants.4 Coverage of this intervention is also low.

Progress and achievements

1. Market maturity of wasting treatments has led to significant cost reductions

The cost of standard peanut RUTF has decreased by around 28% in the last 12 years. There is a general consensus among key stakeholders and producers that this cost has now 'bottomed out' and that further reductions in the cost of treatment could only come about through:

- reducing the amount of product needed to treat wasting
- the scale-up of new formulations and other/ alternative delivery strategies
- the easing of taxation levies on raw materials used in RUF production by national governments
- improving financing and supply chain efficiencies.

2. Local supply now dominates the market, enabling more timely access to treatments

Great effort has been made by several suppliers to produce RUFs in countries where demand is high. Global production capacity now exceeds the global funded demand,⁵ and UNICEF, WFP, USAID, MSF and others now procure RUFs from 19 different suppliers, of which 16 are located in countries with high levels of wasting. Eight of these are part of Nutriset's PlumpyField® franchise. While the procurement cost, in most cases, is not reduced, there can be other advantages of local production, linked to incentivising domestic resource mobilisation, reducing the costs of transport and lead times, and supporting more timely

¹ Black, R. E., Victora, C. G., Walker, S. P., Bhutta, Z. A., Christian, P., De Onis, M., Ezzati, M. et al. (2013). Maternal and child undernutrition and overweight in low-income and middle-income countries. *The Lancet*, 382(9890), 427–451.

WHO/WFP/UNSCN/UNICEF (2007). 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. https://www.who.int/maternal_child_adolescent/documents/a91065/en/

³ See financing brief.

⁴ Keats, E.C., Salam, R.A., Lassi, Z.S., Imdad, A., Black, R. and Bhutta, Z.A. (2021). Effective interventions to address maternal and child malnutrition: an update of the evidence. *Lancet Child Adolesc Health*, online.

UNICEF (2021). Ready-to-use Therapeutic Food: Market Outlook. UNICEF Supply Division. Retrieved from: https://www.unicef.org/supply/reports/ready-use-therapeutic-food-rutf-market-outlook

...ready-to-use
therapeutic food (RUTF)
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access to supplies for the treatment of wasting.⁶ Tax exemptions on raw materials import duties and VAT taxes for local producers in some countries (e.g. Pakistan) make local production competitive with imported/exempted products.

Long-term agreements given to suppliers by some of the main procuring agencies work well. They give visibility in terms of demand, support the ability to get bank financing, maximise the efficiency of procurement of raw materials and of product production, and ultimately help to enable the lowest cost and the shortest lead times for customers.

3. Enhanced product normative guidance has improved global quality standards and compliance

The Supply Division of UNICEF, USAID, MSF and others are now working within the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to develop a guideline for RUTF. This is due to be ratified by summer 2022. Enshrining RUTF within Codex will provide official, harmonised specifications and enable governments to create their own guidance to safeguard the quality of both imported and locally produced RUTF. The specifications contained with the Codex guidance are an important prerequisite for inclusion in national essential medicines lists (EMLs).

Strengthened information-sharing by public and competitive tender processes; market notes; pre-tender consultations and supply meetings; publication of prices; validated suppliers and awarded contracts enhance the market transparency and help to influence price competitiveness. Harmonised quality standards of common facilities used by several agencies, and the

opportunity to provide feedback on procurement specifications by the main procuring agencies/governments, support high-quality product standards across the supplier base and also build capacity when national regulatory authorities are engaged.

The updating of quality assurance and specification requirements to focus on major microbial risks in 2013 has been described as a 'turning point' in awareness regarding the food safety of RUFs. Some of the larger producers have made significant investments in the manufacturing process, including raw materials sourcing, as well as heat-treatment processes to ensure products are free from pathogenic bacteria. This remains the focus of much of the testing effort.

4. Initiation of product innovation could lead to improved treatment coverage and further cost efficiencies

Considerable optimism and effort currently surround the reformulation of RUFs to reduce their cost. There are several alternative formulations at different stages of testing that could reduce the costs of RUTF by between 3% and 11%. Some of these formulations replace the milk powder (the most expensive ingredient of RUTF) with alternative protein sources, while others replace the peanut ingredient with cheaper/more readily and locally available cereals and pulses. Several suppliers have piloted the production and have investigated the acceptability of alternative formulations and are now awaiting guidance on the evidence needed to operationalise them. There are some alternative formulations for ready-to-use supplementary food (RUSF) that are already in use.

Funding seems readily available for research focused on answering specific questions about product efficacy, cost-effectiveness, and programmatic feasibility, and the quality (rigour and relevance) of studies in this space is generally high.

