Ready to Use Therapeutic Food (RUTF) and the WHO Essential Medicines List





Background

Severe Acute Malnutrition (SAM) is one of the greatest child survival challenges in the world today and reportedly affects more than 16.2 million children each year¹. High impact, proven treatment interventions exist yet sadly approximately only 3.2 million children with SAM have access to treatment each year². Thus, there is a need to scale up interventions to improve coverage and access across high burden countries. While efforts are currently underway to expand services in many countries, obstacles remain.

One critical barrier to expanding SAM treatment services is the acceptance, accessibility and utilisation of ready-to-use therapeutic food (RUTF). In some countries and contexts, RUTF is still not fully accepted by community members; while other countries face problems with procurement, storage and supply chain management which impact on availability and use³. Reports from Ghana and Zambia highlighted that stock-outs and logistical challenges are often noted as key contributors to high default rates in outpatient treatment centres⁴.

One proposed method for improving RUTF access is to include the product on the World Health Organisation (WHO) Essential Medicines List (EML). This is "a list of minimum medicine needs for a basic health-care system, listing the most efficacious, safe and cost–effective medicines for priority conditions"⁵. It provides a guide to countries of which medicines to prioritise for national procurement; national health and nutrition decision makers tend to rely on the EML as a guide for determining their own national medicine and commodity lists⁵. Thus, placing RUTF on the Essential Medicines List could potentially assist in prioritising the procurement of RUTF and alleviate some of the distribution and supply chain issues currently seen within countries.

Discussions on whether RUTF should be placed on the WHO EML began in 2009 and at a conference on 'Government experiences of CMAM scale up' in 2011, the question of adding RUTF to national EMLs was identified as critical⁶. To date, there remains a general consensus that placing RUTF on the WHO and national lists of essential medicines could be a positive step but it's limited due to the lack of available evidence. Given this gap in evidence, Action Against Hunger began analysing the potential inclusion of RUTF on the WHO EML as well as national medicines lists. In order to obtain as much information as possible, ACF-F conducted a literature review; two country case studies (in Zimbabwe and Nigeria); a stakeholder mapping exercise as well as interviews with key informants¹. Based on these processes, this paper aims to unpack some of the arguments for and against adding RUTF to the Essential Medicines List as well as the potential implications for doing so.

What are the arguments for placing RUTF on the EML?

1. A substantial body of observational and programmatic data documenting the effectiveness of RUTF exists:

The use of RUTF to treat uncomplicated cases of SAM in children aged between 6-59 months is well established and has been the recommended treatment approach for more than a decade. The 2007 Joint Statement by WHO, WFP, UNICEF and the UNSCN endorsed the use of a community-based approach to SAM treatment, using RUTF to treat uncomplicated cases of SAM⁴. Additionally, the 2013 WHO guideline update for the management of SAM recommended using an outpatient model to treat children diagnosed with SAM, who have passed an appetite test and are clinically well⁷. The guideline included a strong recommendation for the use of RUTF within an outpatient treatment model as well as during the rehabilitation phase of inpatient treatment⁷.

¹ The following stakeholders were interviewed: Alison Fleet and Thomas Sorensen (UNICEF), Zita Weise and Hala Boukerdenna (WHO), Hanane Bouzambou and Charlotte Bienfait (formerly WFP), Steve Collins (Valid International), André Briend (independent, formerly IRD & WHO), Odile Caron (MSF), Jane Badham (HKI), Patti Rundall (IBFAN), Stefano Prato (SID), Thomas Couaillet (Nutriset), Anne-Dominique Israël, Rachel Lozano and Danka Pantchova (ACF).



There is a multitude of grey literature pointing to the effectiveness of RUTF and programmatic evidence for this. A review conducted in 2006 summarised this evidence, noting RUTF to be effective in supporting rapid weight gain and safe to use in a community setting⁸. Low mortality rates and rapid recovery rates were reported comparable or even higher than those achieved in previous inpatient treatment models⁸.

Additionally, research points to the potential for integration of RUTF into supply chains. A report by UNICEF in 2015, noted that the inclusion of nutritional products on national EMLs is an important mechanism for fostering integration into supply chains and to ensure quality assurance⁹. The report recommends that UNICEF country offices support governments to integrate all nutrition products for SAM treatment into National EMLs⁹. Additional literature included one study that highlighted the potential advantages of including RUTF (as well as F-75 and F-100) on the national essential drugs list of Malawi and Ghana⁴. Such advantages related to the supply system and logistical management as well as supporting local production of RUTF⁴. Another recommended RUTF to be added on the EML of Cambodia in order to facilitate procurement of RUTF by the national Government¹⁰.

