Process and impact of integration of ready-to-use therapeutic foods in national essential medicines lists

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Abstract
Severe acute malnutrition is listed in the International classification of diseases. Over 16 million children are affected by severe acute malnutrition globally, and in 2016 approximately 25% of these received treatment, which includes ready-to-use therapeutic foods. This article aims to determine the risks and potential outcomes of adding ready-to-use therapeutic foods (RUTFs) to national essential medicines lists, and to the WHO [World Health Organization] Model List of Essential Medicines (EML). The literature indicates that adding RUTFs to national essential medicines lists in low- and middle-income countries could facilitate procurement and improve the perception of RUTFs. The impact in Zimbabwe and Nigeria varied and included increased funding for procurement, development of local production, improved stock management and distribution, and significant availability of the products in targeted areas. There were no articles found arguing against the addition of RUTFs to essential medicines lists. Key informants provided similar arguments. More research is needed to quantify the impact. Adding RUTFs to national essential medicines lists and the EML is likely to mobilize political commitment to improve the treatment of severe acute malnutrition, to facilitate use, to improve availability and procurement, and to reduce costs. There is limited concern that it would result in high pharmaceutical standards, commodification and misuse. Additional measures are required to improve the prevention and treatment of severe acute malnutrition.

Keywords: acute malnutrition; essential medicines; therapeutic food; ready-to-use therapeutic foods; RUTFs

Introduction
Severe acute malnutrition1 is listed in the International classification of diseases (1). Over 16 million children are affected by severe acute malnutrition globally (2), and in 2016 approximately 25% of these (3) received treatment for this life-threatening disease (4). Considering current initiatives around universal health coverage, such as the Sustainable Development Goals (5) (target 3.8 aims to achieve universal health coverage) and one of the objectives of the World Health Organization (WHO) 13th General Programme of Work (6), renewed efforts are needed to address severe acute undernutrition.

The Lancet series on maternal and child undernutrition in 2008 (7) and 2013 (8) showed that treatment of severe acute undernutrition is an essential health intervention, and nutrition services need to be better integrated in the health system. Since 2015, at least four new countries (Kenya (9), Liberia (10), Nigeria (11) and

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1 The term used in some documents is severe acute malnutrition, although with the WHO broader definition of malnutrition in all its forms, which includes undernutrition (wasting, stunting, underweight), inadequate vitamins or minerals, overweight, obesity, and resulting diet-related noncommunicable diseases, the term undernutrition is used here to convey that reference is made to undernutrition only and not to all other types of malnutrition [https://www.who.int/en/news-room/fact-sheets/detail/malnutrition].
Zimbabwe (12) have added ready-to-use therapeutic foods (RUTFs) to their national essential medicines lists. RUTFs are high-energy fortified ready-to-eat foods used for the management of uncomplicated severe acute undernutrition.

No specific research has been conducted on the inclusion of RUTFs in national essential medicines lists, or on their potential inclusion in the WHO Model List of Essential Medicines (EML) (13), but existing literature suggests it could facilitate access to treatment (14–16). This article aims to determine the risks and potential outcomes of adding RUTFs to national essential medicines lists, and to the EML.

Materials and methods

This study comprised a literature review, review of national medicines and commodities lists, country case-studies and interviews with key informants.

A review of the literature relating to RUTFs and essential medicines lists was conducted between January and March 2015, and updated in August 2018, using PubMed, Embase, Google and Google Scholar. Each database was searched using the following terms: “RUTF”, “ready-to-use food”, “essential medicines list”, “essential drug list”, “commodities” and “WHO”. The search was conducted in English and in French and returned results from 2003 to 2018. Additional scans of citations in the documents were found, and some key informants also provided institutional reports.

For the mapping of the status of RUTFs in national essential medicines lists and local regulatory frameworks, a desk-based review of national medicines and commodities lists was done between January and March 2015 and updated in August 2018. In some cases, the paper copies of documents not available online were accessed thanks to the support of Action Against Hunger country teams. The search returned lists updated as recently as 2017.

The country case-studies were conducted by performing desk-based reviews and interviews between November 2015 and August 2018. This involved a review of relevant reports; interviews with key informants in countries with Action Against Hunger missions (for ease of access to informants), including Burkina Faso, Chad, Côte d’Ivoire, the Democratic Republic of the Congo, Haiti, Nigeria, Sierra Leone and Zimbabwe; and in-depth research conducted on the ground in Nigeria and Zimbabwe between October 2015 and January 2016.