The development of ready-to-use products for moderate wasting has been convenient in high-burden and humanitarian contexts, and lipid-based nutrient supplements, such as RUSF, are thought to be slightly more effective (a 5% increase in recovery rate) as a treatment than fortified blended foods, such as CSB++.^{7,8}

⁶ Mates, E. & Sadler, K. (2020). ENN RUTF Scoping study. https://www.ennonline.net/rutfscopingstudy

Gluning, I., Kerac, M., Bailey, J., Bander, A. and Opondo, C. (2021). The management of Moderate Acute Malnutrition (MAM) in children aged 6-59 months: A systematic review and meta-analysis. *medRxiv*. Jan 1.

⁸ Lelijveld, N., Beedle, A., Farhikhtah, A., Elrayah, E.E., Bourdaire, J. and Aburto, N. (2020). Systematic review of the treatment of moderate acute malnutrition using food products. *Maternal & child nutrition*, 16(1), p.e12898.

While official WHO guidelines around the use of products and which products to use to treat moderate wasting are currently lacking, there has been a recent surge in research and subsequent interim guidance on this topic, including the WHO technical note on the composition of

foods for treating moderate wasting, the exploration of the use of RUTF for managing moderate wasting,⁹ and the 'MAM decision tool', which allows for some flexibility in treatment products used.^{10,11,12}

Challenges and change needed

 Every facility needs to be stocked with the supplies needed to treat, according to national priorities and protocols, all children and PLW affected by wasting

There is currently insufficient availability of commodities for the early detection and treatment of children and PLW with wasting – in particular RUTF. The scale and reach of treatment services today are directly proportional to the resources available for RUTF; and resources are in turn heavily dependent on the availability of emergency/ humanitarian funding.

2. Improve the cost-effectiveness of wasting product production and programmes

The treatment of child wasting is widely perceived as being costly. High treatment costs per child are largely the result of late presentation (which leads to longer treatment duration), absence of moderate wasting treatment (where only severe wasting is treated), suboptimal use of key commodities and the overall cost of producing and delivering these commodities.

3. Strengthen supply chain management

Weak and inefficient supply chain management at multiple levels, including separate programming for moderate and severe wasting treatment (which results in parallel supply chains for therapeutic milks, RUTF

and RUSF) contribute to high costs and significant shortfalls in the supply of key commodities at programme level. Separate programming and supply chains for wasting treatment, outside of national health supply chains, fills an immediate need but inhibits sustainable treatment access.

The *environmental footprint of RUTF production* is too big and continues to cause concern.

4. Fill knowledge and guidance gaps

There are knowledge gaps with regard to our understanding of how best to address wasting with products. These include the following: the efficacy of different products to address outcomes other than reversal of wasting but that are important for the complete recovery of a malnourished child (including cognitive functions, body composition and linear growth); the effectiveness of different products to address wasting and birth outcomes among PLW; the cost-effectiveness of different approaches in different contexts (including humanitarian, urban and Asian); and the impact of programme (versus product) quality on effectiveness. There is also weak coordination of research, as well as dissemination of findings. When research projects are complementary and fill niche knowledge gaps, it is more by luck than design.

⁹ See: WHO (no date) Supplementary foods for the management of moderate acute malnutrition in children aged 6–59 months. Available at https://www.who.int/elena/titles/food_children_mam/en/

Bailey, J., Opondo, C., Lelijveld, N., Marron, B., Onyo, P., Musyoki, E.N., Adongo, S.W. et al. (2020). A simplified, combined protocol versus standard treatment for acute malnutrition in children 6–59 months (ComPAS trial): A cluster-randomized controlled non-inferiority trial in Kenya and South Sudan. *PLoS medicine*, 17(7), p.e1003192.

¹¹ Lelijveld, N., Godbout, C., Krietemeyer, D., Los, A., Wegner, D., Hendrixson, D.T., Bandsma, R. et al. (2021). Treating high-risk moderate acute malnutrition using therapeutic food compared with nutrition counselling (Hi-MAM Study): a cluster-randomized controlled trial. *The American Journal of Clinical Nutrition*.

¹² GNC MAM Task Force (2017). Moderate acute malnutrition: a decision tool for emergencies.