2. A number of countries are already placing RUTF on their on EMLs

Various countries have already placed RUTF on their national EMLs or registered the product as a medicine, as the table below outlines:

What is the st	atus of RUTF in the	e following co	untries?				
(non-exhaustive list, as of August 2016)							
Countries	On the Essential medicines/drugs list*	as a	Other				
			Registered as a Food	Registered as essential commodity	Other		
Ethiopia				x	Registration by Food Medicine and Healthcare administration and Control Authority (2010-2015)		
Kenya, South Africa			x		Registration by Ministry of Public Health and Sanitation (2010)		
Niger		X	x		Registration by the Health Authority (Department of Pharmaceutical and Medical Products)		
Zimbabwe	x	х	х				
South Africa			х		Registration by the Department of Agriculture, Forestry and Fisheries		
Sudan,					Registration by Health Authorities (not clear whether medicine status or not)		



South Sudan			Registration by Health Authorities (not clear whether medicine status or not)
Guinea- Conakry			In the 'Guide Thérapeutique National' (synthesis of EML and national pharmaceutical protocols)
DRC		x	
Vietnam		х	In process
Tanzania		x	Registration by the Food Drugs Authority
Haiti	×		
Burkina Faso	×		
Côte d'Ivoire	x		
Uganda	x		
Malawi	×		
Nigeria	In process		On-going process to add RUTF to EML
Ghana	In process		On-going process to add RUTF to EML
Liberia	In process		On-going process to add RUTF to EML



3. Placing RUTF on the EML would assist in prioritising SAM at a global and national level

The WHO EML is a critical tool to identify priority medicines of public health importance. Implicit in adding medicines to the list is the imperative that countries need to make these medicines available and affordable. Despite the WHO EML not being automatically linked to national EMLs, the list is used as the foundation of many national essential medicine lists¹¹. In addition, high burden countries often- but not systematically- allocate budgets in priority to the drugs listed in their EML. Thus, the integration of RUTF on this list could create political drive to prioritise SAM treatment. Many interviewees assumed it could also support in making the product more affordable and available; this has been demonstrated in the past where improved availability of TB drugs were a result of their inclusion in the 2015 amendments to the list¹². Similarly, a research paper by Bazargani et. al. in 2014 concluded that medicines placed on the EML are more available than other medicines at a global level¹³.

Most key informants further highlighted that it could potentially impact on political decision-making at a national level, as it would contribute to prioritising SAM treatment at a health facility and community level. Prioritising SAM could lead to more resources being allocated to treatment, and more awareness being created at a health facility and district level.

Zimbabwe Case Study

In 2006, Zimbabwe began implementing community-based therapeutic care (CTC, now known as CMAM) to treat acute malnutrition, with guidelines being published in 2008. In the beginning, high energy milk was listed on the Essential Drug List of Zimbabwe (EDLIZ) but not RUTF or the therapeutic milks (F75 and F100) used in inpatient care.

Despite this early uptake of a community-based approach to SAM treatment, outcomes were poor and thus, in 2014, focus was placed on integrating the model into broader health services, in particular, childhood illness management, and the model moved to integrated management of acute malnutrition (IMAM). This move sparked discussions on how to integrate nutrition products (RUTF, F75 and F100) with other routine medicines and drugs distribution systems.

In fact, such conversations began in 2013 with the National Nutrition Department (NND) contacting the directorate of Pharmacy and the Essential Drug Listing Committee. At the EDLIZ Committee's request, a technical team, comprising of nutritionists, paediatricians and dieticians, was set up to design the specifications, dosage and treatment guidelines for the proposed products for submission to the EDLIZ committee. In 2015, the inclusion of the nutritional products (including RUTF, F75, F100, ReSoMal and Combined Mineral Vitamin Mix) into the EDLIZ received final approval. Under the updated EDLIZ, RUTF is classified as both food and medicine. This classification was meant to have the health workers present RUTF as a health item that can be eaten while at the same time, also treated as a medicine used to treat malnutrition.

The process of getting RUTF onto the EDLIZ took two years and was met with no opposition. It was led by the Ministry of Health Department of Nutrition, with support from UNICEF and the World Food Programme.