Interviews with key informants were conducted from July 2015 to August 2016. Further informal discussions took place with some of them between September 2016 and March 2017. Key professionals from the United Nations, nongovernmental organizations and the private sector were identified, based on existing policy work on the topic, including advocacy; academic research, including development of the product; and operational work. A total of 16 informants were identified and agreed to be interviewed. Interviews were conducted using a semi-structured questionnaire (see Appendix A3.3.1) informed by the literature review. Interviews lasted between 15 minutes and 2 hours, with an average of 1 hour. As some organizations did not have an official position on the matter, some respondents highlighted that they were responding in their own name. Some respondents may not agree with all the interpretations and conclusions of this article.

Results

Literature review

Limited academic and technical literature is available on RUTFs, national essential medicine lists and the EML. This is probably because RUTFs are included in only a few national essential medicine lists, meaning that only a small number of examples can be studied. Most search results pertained to the efficacy of RUTFs and community-based management of acute undernutrition. Thirteen articles with mentions of RUTFs and essential medicine lists were found: eight pertained to the topic of enquiry, including four from peer-reviewed journals.
All articles discussed in this section, apart from the first, cite the benefits of inclusion of RUTFs in national essential medicines lists or the EML, with reasons that fall into two broad categories: facilitating the procurement of RUTFs and improving the perception of RUTFs. Most of the literature called for more research to be conducted into the potential outcomes of adding RUTF to national EMLs.

A 2007 joint statement by WHO, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund (UNICEF) recommends the use of RUTFs through community-based management of acute malnutrition and encourages local production of RUTFs (4). A 2016 study by UNICEF in eastern and western Africa found that the absence of nutritional products on national essential medicines lists makes it less likely for them to be included in national distribution systems (14).

A 2015 study by Prak and colleagues recommends inclusion by the Government of Cambodia to facilitate purchasing, and to make the procurement of products for treatment of severe acute malnutrition less dependent on donors (15).

A 2012 UNICEF case-study on Ethiopia argues that a reliable supply of RUTFs depends on them being registered in the national system and on the national essential medicines or commodities list (16). The study cites challenges such as community-based management of commodities for acute malnutrition, and supplies being sent back to the country of origin because they could not clear customs. The study recommends registration of RUTFs on the essential medicines list, to avoid supply issues and import regulations.

Maleta and Amadi reported on studies performed in Ghana, Malawi and Zambia on the integration of community-based management of acute malnutrition into essential health packages (17). In Ghana and Malawi, RUTFs were distributed using the same health system distribution as for other medicines. In Zambia, a budget line was created for RUTFs. The authors found that strong government leadership and integration of community-based management of acute malnutrition in health policies has allowed the scale-up of coverage and treatment outcomes.

De Bustos and colleagues maintain, in a 2016 article, that in east Asia and the Pacific, the weak legal framework and lack of infrastructure around RUTFs leads to misconceptions about local RUTF manufacture, recipes and pricing (18). They also note that storage conditions are often inadequate, leading to product deterioration and loss. Without dedicated policies and protocols, procurement is laborious. The authors recommend the inclusion of RUTFs in essential medicines lists, to clarify perception and facilitate logistics.

In a 2012 publication, Neequaye and Okwabi state that distribution using the same channels as other health supplies in Ghana, including the same transport and warehouse, has reinforced government ownership and minimized public perceptions of the intervention as “vertical”, as well as increasing the likelihood of the distribution system being sustained (19).

**Status of ready-to-use therapeutic foods in national essential medicines lists and regulatory frameworks**

A total of 16 countries have added RUTFs to their national essential medicines list, but 20 have not (see Table A3.3.1). RUTFs are registered variously as medicines, foods or commodities. This has been done at the national level to accommodate varying national legislation, and in some cases to facilitate customs clearance. In many countries, integration of a product in the essential medicines list does not systematically trigger its inclusion in the national supply chain; more research is needed to map out the integration of RUTFs in supply chains.
Table A3.3.1. Status of ready-to-use therapeutic foods (RUTFs) in national essential medicines lists (non-exhaustive list, updated September 2018)

