

MEETING REPORT

**WHO technical consultation:
Nutrition-related health products and the
*World Health Organization Model
List of Essential Medicines* –
practical considerations and feasibility**

Geneva, Switzerland
20–21 September 2018



**World Health
Organization**

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ABBREVIATIONS

ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency), Brazil
COFEPRIS	Federal Commission for Protection against Sanitary Risk, Mexico
EML	<i>WHO Model List of Essential Medicines</i>
EMLc	<i>WHO Model List of Essential Medicines for Children</i>
FAO	Food and Agriculture Organization of the United Nations
GPW13	World Health Organization Thirteenth General Programme of Work 2019–2023
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
RUSF	ready-to-use supplementary food
RUTF	ready-to-use therapeutic food
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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EXECUTIVE SUMMARY

Access to essential medicines is a core element of universal health coverage and therefore a priority for the World Health Organization (WHO). Nutrition-related health products are commonly used in public health and clinical settings to address any form of malnutrition, and particularly to prevent and treat undernutrition¹ or micronutrient deficiencies. These include formulations such as ready-to-use therapeutic foods (RUTFs),² therapeutic milks (F-75, F-100), iron-containing multiple-micronutrient powders, and vitamin and mineral supplements. Other medicines or health products used in disease prevention, treatment and management and rehabilitation and palliative care services, may have relevance for nutrition-related conditions and throughout the life-course. Access to and availability of these nutrition-related health products is of high priority, owing to the unabating trends in undernutrition in some parts of the world. Undernourished children, particularly those with severe undernutrition,³ have a higher risk of death from common childhood illnesses such as diarrhoea, pneumonia and malaria. Nutrition-related factors contribute to about 45% of deaths in children under 5 years of age.⁴ In 2017, 2.4% of the children worldwide under 5 years of age were affected by severe wasting, corresponding to a global burden of 16.4 million.⁵ The WHO regions most affected were the South-East Asia Region (8.7 million), the African Region (3.4 million) and the Eastern Mediterranean Region (3.2 million). It is indicated that children affected by severe wasting have a higher risk of mortality.⁴ The prioritization of, subsequent access to, and availability of, medicines at the country level is often guided by the *WHO Model List of Essential Medicines* (EML). Including nutrition-related health products in the EML can support the development, review and updating of national lists of essential medical products.

The WHO Department of Nutrition for Health and Development, in collaboration with the Department of Essential Medicines and Health Products, convened a technical consultation in Geneva, Switzerland on 20–21 September 2018, to gather stakeholders' views on considerations related to, and the feasibility of, including nutrition-related health products in the EML. Stakeholders at the consultation included representatives from governmental agencies, intergovernmental agencies, non-state actors in official relations with WHO, and the private sector.

The objectives of this consultation were to (i) identify common criteria that characterize a nutrition-related health product for potential listing in the EML; (ii) evaluate advantages and disadvantages of listing RUTFs and other nutrition-related health products in the EML, in particular considering manufacturing standards for foods and pharmaceuticals; (iii) identify which dimensions and elements (e.g. availability, access, cost, alternative formulations, quality, country preferences) and trade-offs are considered by stakeholders when assessing RUTFs and other nutrition-related health products for improved access in public health; and (iv) discuss country experiences in the regulatory processes that could help to improve access to nutrition-related health products.

This report summarizes the presentations, some country perspectives and discussions that occurred during the technical consultation and does not contain any official WHO recommendations.

Before the meeting, WHO launched a call for authors covering the proposed objectives. Six papers were selected and presented at the meeting, which also included presentations on other topics of interest and several discussion sessions. Five of the six commissioned papers are published as part of this report.

¹ Guideline: updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013 (https://apps.who.int/iris/bitstream/handle/10665/95584/9789241506328_eng.pdf?ua=1, accessed 25 February 2019).

² Ready-to-use therapeutic foods (RUTFs) are specially formulated foods for the treatment of infants and children aged 6 months or older, with severe acute undernutrition, who have appetite and do not have medical complications. These health products are nutrient dense, and contain adequate protein and other essential nutrients such as vitamins and minerals. These foods are soft or crushable and can easily be eaten without any additional preparation. They are consumed without adding water, have a low risk of bacterial contamination, require no refrigeration and have a nutritional composition based on the F-100 therapeutic milk used in hospital settings.