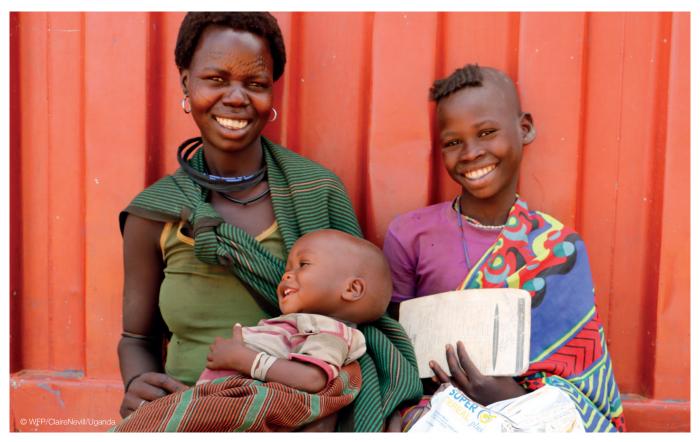
Actions How will change happen

Specific actions required	By whom?				
Improve global availability of products					
 Incentivise global financing mechanisms to play a more active role in domestic resource allocation for wasting products (see actions on this and others in the financing brief) United Nations agencies and donors need to be better coordinated, and therefore more efficient, across humanitarian and development funding mechanisms, in their efforts to fill national funding gaps for product procurement More detail on treatment financing in general can be found in the financing brief 	UN, governments, donors				
 Identify/develop an appropriate category for RUTF in the Model Essential Medicine List (EML) Review and analyse (take into account) country-level assessments on benefits versus potential harms of adding RUTF to the EML Provide technical support for products to be registered and their standards/composition approved by National Drug Authorities (or similar) to facilitate import and market availability/commercialisation Account for progress against this change: track the status of model and country-level EMLs 	UN, governments, and private sector partners				
 Build the capacity of local producers for RUF and other key commodity production through innovation and support for the transfer of technology from larger global/ regional producers to smaller national producers Develop mechanisms for the exemption from import duties and taxes on the inputs used for local production (Pakistan, Niger, Nigeria) Ensure the safety and quality standards of locally produced RUFs through: developing safety and quality standards at national level, building on new Codex guidance ensuring the capacity development of quality control staff within national ministries to ensure quality monitoring of therapeutic and supplementary foods. Support efforts to prevent and reduce aflatoxin and other toxins in therapeutic foods Account for progress against this change: track the proportion of RUTF procured from suppliers within the same region where treatment is delivered 	UN, governments, and private sector partners				
Reduce the cost of products and treatment per child					
 Accelerate the testing and rollout of a new generation of RUFs that explore the use of cheaper, more locally available ingredients and leverage the food system for longer-term benefits in both locally produced and offshore supplies of RUFs. This requires funding for research and development and field testing, and clarity around the evidence needed in terms of demonstrating product effectiveness as well as mitigating risks linked to potential anti-nutritional factors brought by (cheaper) cereals. WHO is working on a statement to encourage and provide further clarity on the generation of evidence on new RUTF formulations Review the complex issues of patenting new products, including potential alternative mechanisms to share the risk and benefits of innovations Account for progress against this change: track the number of alternative RUF formulations assessed by UNICEF, WFP, USAID, MSF and others that are safe, acceptable and represent value for money with a final outcome and the number of countries where alternative RUF formulations have been introduced 	UN, governments, academic and private sector partners				
	 Incentivise global financing mechanisms to play a more active role in domestic resource allocation for wasting products (see actions on this and others in the financing brief) United Nations agencies and donors need to be better coordinated, and therefore more efficient, across humanitarian and development funding mechanisms, in their efforts to fill national funding gaps for product procurement More detail on treatment financing in general can be found in the financing brief Identify/develop an appropriate category for RUTF in the Model Essential Medicine List (EML) Review and analyse (take into account) country-level assessments on benefits versus potential harms of adding RUTF to the EML Provide technical support for products to be registered and their standards/ composition approved by National Drug Authorities (or similar) to facilitate import and market availability/commercialisation Account for progress against this change: track the status of model and country-level EMLs Build the capacity of local producers for RUF and other key commodity production through innovation and support for the transfer of technology from larger global/ regional producers to smaller national producers Develop mechanisms for the exemption from import duties and taxes on the inputs used for local production (Pakistan, Niger, Nigeria) Ensure the safety and quality standards of locally produced RUFs through: developing safety and quality standards of locally produced RUFs through: developing safety and quality standards at national level, building on new Codex guidance ensure the safety and quality standards at national level, building on new Codex guidance ensure the safety and representation of representation of RUFs that explore the use of cheaper, more locally produced and offshore suppliers within the same region where treatment is delivered Accelerate the testing and rollout of a				