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<th>Country</th>
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<td>RUTFs not included</td>
<td>RUTFs registered as medicines</td>
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<td>Plurinational State of Bolivia</td>
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<td>Burkina Faso, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Liberia, Malawi, Sierra Leone, South Sudan, Sudan, Uganda</td>
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### WHO TECHNICAL CONSULTATION: NUTRITION-RELATED HEALTH PRODUCTS AND THE WORLD HEALTH ORGANIZATION MODEL LIST OF ESSENTIAL MEDICINES – PRACTICAL CONSIDERATIONS AND FEASIBILITY

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List of Essential Medicines. Hanoi: Ministry of Health, Viet Nam; 2008 [http://apps.who.int/medicinedocs/documents/s19532vi/s19532vi.pdf?ua=1](http://apps.who.int/medicinedocs/documents/s19532vi/s19532vi.pdf?ua=1) | × | × | - |
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<td>Cameroon,</td>
<td>Liste Nationale des Médicaments Essentiels: Cameroun. Yaoundé: Ministère de la Santé, Cameroun; 2017</td>
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<td>Madagascar,</td>
<td>Antananarivo: Ministry of Health, Madagascar</td>
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The table presents information found at the time of the study for countries with a high burden of undernutrition. It is non-exhaustive. Regarding the registration of RUTFs, information was not systematically available; therefore, if there is no entry in a cell, it should be read as no information is available. Assessing how RUTFs are registered gives an indication of how these products are considered at the country level and of the degree of ownership of their use by ministries of health.
**Country case-studies**

The purpose of adding ready-to-use therapeutic foods to national essential medicines lists

RUTFs were added to national essential medicines lists for different reasons: to decrease stockouts of nutrition-related products by addressing parallel supply chains (Zimbabwe); to lower barriers to RUTF production and import, eventually leading to a decrease in cost (Nigeria); and to mobilize political and financial commitment (Haiti).

In Zimbabwe, based on the most recent Demographic and Health Survey (2015), the overall rate of acute undernutrition was 4.2%, with 1% of people having severe acute malnutrition (20). RUTFs were supplied in parallel to the regular supply chain of the Zimbabwean Ministry of Health. The national nutrition department identified weaknesses in the distribution of nutrition-related products and asked for advice from the Directorate of Pharmacy and the Essential Drug Listing Committee on the matter, and potential linkage with the essential medicines list. The Zimbabwean Ministry of Health commissioned the World Food Programme to identify mechanisms to improve the supply chains of RUTFs; the World Food Programme recommended that RUTFs should be added to the regular supply-chain mechanism. For this to happen, inclusion of RUTFs in the national essential medicines list was deemed a necessary step.

In Nigeria, the process was initiated to decrease the cost of treatment. Nigeria is among the countries with the highest burden of severe acute malnutrition (10% of the global burden (21)), which affects children at a rate of 1.8% (22). The Nigerian Government operates community-based management of acute malnutrition in 12 northern states, in partnership with nongovernmental organizations and donors. By adding RUTFs to the national essential medicines list, the Nigerian Government sought to increase the availability of RUTFs and decrease their cost. One official from the Ministry of Health stated: “If RUTFs are included on the [national essential medicines list] there will be universal availability, accessibility and utilization of RUTFs across Nigeria”. According to another official, the inclusion of RUTFs on the national essential medicines list will allow the establishment of local production of RUTFs and address 50% or more of the cost burden attributed to RUTFs in community-based management of acute malnutrition. With no national production, RUTFs constitute the largest share of the total cost of community-based management of acute malnutrition. Officials believe this move may foster local production and lower costs.

Countries frequently allocate budgets by priority, according to the medicines listed in their essential lists. Treatments with official status on the national essential medicines list tend to be prioritized in terms of resources and programme support. In Haiti, integration of RUTFs in the essential medicines list was done to generate more political support and resources for treatment of undernutrition.

The process for inclusion of ready-to-use therapeutic foods in national essential medicines lists

In Zimbabwe and Nigeria, the initiative to add RUTFs to the national essential medicines lists was government led and took about 2 years. The process was sometimes supported by United Nations agencies, and only in a limited way by civil society. The involvement of the private sector was stronger in Nigeria than in Zimbabwe. No opposition was met internally.