4. Inclusion of RUTF on the EML would lead to improved integration of nutrition within health systems

Previously, SAM treatment programmes were largely led and run by NGOs with siloed systems created for the delivery and distribution of nutritional products⁸. Recent years have seen a shift in many countries to government ownership of programmes and while integration into national health systems has greatly improved, more is required to ensure systems are fully integrated. The potential to support integration is one of the strongest arguments in favour of adding RUTF to the EML.

Most key informants agreed that it would lead to better integration of SAM treatment within health systems, avoid vertical, parallel programmes being created and empower more national authorities to ensure the product is available. One respondent commented, "integration [of RUTF within national EMLs] is part of a larger movement for better integration of nutrition and stronger health systems and [is critical] to achieve sustainable results."

Another respondent added, "RUTF has not been well integrated into national distribution systems. Supply chains should not be separated within a health system, especially in light of a health system strengthening approach. Governments should own this matter and become accountable for it. Intuitively we agree that we need to integrate RUTF within national distribution systems, and on the ground, we need to take it forward." Additionally, including RUTF as an essential medicine/ commodity allows easier integration into national supply



systems (easier clearance of supplies at port, government storage at central medical stores, and governmentled distribution and logistics).

5. RUTF on the EML would result in better management of SAM treatment programmes

As noted above, studies have shown that EMLs have the ability to influence the provision of medicines and have resulted in an increased availability of essential medicines compared to non-essential medicines, particularly in low- and middle-income countries¹³. Thus, placing RUTF on the EML could lead to fewer stock-outs as stock management and distribution improves.

Such positive benefits have been seen in Zimbabwe where it was noted that there was better integration of nutrition products into the national distribution system after adding the product to the national EML as well as improved data availability of stocks and delivery. Distribution is now overseen by the National Pharmacy although RUTF is stored separately from other medicines (to avoid attracting rodents). As a result of this change in management, RUTF is now included in the national forecasting and quantification exercise. This exercise allows the identification of requirements, funding gaps and supply forecasting. The current system provides supply chain management data routinely, which was not the case prior to integration into the national supply chain. The routine data now provides reports on stock status, stock-outs and delivery coverage. Such information helps to reduce the potential for RUTF stock-outs at a health facility level. In fact, between Q3 2013 and Q3 2015, it was noted that between 94% and 100% of the health facilities targeted by the Zimbabwean Government to receive RUTF had effectively received the products.

6. Increased financial resources would be available for RUTF and it would potentially decrease overall cost

The addition of RUTF on EMLs opens doors for treatment, as governments would thus be required to allocate adequate budget to the purchasing of RUTF. Most importantly, the inclusion of RUTF onto a national supplies list will likely ensure there is dedicated national health budget for community programmes that use RUTF. For example, adding RUTF on the Zimbabwean National EML and the distribution system has led the Government of Zimbabwe to decide to allocate funds (15%) to cover some of the RUTF procurement and distribution. Integration into the national distribution system has led the Ministry of Health to perform supply planning for RUTF, which influences the cost and budget allocation.

Some key informants also thought it would contribute to decreasing the cost of RUTF, which would then allow countries to buy more supplies with the same amount of money. This is because (1) it would stimulate local production of RUTF (as believed by some stakeholders in Nigeria) and (2) harmonisation of standards could lead to a potentially larger scale of production for bigger producers and decrease in the cost of production per sachet. However, the first reason was deemed as not being feasible by other respondents, as local production has shown to be equivalent to, or higher than,

Nigeria Case Study

In 2009, the Government of Nigeria, with the support of UNICEF, began SAM treatment by introducing the CMAM model within the country. CIFF and DFID further supported implementation and scale up of SAM treatment. The aim from the beginning with these pilots was to introduce CMAM into the existing health system and explore ways in which CMAM could become part of routine service.

As a mechanism to integrate services, there was a push for RUTF to be placed on the national EML. The decision to start the processes of integrating RUTF into the national EML has been based on some key ingredients: Soft lobbying by NGOs which provided the evidence needed as well as leadership on the matter and political will by high level decision makers.

In 2014 a CMAM taskforce began initiating such discussions. This taskforce was made up of MoH officials, donors (including DFID and CIFF), NGOs and bilateral organisations) and was supported by the private sector (including Nutriset and Dangote). In September 2014, the CMAM taskforce agreed on the need to include RUTF in the EML. The Minister of Health subsequently approved the request from the nutrition department for supporting the need to add RUTF and other nutrition commodities into the EML. A presentation was done by the Nutrition Department in February 2015 to expert clinicians highlighting the need to include RUTF on the EML. A letter was also sent to the National Agency for Drug Administration and Control (NAFDAC) as well as the Department of Food and Drugs Services requesting RUTF to be added on the EML. Both letters are currently awaiting a response. As of June 2016, Nigeria was in the advanced stages of adding RUTF to the national list.



international production standards. If indeed adding RUTF to WHO and national EMLs could contribute to scaling up production of RUTF, it is not clear whether this could definitely have a significant impact on the cost of RUTF due to the large fixed cost of the raw material (Nutriset). Thus, more evidence is required to understand if adding WHO to the EML would decrease the cost of the product.