Change needed	Specific actions required	By whom?			
Reduce the cost of products and treatment per child					
Improve the estimation of needs over the short to long term, and improve the visibility of demand for suppliers to enable more cost- efficient production	 Develop a formal/informal way to communicate upcoming demand (for example, a non-binding quarterly demand forecast which is shared with all suppliers in the industry) Adopt the model of long-term agreements with suppliers for product procurement where this is feasible Account for progress against this change: ensure quarterly or biannual forecasts are published 	UN agencies			
Streamline the process of quality testing and verification of RUTF to reduce the costs associated with production	 Reduce the duplicate testing currently performed by both supplier and procurement agency inspection partners Adopt a supplier verification model that focuses on process control and preventive controls, and less on quality control models for release 	Private sector, governments, UN agencies			
Support more frequent opportunities to make price adjustment of RUFs depending on a commodity price index, to improve production efficiency	 Develop an index linked to the main cost drivers of raw materials used by suppliers Develop flexible long-term agreement approaches that can help suppliers manage ingredient cost fluctuations 	Private sector, governments, UN agencies			
Adopt simplified programmes that treat wasting with dosage that is tailored according to risk	Identify optimum admission/discharge criteria, age-specific targeting and RUF dosage for the treatment of wasting. This may include adopting a single product for all children with wasting in need of therapeutic treatment, and optimising the amount of product used for the treatment of child wasting	UN, governments, academic, NGOs, the simplified approaches working group ¹³			
Reduce the demand for expensive treatment products by systematic preparedness strategies using less costly earlier interventions, such as super cereals for vulnerable and atrisk groups	Invest in and scale up the use of appropriate products for evidence-based prevention of wasting strategies (see the prevention brief)	Multiple			
Strengthen supply chains					
Integrate the procurement, distribution and general management of wasting products into national supply chain systems of the health sector where appropriate. This will help to streamline and integrate supply chain systems for the delivery of multiple key commodities (especially therapeutic milks/RUTF/RUSF) for the treatment of wasting	 Build the capacity of government departments for the accreditation and validation of suppliers, procurement, distribution and general management of the wasting products pipeline Explore different approaches to the transport, storage and distribution of therapeutic milks/RUTF/RUSF on the ground and carefully document the impact of these approaches on the cost and availability of key commodities at programme level Account for progress against this change: track the number of countries that are delivering wasting products through their national supply chain 	UN and private sector partners			
Better understand pipeline breaks and stockouts, including the problem of loss/leakage of RUFs at programme level	Develop a mechanism for better reporting and analysis of pipeline breaks, stockouts and loss/leakage of RUFs, including through sharing of the product at household level	UN, Governments and NGO partners			

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Change needed	Specific actions required	By whom?
Ensure more sustainable production and procurement of RUF	 Develop guidance to ensure RUF procurement supports local economic and social development with the least environmental impact and the best value for money Apply the same quality, sustainability and ethical standards set by interagency quality assurance team to local and offshore suppliers without exception Accept a price difference if more sustainable raw materials are used 	UN, private sector
Fill knowledge and gu	idance gaps linked to the effectiveness of treatment products	
Ensure there are more coordinated, multi-arm and longitudinal studies in different contexts that follow children post-discharge over several seasons/years and monitor multiple outcomes in different contexts	 Increase donor support for larger, longer-integrated research, rather than piecemeal studies Explore and establish a role for a lead coordinating body for product development and research, and increase the involvement of donor and procurement agencies in study question-setting, following research, and the dissemination of findings Increase the commitment from operational agencies to support/facilitate studies in a range of contexts (to assess the real cost-effectiveness in programmatically challenging settings), not just the product's effectiveness in treating wasting 	Academia, donors, UN, NGO partners
Develop clear guidance on dietary treatment products and/or local foods for moderate wasting, and strengthen regulatory framework for product use	 Build on recent evidence and interim guidance to generate guidelines for dietary treatment, including different types of specialised nutritious foods for children with moderate wasting. Guidance should account for context and different population-level risk factors that impact the health outcomes of children with MAM Reconsider the regulatory frameworks that limit the distribution of RUTF as a treatment for children with SAM only 	WHO, UN



Annex 1

Members of the Working Group

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23	Maria Wrabel	Action Against Hunger USA
24	Mamane Zeilani	Nutriset

Sources used but not cited directly in the text:

- · Notes from working group members
- Background/summary information for products working group (including points from the Global Action Plan on Child Wasting (GAP) and GAP Operational Roadmaps, No Time to Waste, No Wasted Lives)
- Summary mapping from UNICEF, Guerrero, 9 July products section, simplified protocols and investment for scale-up
- WHO guidelines on the dairy protein content in ready-to-use therapeutic foods for treatment of uncomplicated severe acute malnutrition
- Akomo, P. and Collins, S. (2021). Commentary on WHO guide: Ready to use therapeutic foods with <50% protein from dairy. *J Food Technol Pres*, 5(5)
- Supplies sections of R4D-UNICEF integration manual (DRAFT not to be shared).
- Nel, E. and Lombard, M. (2021). Ready-to-use therapeutic foods for the treatment of malnourished children and infants. *Curr Opin Clin Nutr Metab Care*.

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