In Zimbabwe in 2013, the President launched the national Food and Nutrition Security Policy. In the same year, the right to food was recognized and nutrition was presented in the national development policy as a key strategic area (23). The National Nutrition Department began discussions to add nutritional products, including RUTFs, to the national medicines distribution system and the *Essential Medicines List* of Zimbabwe in 2013. The National Nutrition Department cooperated with the Directorate of Pharmacy and the Essential Drug Review Committee to review the request, and later that year a technical team was formed to design the specification, dosage and guidelines. Key informants highlighted that the World Food Programme and UNICEF encouraged the process and recommended that RUTFs be added to the national medicines distribution system. Based on the findings of the present study, nongovernmental organizations and the private sector did not play any role. The process was completed in less than 2 years, and in 2015 inclusion of RUTFs took place, along with other
nutritional products for complicated severe acute malnutrition and for moderate acute malnutrition (F-75, F-100, ReSoMal, combined mineral vitamin mix) (12, 24).

In Nigeria, the national Community-based Management of Malnutrition Taskforce – a component of the Ministry of Health – initiated discussions on inclusion of RUTFs in their essential medicines list in 2014. Nigeria had a wealth of partners in the process, including the international RUTF producer Nutriset and the Nigerian conglomerate Dangote, international nongovernmental organizations, and bilateral organizations such as the Department for International Development and the Children's Investment Fund Foundation. In February 2015 the Nutrition Department presented its case to expert clinicians, and in November 2017 the National Drug Formulary and Essential Drug Review Committee met and approved the request to add RUTFs to the Nigerian essential medicines list, along with other nutritional products (F-75, F-100, ReSoMal, vitamin A, micronutrient powder) (11, 25).

The impact of adding ready-to-use therapeutic foods to national essential medicines lists

According to the interviews, the measure has had various levels of impact: no impact was recorded in Chad (Guegma F, Petry M. Interviews with Action Against Hunger Chad advocacy and health and nutrition teams, November 2016) or the Democratic Republic of the Congo (Sahabi S. Interview with Action Against Hunger health and nutrition team in the Democratic Republic of Congo, February 2018); a change in perception of RUTFs was recorded in Zimbabwe; and significant availability of RUTFs in targeted areas was recorded in Zimbabwe (24, 25).

In Chad and the Democratic Republic of the Congo, RUTFs are officially on the national essential medicines lists (Guegma F, Petry M. Interviews with Action Against Hunger Chad advocacy and health and nutrition teams, November 2016; Sahabi S. Interview with Action Against Hunger health and nutrition team in the Democratic Republic of Congo, February 2018). However, Chad's list has not been officially published, and, according to respondents, integration of RUTFs has not led to any change in supply chains or procurement (26). In the Democratic Republic of the Congo, the list has been published but it has not led to noticeable changes (Sahabi S. Interview with Action Against Hunger health and nutrition team in the Democratic Republic of Congo, February 2018).

In Zimbabwe, perception of RUTFs as therapeutic agents has increased. Health workers reported that the inclusion of RUTFs has changed their perception and pushed them to handle RUTFs as therapeutic agents. According to an official from the Zimbabwean Ministry of Health, the inclusion of RUTF in the essential medicines list “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” (24).

In Burkina Faso and Zimbabwe, according to respondents, the process led to the creation of budget lines for RUTFs and plans to scale up government funding. After Burkina Faso added RUTFs to its national essential medicines list in 2014, advocates called for government investment specifically into the purchasing of RUTFs. A budget line was added for up to 1 billion west African francs (CFA) in 2017, with a commitment to increase it each year. In 2018, this budget surpassed 1.5 billion CFA (Biga A. Interviews with Action Against Hunger health and nutrition team in Burkina Faso, November 2016 and August 2018). In Zimbabwe, a national budget line was created for RUTF procurement, with the objective to increase the share covered by the government gradually. However, according to respondents, most of the cost (nearly 90% in 2016) was still covered by UNICEF (24). In Nigeria, the addition of RUTFs to the essential medicines list was done in late 2017, after states had already passed their budgets for 2018. However, the Nigerian Government invested 1.2 billion Nigerian naira in the procurement of RUTFs in 2017 and 1.1 billion Nigerian naira in 2018. At the time of writing, as the budget cycle had just begun, it is expected that a budget line for RUTFs will be included. This would complement the existing budget that some states already have for nutrition (25).
Inclusion of RUTFs in the Nigerian essential medicines list has facilitated the development of local production of RUTFs, which could improve local availability and potentially decrease costs in Nigeria. According to various key informants, in 2017 manufacturers expressed that they were not able to produce RUTFs locally because they did not have approval from the national drug regulatory body on the official need in the country. The addition of RUTFs to the national essential medicines list has allowed the Nigerian Government to explicitly state the need for RUTFs. National production has been authorized and has begun. An industrial local conglomerate, in collaboration with an international manufacturer, is preparing to produce RUTFs, while another company is already manufacturing RUTFs (25).