7. Inclusion on the EML would assist in changing perceptions around RUTF

An interesting impact seen in Zimbabwe after adding RUTF to the national EML was how it led to RUTF being seen more as a therapeutic product, rather than simply food. Health workers interviewed noted that the integration on EML changed their perception and pushed them to handle RUTF as a treatment rather than merely food. It contributed to raising awareness of treatment, as well as on under-nutrition in general. The inclusion of RUTF onto the Zimbabwean EML "makes health workers see its importance and start handling it as a therapeutic agent, not just as peanut-butter from the kitchen or nutrition department". Critically it was felt that the shift would help RUTF to be seen as medicine and would help to motivate healthcare workers.

Further ad hoc evidence of this was noted in Tanzania where, according to UNICEF, RUTF was being misused as mothers shared or resold it. A key informant commented that as result of it being later distributed through pharmacies, it slowly started to be seen as a medicine, which helped to control the misuse. Seemingly, integration of RUTF into the EML "protects" RUTF from being seen simply as food, and more caution is applied to its use.

8. Adding RUTF to the EML is complementary to the efforts to include on the Codex list

Since 2014, UNICEF have been developing a guideline for placing RUTF on the Codex Alimentarius¹⁴. Codex aims to set regulatory standards to ensure safe and good foods for international trade¹⁴. It is felt that this will assist to ensure the safety of the global supply of RUTF, improve importing and exporting procedures and build regulatory capacity¹⁴. While including RUTF on the EML and Codex are two independent processes, key informants noted that the processes were complimentary. This is because the aims of each differ: The Codex aims to set standards for quality production. Countries have to adopt Codex standards. However, the WHO EML is a list of products. An expert committee has decided that these products are safe and should be provided in priority to the population. Countries do not have to adopt the medicines listed on the WHO EML on their national EML. Hence, ensuring that RUTF is placed on both the EML and the Codex will assist in improving safety quality and supply.

What are the arguments against placing RUTF on the EML? 1. There is not enough evidence for placing RUTF on the EML

Despite the large amount of programmatic evidence, one of the leading barriers in adding RUTF to the WHO Essential Medicine List to date has been the limited amount of impact studies of high quality assessing the effectiveness of RUTF. Two systematic reviews on the use of RUTF for the treatment of SAM in children aged between 6-59 months were published in 2013. Both studies found the available evidence is generally very low quality with only a small number of randomised controlled trials published.

The 2013 Cochrane Review included three quasi-randomized trials comparing RUTF with a standard flour porridge diet for the treatment of SAM. The meta-analysis found that RUTF improved recovery slightly (with a relative risk of 1.32) but the evidence was too limited to draw definitive conclusions on relapse, mortality or weight gain¹⁵. An additional systematic review and meta-analysis on severe and moderate acute malnutrition was published in the same year, comparing children who received RUTF with those who received standard care (in-patient treatment followed by provision of corn soy blend (CSB) food for feeding at home)¹⁶. The review



and meta-analysis found that children given RUTF for the community-based treatment of SAM were 51% more likely to achieve nutritional recovery (WHZ \geq -2) than the standard care group (Relative Risk 1.51)¹⁶. Weight gain in the RUTF group was also higher, this was statistically significant but small (MD: 1.27; 95% CI 0.16 – 2.38)¹⁶.

Since these reviews were published in 2013, a handful of additional studies have been conducted, documenting the acceptability of RUTF formulation and program evaluation. However, only a single additional clinical impact study has been conducted¹⁷.

A further critical component of the WHO EML application process involves establishing the cost-effectiveness of the medicine/ commodity. Three studies have examined the cost-effectiveness of community-based management of acute malnutrition (CMAM) and noted that RUTF made up a high proportion of the costs of the programme¹⁸¹⁹²⁰. Due to the high milk powder content of RUTF, the costs of the product are relatively high. Several studies have examined reducing the milk content or using alternative or local formulations²¹ but the standard milk-based formulation remains the most common.