³ 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 herewith to convey that reference is made to undernutrition only and not to all other types of malnutrition.

⁴ Children: reducing mortality. Factsheet. Geneva: World Health Organization; 2018 (<http://www.who.int/mediacentre/factsheets/fs178/en/>, accessed 25 February 2019).

⁵ Levels and trends in malnutrition. UNICEF/WHO/World Bank Group joint child malnutrition estimates. Key findings of the 2018 edition. New York, Geneva and Washington (DC): United Nations Children's Fund (UNICEF), the World Health Organization and the International Bank for Reconstruction and Development/The World Bank; 2018 (<https://www.who.int/nutgrowthdb/2018-jme-brochure.pdf?ua=1>, accessed 25 February 2019).

The topics covered included the EML and the criteria for selection of medicines included in it; data on the efficacy, safety, feasibility and availability of products; and a mapping of the nutrition-related health products in the 2017 EML and the *WHO Model List of Essential Medicines for Children* (EMLc), showing efficacy data on vitamins and minerals used in the management of anaemia or as coadjuvants in the treatment of diarrhoea, and as dietary supplements.

Some of the current WHO recommendations that involve nutrition-related health products were discussed. It was made clear that, although the WHO guidelines and other official documents make recommendations for nutrition interventions that include nutrition-related health products, not all recommended nutrition-related health products are currently included in the EML.

The public health sector perspectives on the regulatory aspects of nutrition-related health products included country-specific perspectives from Brazil, Cameroon, India, Mexico, Nigeria, the Plurinational State of Bolivia, South Sudan and Sudan. In Brazil and Mexico, nutrition-related health products are regulated under their current regulatory frameworks, although RUTFs are not currently included in their national lists. The Plurinational State of Bolivia, Nigeria, Sudan and South Sudan already include RUTFs and other nutrition-related health products in their national lists. The Food Safety and Standards Authority of India has specific classifications for nutrition-related health products that are likely to classify RUTFs as foods for special medical purposes. The regulatory framework that defines nutrition-related health products as foods, medicines or foods for special medical purposes varies across countries.

The role of the Codex Alimentarius,¹ particularly the Codex Committee on Nutrition and Foods for Special Dietary Uses, in relation to the status of the ongoing project to develop a guideline for RUTFs, was discussed in a presentation about international guidelines and standards in the production of foods for special dietary uses and foods for special medical purposes.

The WHO Department of Food Safety and Zoonoses presented on the food safety considerations related to nutrition-related health products. WHO also provided context on therapeutic milks² and supplementary foods³ in the management of acute undernutrition, which outlined severe and moderate acute undernutrition and the specific recommendations. RUTFs are developed as foods that are ready to use without preparation at home, for treatment of infants and children with severe acute undernutrition without medical complications.⁴

An assessment of the perceptions of some stakeholders about the inclusion of RUTFs and other nutrition-related health products in the EML was widely discussed and summarized. It was reported that nutrition-related health products are not consistently classified by various governmental regulatory agencies in WHO Member States. In various countries, RUTFs, for example, are defined as either foods for special dietary uses or medicines. While most stakeholders identified the availability of and access to RUTFs as a challenge in many countries, particularly due to perceived cost, their views varied on whether inclusion in the EML would help or aggravate these challenges. Another assessment weighed the benefits and costs of adding RUTFs and other nutrition-related health products to the EML. The views of stakeholders were divergent and raised concerns on the potential impact that the inclusion might have on local production and alternative formulations, and on uncertainties about how categorization and regulation in the country might impact on access to these products.

¹ Joint FAO/WHO Codex Alimentarius Commission. Codex Alimentarius: procedural manual, 26th ed. Rome: World Health Organization/Food and Agriculture Organization of the United Nations; 2018 (<http://www.fao.org/3/i8608en/i8608EN.pdf>, accessed 25 February 2019).

² Therapeutic milks are specially formulated foods used in the treatment of severe acute undernutrition. Therapeutic milks include feeding formulas such as F-75 and F-100, used in the stabilization and rehabilitation phases in hospital settings.