RUTFs have been integrated in the health system supply chains in Burkina Faso and Zimbabwe, and partly in Nigeria. In Burkina Faso, the central purchasing mechanism for medicines and medical products for the government now handles all purchasing and distribution of RUTFs (Biga A. Interviews with Action Against Hunger health and nutrition team in Burkina Faso, November 2016 and August 2018). In Zimbabwe, RUTFs are integrated into the regular supply chain and are ordered and distributed with other medications. The National Pharmacy in Zimbabwe now handles distribution of RUTFs, although storage of RUTFs is separate from other medicines, to avoid attracting rodents. According to respondents, this progress has to be nuanced by limited funding for cascading RUTF supply-chain management training to key cadres, and lack of funding to include nutritionists and other key personnel in peripheral health centres, resulting in potential issues for a reactive management of supplies and heavy reliance on UNICEF to cover most procurement costs (24). In Nigeria, according to one key respondent, RUTFs are procured by UNICEF, which then delivers them in some cases to government warehouses. In other cases, UNICEF distributes RUTFs directly – a memorandum of understanding has been signed between the Nigerian Government and UNICEF for the procurement of RUTFs (25).

The measure has led to an improvement in the management of supply chains by the Ministry of Health in Zimbabwe. According to a representative of the Ministry of Health, the National Pharmacy Company is now seen as having full capacity to manage the supply chain and provide technical expertise, and to have sufficient storage facilities and adequately sized vehicles for distribution. Integration into the national distribution system has led the Ministry of Health to perform quantification and supply planning for RUTFs, generating an increase in the data available on stocks and deliveries, which influences the budget allocated to RUTFs by the government (24).

The measure has contributed to significant availability of RUTFs in targeted areas in Zimbabwe. As RUTFs are now included in national forecasting and quantification, 94–100% of health facilities targeted by the government to receive RUTFs effectively received them in quarter 3 of 2013 and quarter 3 of 2015 (26–28). It was not clear how representative the health facilities targeted are of the needs at country level. Early findings suggest that stockouts remain a problem, owing to lack of reporting by health facility staff and lack of funding (24).

Interviews with key informants
This section is a synthesis of the personal views of the 16 respondents interviewed, as they relate to the themes of the article. It represents a summary of their responses to the question of adding RUTFs to national essential medicines lists and the EML. The findings are divided between two parts: in the first part, respondents defined under which conditions RUTFs could be added to an essential medicines list; the second part related to opportunities and threats generated by this move.

Respondents were asked whether RUTFs should be added to national essential medicines list and the EML. Most of them expressed that before assessing threats and opportunities, the specific circumstances under which RUTFs could be added to an essential medicines list should be defined.
Preliminary conditions as described by respondents

Risks associated with pharmaceutical standards

RUTFs are not a single product. Recipes can differ but have the same or similar nutritional value. Some respondents argued that RUTFs are foods with therapeutic properties, but others argued that they have an active principle, which makes them medicines. All respondents agreed that RUTFs had benefits that could be labelled as therapeutic and life-saving. Four respondents argued that although RUTFs are medicines in part, developing pharmaceutical standards for RUTFs would hinder local production or drastically increase production costs because products added to the EML must follow specific pharmaceutical standards. Eleven respondents agreed that RUTFs could be added to an essential medicines list if there were no associated pharmaceutical standards.

Microbiological safety

The current recommendations as per the joint statement by WHO, UNICEF, the World Food Programme and the United Nations System Standing Committee on Nutrition on community-based management of severe acute malnutrition are to hold RUTFs to standards set by the Codex Alimentarius. However, this was seen as insufficient to guarantee microbiological safety: 12 respondents felt that along with integration of RUTFs in the EML, a specific Codex guideline for RUTFs should be developed to further ensure the microbiological safety of RUTFs; to ensure there are uniform standards for composition of RUTFs; and to avoid countries adopting different national standards for RUTFs. However, two respondents expressed concern that creating a Codex guideline risks “commodifying” RUTFs, indicating to the public that they are sold everywhere and for regular use.