Despite the lack of impact and effectiveness randomised control trials for RUTF, the progression of treatment of SAM with RUTF over the past 10 years reflects the broader community's acceptance of strong programmatic data. This data demonstrates that high recovery rates and, just as importantly, higher coverage rates are possible when compared to in-patient treatment of severe acute malnutrition⁸.

2. Classifying RUTF as a medicine can be problematic in some countries

Adding RUTF to the EML could imply that the product is a medicine and many are cautious of classifying it as such. During a CMAM conference in 2011, it was argued that recognising RUTF as a medicine allows governments to treat it in a similar manner to all other drugs they supply⁶. However, there are various challenges to this; recognising the product as a medicine requires it to go through stringent quality assurance measures which would likely dissuade local producers. Hence, considering RUTF as a commodity may be more beneficial⁶. Most key informants felt that RUTF is a food with therapeutic claims or a medicinal food. However, placing RUTF on the WHO EML would not transform it into a medicine nor, would RUTF need to be a medicine prior to it being listed on the WHO EML. In fact, general consensus from the key respondents is that RUTF should fall into the general/non-medical category of the WHO EML. The WHO EML has a category for miscellaneous items such as sterilized water. RUTF could fall into this category.

Furthermore, there appears to be general opposition to product-based approaches (mostly concerned with the marketing of RUTF and the risk that it undermines breastfeeding.) Adding RUTF to the WHO EML can be seen as a way to promote a product based-approach to SAM, negating its causes and mitigating them through cost-effective interventions, such as the promotion of breastfeeding. However, international investments and efforts to address the prevention of malnutrition have risen significantly in recent years.

3. It may lead to the promotion of other products

The addition of RUTF on the EML could leave the door open to the promotion of other products within the EML, such as Ready to Use Supplementary Food (RUSF). However, looking into the EML of the countries which added RUTF recently, the study by ACF-F could not find any country adding RUSF (to commodities' list or EML). If RUTF is added to WHO and national EML, this risk should imperatively be flagged and it should be made very clear that it is solely RUTF which should be added.



4. Low capacity of national health systems and pharmacies would be further stretched

Countries which would likely benefit the most from RUTF inclusion on their national EML often experience humanitarian emergencies and have low capacity to implement such measures as well as the low-tech capacity of pharmacies. Adding RUTF to the national EML in these countries could increase the burden placed on pharmacies and the health system in general as they would then be required to manage and distribute an additional product, one that is bulky and requires large storage space. With pharmacies already struggling, there is a concern that adding additional services, without giving consideration to the need for health system strengthening, would only serve to weaken the services further.

5. There is a risk of potential conflicts of interest

The demand for RUTF is expected to increase as more countries add RUTF on their EML. Investors and some major dairy companies have investigated the market and are forecasting that it will grow significantly in the coming decades²². The private sector will benefit from a new "market" and become interested in a matter that has been so far a niche market²². Their future influence will need to be carefully monitored, to ensure that future decisions in the field of acute malnutrition do not solely rely on product-based approaches and favouring the development of new businesses for the sake of it.

What is the process of putting RUTF on the WHO EML?

Every two years, over a week, a committee of technical experts from WHO assesses whether a product should be added to the list, removed, or if dosage should be changed. The selection of essential medicines depends on various factors, such as the disease burden, adequate data on the efficacy, safety, and cost-effectiveness of available treatments. In the case of a lack of adequate evidence on the current treatment of the disease, the Expert Committee either waits for more evidence or chooses to make recommendations based on expert opinion and experience.

Conclusion

While there is limited evidence for the implications of adding RUTF to the WHO EML, ACF-F concluded through their research that there is a strong value-add for RUTF being added to the EML as a therapeutic food. There is an overwhelming amount of programmatic and observational evidence for the effectiveness of the product and there appear to be many positive benefits to adding RUTF to the WHO EML.

There is no silver bullet for increasing access to SAM treatment but adding RUTF to the WHO EML can act as a catalytic initial step in this process. Global action could influence countries to integrate the product into national EMLs, ultimately leading to increased prioritisation of SAM treatment with RUTF, increased budget allocation and improve inclusion within the health system and supply chain. These are critical factors to increase the availability and access to SAM treatment. Given the potential implications, an application to adding RUTF to the WHO Essential Medicines List should be strongly considered and supported.

This report was compiled by Natalie Sessions based on an Action Against Hunger report written by Aurélie du Châtelet with support from Anne-Dominique Israel, Elise Rodriguez, Wisdom Dube, Laetitia Battisti and Magali Garcia.



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