³ Supplementary foods are specially formulated foods in ready-to-eat or milled form that are modified in their energy density, and protein, fat or micronutrient composition, to help meet the nutritional requirements of specific populations. Supplementary foods are not intended to be the only source of nutrients and are different from complementary foods, in that the latter are intended for progressive adaptation of infants aged 6 months and older to the food of the family. Supplementary foods are also different from food supplements, which refer to vitamin and mineral supplements in unit dose forms, such as capsules, tablets, powders or solutions, where national jurisdictions regulate these products as foods. Supplementary foods have been used to rehabilitate people with moderate acute malnutrition and to prevent deterioration of the nutritional status of people most at risk, by meeting their additional needs, focusing particularly on children aged 6–59 months, pregnant women and lactating women. Examples of supplementary foods include fortified blended foods (corn–soy blend, wheat–soy blend) and lipid-based nutrient supplements (ready-to-use supplementary foods).

⁴ World Health Organization. e-Library of Evidence for Nutrition Actions (eLENA). Transition feeding of children 6–59 months of age with severe acute malnutrition (https://www.who.int/elena/titles/transition_feeding_sam/en/, accessed 25 February 2019).

Other presentations covered various aspects of the inclusion of nutrition-related health products in the EML. One covered the process and impact of integration of RUTFs in national essential medicines lists and reported that adding RUTFs to national essential medicines lists and the EML would probably mobilize political commitment to improve treatment of severe acute undernutrition, improve the availability of these products, facilitate their use and reduce costs. A case-study of RUTFs being included in a national essential medicines list was presented; it focused on the public health relevance of including specialized nutrition-related health products in the *South Sudan Essential Medicine List* and summarized the complex multisectoral process that is being undertaken by the Ministry of Health, aided by WHO and other partners. The inclusion of nutrition-related health products (RUTFs, ready-to-use supplementary food [RUSFs], therapeutic milks F-75 and F-100) in national essential medicines lists supports national prioritization, procurement and distribution, and their use in the existing health-care system. In another case-study from the Plurinational State of Bolivia, the availability of RUTFs for the management of acute undernutrition drew attention to factors such as the existing legal framework, public health insurance, and the implementation of the Programa Multisectorial Desnutrición Cero¹ (Zero Malnutrition Programme), which seem to have facilitated the process of including RUTFs in the national list and ensuring the sustainability of their use.

A panel discussion with manufacturers, intergovernmental agencies and nongovernmental organizations reflected on challenges at the country level in access to nutrition-related health products, with a focus on purchasing and production. It was noted that there are clear challenges with regard to the coexistence of positive and negative considerations for inclusion of RUTFs and other nutrition-related health products in the EML and EMLc.

Overall, the presentations and discussions covered the proposed meeting objectives and some challenges were identified. A definition of common criteria is needed to consider the inclusion of nutrition-related health products in the EML, since stakeholders' perceptions of including RUTFs in the EML vary and are sometimes contradictory. Most of the divergences found in the experts' assessments are explained by the uncertainties about how RUTF products will be classified and regulated at the country level. On the other hand, country case-studies concluded that the inclusion of RUTFs in national essential medicines lists has supported national prioritization, procurement and distribution, as well as their use in the existing health-care system.

This technical consultation and a statement by the WHO Department of Nutrition Health and Development on RUTF,² constitute part of the analysis requested by the Expert Committee on Selection and Use of Essential Medicines when considering the application for inclusion of RUTFs in the WHO EML for the dietary management of uncomplicated severe acute undernutrition in children under 5 years of age. These activities are in line with WHO functions and efforts to accelerate progress towards achieving the Global Nutrition Targets,³ as well as the WHO triple billion goals,⁴ in the key areas of guidance; policy; surveillance; and engagement for achieving universal health coverage, addressing health emergencies and promoting healthier populations.

Nutrition-related health products are already included in the EML and EMLc and in various national essential medicines lists. The process of considering the feasibility and practicality of including nutrition-related health products with a food matrix poses a different challenge. The case raised by the application of RUTFs can be used as an index case to develop the needed framework that may be applicable to additional nutrition-related health products in the future, and the feasibility of creating a new list for nutrition-related health products or a new section for nutrition-related health products in the EML.