Appropriate category in the WHO Model List of Essential Medicines

To avoid the risk of the process of integration of RUTFs in an essential medicines list starting the development of unwanted pharmaceutical standards, six respondents felt that RUTFs could fall under a specific category, “miscellaneous”, which was believed to not be directly associated with pharmaceutical standards. One respondent suggested that a new category, “blood and nutrition”, should replace the current “blood” section in the EML. The EML is based on the British National Formulary (BNF), and the category in the BNF for Children was changed to “blood and nutrition” in 2009 to include oral nutrition and food for special diets.

Arguments in favour of and against adding ready-to-use therapeutic foods to the WHO Model List of Essential Medicines

Arguments in favour

Fourteen respondents were in favour of adding RUTFs to the EML. Their arguments are described here.

- Political commitment to address acute undernutrition: 10 respondents emphasized the political and psychological impact that inclusion in the EML would have on decision-makers at the national level. Stakeholders believed it would contribute to prioritizing treatment for severe acute undernutrition and potentially encourage governments to include a provision for management of severe acute undernutrition in their national budgets. However, given that the EML and national essential medicines lists are not systematically linked, two respondents highlighted that impact at the national level was not guaranteed, especially in low-resource settings.

- Integration of nutrition within health systems: interviewees argued that the addition of RUTFs to the EML would lead to better integration of treatment for severe acute undernutrition within national health systems and avoid vertical parallel set-ups. This was the most recurring theme from respondents. Interviewees argued it would empower more national authorities to ensure RUTFs are available. One respondent expressed that “integration of nutrition within health systems is part of a larger movement for better integration of nutrition and stronger health systems and to achieve sustainable results”.

- Complementing existing efforts: interviewees argued that the addition of RUTFs to the EML would complement existing national efforts to address acute undernutrition. They believed it would provide a framework for national authorities to ensure RUTFs are available and accessible to the population.
• **Financial resources**: two respondents argued that the addition of RUTFs to the EML would prompt governments to allocate budgets to purchase RUTFs. Four respondents thought this could contribute to a decrease in the cost of RUTFs, which would then allow countries to buy more RUTFs and thus increase coverage. Six respondents argued that having RUTFs in the EML would stimulate local production of RUTFs and lead to potentially larger-scale production, which would decrease the cost per sachet.

• **Better use**: according to one respondent, there were occurrences of misuse of RUTFs in the United Republic of Tanzania – mothers shared them between their children as meals or resold them. However, once RUTFs were distributed through pharmacies and on prescription, they began to be considered as medicines, which helped to control misuse.

• **Easier procurement**: six respondents argued that adding RUTFs to the EML would encourage national governments to integrate RUTFs into their national distribution systems along with other essential medicines. These respondents argued that this would make the procurement of RUTFs easier and thus they would be more accessible for people who need them. This would also decrease the chance of stockouts, which are a frequent problem. However, one respondent raised the concern that it could also overburden national pharmacies with additional stocks.

**Arguments against**

Numerous risks associated with adding RUTFs to the EML were identified by respondents. These concerns are outlined here.

• **Quality control**: two respondents were concerned with the standards that may be applied to RUTFs if they were added to the EML as medicines, even if they were under a specific category. If the pharmaceutical or microbiological standards are too strict, this may limit producers’ ability to meet them, thus reducing local production. If the standards are too lax, the quality of RUTFs would diminish.

• **Commodification**: seven respondents raised the issue of the perception of RUTFs by the public. These respondents were concerned that adding RUTFs to the EML, and inspiring countries to add RUTFs to their own essential medicines lists, does not guarantee how national governments will categorize them. Two respondents feared that if RUTFs were to be perceived as commodities that are easily bought and sold, rather than as important nutritional or medical products, then they could be misused. One respondent feared that the development of a Codex guideline to ensure the microbiological safety of RUTFs could lead to availability of RUTFs outside of the health system, such as in supermarkets, thus jeopardizing other food-based, preventive approaches.

• **Overmedicalization**: two respondents expressed concern that the treatment of severe acute malnutrition is becoming too medicalized and product focused. Some respondents voiced further concern about this product-based approach, citing its potential to undermine breastfeeding practices, which are a deterrent to undernutrition.

• **Low capacity of some national health systems**: two respondents argued that having RUTFs in national essential medicines lists and the EML is not a suitable option for all contexts. For example, in fragile contexts with low capacity of national pharmacies and health workers, the centralized acquisition and distribution of RUTFs by governments could put at risk existing efforts to increase national coverage, by deconstructing existing parallel supply chains, leading to stockouts.
Discussion

National essential medicines lists

Not an option in specific settings
The cases of Chad and the Democratic Republic of the Congo suggest that inclusion is not associated with any impact if the list is not used routinely in supply-chain management. This measure is thus likely to have a limited impact in countries with fragile health systems. It could even overburden the health system. Interested countries should thus assess the capacity of national pharmacies beforehand.

Increase in government funding available and required by governments and donors
In Burkina Faso and Zimbabwe, inclusion has led to an increase in government funding allocated to procurement of RUTFs. This is a clear indication of an increase in political commitment towards eradication of severe acute undernutrition. It also suggests increased ownership of this matter by the government. However, 100% coverage of the costs by governments seems unlikely in the coming years. Plans to scale up government contributions will need to be monitored carefully by nutrition advocates, to avoid decreased prioritization. Donors will need to continue to fill the funding gap and increase their resources, in order to increase treatment coverage for severe acute undernutrition and strengthen preventive efforts. Indeed, increased funding is also needed for other components of the management of severe acute undernutrition (human resources) and to increase its prevention.

Conflicting perspectives on decrease of cost
Given existing price constraints, and if the quality and safety of RUTFs are to be maintained, there is little evidence that adding RUTFs to national essential medicines lists will decrease their cost.

Sustained efforts to strengthen supply chains are needed
Burkina Faso and Zimbabwe have integrated RUTFs into their government supply chains, potentially addressing availability issues. However, transportation and stockouts have not disappeared and still need to be mitigated by authorities and partners who offer support. In addition, a significant amount of research is needed to assess the long-term impact on stockouts and their prevention.

The WHO Model List of Essential Medicines

Caution needed on mechanisms to ensure safety
Quality assurance of RUTFs remains a sensitive issue. RUTFs should not be held to pharmaceutical standards, but a Codex guideline also represents a threat if it is too stringent or too lenient. Countries have added RUTFs to their national essential medicines lists without much debate on quality-assurance mechanisms, suggesting that these are not seen as a barrier to integration or that the risk is offset by the expected benefits.

Regarding the concern that creating a Codex guideline would risk commodifying RUTFs, a Codex guideline does not have a direct impact on that issue. It sets common standards for RUTFs (e.g. definition, use, ingredients, nutritional requirements, labelling, hygienic practices). Codex guidelines do not determine where RUTFs can be sold, but on the other hand they do not explicitly prevent RUTFs from being supplied to individuals or supermarkets – it is currently the responsibility of RUTF producers to avoid this situation. A formal ban on selling RUTFs to anyone not representing the not-for-profit sector (UNICEF, nongovernmental organizations, governments) could be considered.
Expected catalytic impact at country level

It is difficult to speculate on the potential outcomes of adding RUTFs to the EML, as there is only experience at the country level to draw upon.

Many respondents raised the idea that having RUTFs on national essential medicines lists would probably improve the perception of the treatment, encouraging proper use. This expected impact should be quantified through further studies. At the time of the study, it was not possible to access quality data to assess the effective impact over the years in terms of reduced stockouts in Zimbabwe. More research is needed to quantitatively assess the impact in countries that have added RUTFs to their national essential medicines lists.

Addition of RUTFs to national lists in some countries highlights that national essential medicines lists and the EML are not systematically linked. However, the EML remains a normative reference for many countries. In practice, the EML is used as the foundation of many national essential medicines lists (31). More often than not, the addition of a product by WHO to the EML is taken by countries as an indication that they should make this product available and affordable. Thus, it is likely that the integration of RUTFs in the EML would create the political will to prioritize treatment of severe acute undernutrition and the addition of RUTFs to national essential medicines lists. If RUTFs are integrated in the EML, then it can also be used as a tool for advocates to increase the availability of targeted medicines.

A key measure out of the many needed to address undernutrition

As highlighted by respondents, RUTFs are the recommended treatment for uncomplicated severe acute undernutrition for children aged under 5 years. The scientific evidence on the impact of RUTFs is limited, as are comparable national data on programming and cure rates for severe acute undernutrition. RUTFs are expensive, and low coverage rates suggest that current efforts are insufficient. Innovative methods are needed to ensure more children with severe acute undernutrition are treated. Efforts to increase treatment coverage for severe acute undernutrition are needed but should not overshadow the broad range of measures needed to adequately prevent undernutrition. In particular, respondents highlighted the need to strengthen health systems.

This study does not allow conclusions to be drawn on other nutritional products. The discussion of adding RUTFs to the EML does not extend to other products.

Conclusion

The findings from this study demonstrate the public health relevance of and support for adding RUTFs to national essential medicines lists and the EML. The literature review suggests that adding RUTFs to national essential medicines lists would facilitate procurement of RUTFs and encourage governments to incorporate them into their budgets. The country mapping showed that RUTFs are classified in a variety of different ways around the world, as governments manoeuvre to register and facilitate procurement of these products. Through government-led efforts, Zimbabwe and Nigeria recently added RUTFs to their national essential medicines lists within 2 years. To a certain extent, this led to an increase in the funding available for the management of severe acute undernutrition and local production of RUTFs, and improvement of management of RUTF supplies and availability. Some concerns remain over the best ways to establish safety standards for RUTFs. More research is needed to quantify impact. Adding RUTFs to national essential medicines lists and the EML is likely to mobilize political commitment to improve the treatment of severe acute undernutrition, and to facilitate use, availability, procurement and cost reduction. Additional measures are required to improve prevention and treatment of severe acute undernutrition.
References


Appendix 3.3.1
Interviews of key informants: standard questionnaire

Introduction: Brief the respondents on the objectives and method of the study

A. Questions on the method of the study
   a. Ready-to-use therapeutic food (RUTF) as essential medicine: what do you think about this idea? Would it help secure national supplies of RUTFs?
   b. What do you think about our objectives and our methodology?
   c. Who are the international key players who decide on this matter for the World Health Organization (WHO) list? Who should we interview? Can you introduce them to us?

B. On the WHO Model List of Essential Medicines (EML) and process of inclusion in WHO and national lists of essential medicines
   1. Objectives:
      a. Why is this change promoted by some?
      b. What is the evidence base to support this claim?
      c. What kind of change is promoted and why this change exactly? (Probes: RUTF, F-75 and F-100, or RUTF solely, RUTF on the EML, RUTF on the commodities list? Listed as an item? Can locally produced RUTF be "eligible"?)
      d. Does addition in the EML play a normative role in acceptance of RUTF?
   2. Status of ready-to-use therapeutic foods: the WHO Model List of Essential Medicines and the Codex
      a. Are RUTFs a drug, a food or both?
      b. Have technical implications of a potential inclusion already been mentioned, and which are they? (Probes: for instance, will RUTFs be recognized as medicines? Does it change technical standards for RUTFs in country?)
   3. Key stakeholders
      a. Who are the actors who are contributing to the decision to add RUTFs to the EML?
      b. What is the role of the private sector? And, specifically, of RUTF producers?
   4. Implementation
      a. If RUTFs are integrated in the EML, what will be the impact on national medicines lists?
      b. Will the United Nations Children’s Fund (UNICEF) and WHO in high-burden countries push for addition in national essential medicines lists?
      c. Do you know examples of countries that have added RUTFs to their national essential medicines list and have had successful outcomes?
      d. Does integration of RUTFs in national essential medicines lists potentially include locally produced RUTFs, or only imported RUTFs? What kind of locally produced RUTFs would be eligible to be distributed? (Probe: solely validated by UNICEF, Médecins Sans Frontières International or the World Food programme, or other national available products)
      e. What are the cost implications, logistics and practical considerations? (Probe: increase of budget in WHO or UNICEF to avoid stockouts? Is addition of a drug to the EML linked with addition of a budget line for this drug?)
   5. Distribution systems at national level
      a. What are the links between the national essential medicines list and national distribution systems? (Probe: does an addition on the national essential medicines list automatically imply a legal obligation to add RUTF or other medicines to national distribution systems? Is this the case in other countries?)