The presentations and discussions are summarized in this report, which also contains the full-text versions of five of the manuscripts that served as the basis for the consultation.

¹ Programa Multisectorial Desnutrición Cero (<https://www.plataformacelac.org/en/programa/174>, accessed 1 April 2019).

² World Health Organization. Essential medicines selection. Report on ready-to-use therapeutic food (RUTF). 22nd Expert Committee on the Selection and Use of Essential Medicines (https://www.who.int/selection_medicines/committees/expert/22/applications/rutf_nhd-report/en/, accessed 25 February 2019).

³ World Health Organization. Global Nutrition Targets 2025. Policy brief series (https://www.who.int/nutrition/publications/globaltargets2025_policybrief_overview/en/, accessed 25 February 2019).

⁴ World Health Organization. 13th General Programme of Work. Overview. Geneva: World Health Organization; 2018 (<http://g2h2.org/wp-content/uploads/2018/01/Peter-A-Singer-GPW-briefng.pdf>, accessed 25 February 2019).

INTRODUCTION

Access to essential medicines is a core element of universal health coverage and therefore a priority for the World Health Organization (WHO). Nutrition-related health products are commonly used in public health and clinical settings to address any form of malnutrition, and particularly to prevent and treat undernutrition (1), or micronutrient deficiencies. They include formulations such as ready-to-use therapeutic foods (RUTFs),¹ therapeutic milks (F-75, F-100), iron-containing multiple-micronutrient powders, and vitamin and mineral supplements. Other medicines or health products used in disease prevention, treatment and management and rehabilitation and palliative care services, may have relevance for nutrition-related conditions throughout the life-course. Access to and availability of these nutrition-related health products is of high priority, owing to the unabating trends in undernutrition in some parts of the world. Undernourished children, particularly those with severe acute undernutrition,² have a higher risk of death from common childhood illness such as diarrhoea, pneumonia and malaria. Nutrition-related factors contribute to about 45% of deaths in children under 5 years of age (3). In 2017, 2.4% of the children worldwide under 5 years of age were affected by severe wasting, corresponding to a global burden of 16.4 million (4). The WHO regions most affected were the South-East Asia Region (8.7 million), the African Region (3.4 million) and the Eastern Mediterranean Region (3.2 million). In 2013, 7.4% of all deaths among children under 5 years of age were related to severe wasting (516 000 deaths) (5). Globally, it is estimated that less than 15% of severe wasting in children under 5 years of age is treated (6).

WHO recommended the approval of its draft Thirteenth General Programme of Work 2019–2023 (GPW13) by the 71st World Health Assembly (7). The GPW13 is focused on three interconnected strategic priorities to ensure healthy lives and promote well-being for all at all ages, by advancing universal health coverage, addressing health emergencies, and promoting healthier populations.

It is estimated that half of the world's population cannot obtain essential health services (8). Universal health coverage means that all people receive the quality health services they need without suffering financial hardship. These include public health services designed to promote better health, to prevent illness, and to provide treatment, rehabilitation and palliative care of optimal quality. Appropriate access to affordable and quality-assured medicines, vaccines and health products (including diagnostics and devices, blood and blood products, and nutrition-related health products) is part of universal health coverage.

Access to nutrition-related health products may be improved by including them in the *WHO Model List of Essential Medicines* (EML) (9), a core element of universal health coverage. In addition, some of these products may be registered as foods for special medical purposes at the country level.

Over the past years, nutrition-related health products used in public health and clinical interventions have been developed to prevent and treat undernutrition: ready-to-use therapeutic foods (RUTFs), ready-to-use supplementary foods (RUSFs), therapeutic milks (F-75 and F-100), iron-containing multiple micronutrient powders, fortified staple foods, and vitamin and mineral supplements.

Undernutrition such as wasting,³ stunting⁴ and micronutrient deficiencies increases the risk of morbidity and early death in mothers, infants and young children, and impaired physical and mental development in young people (6, 11).

¹ Ready-to-use therapeutic foods (RUTFs) are specially formulated foods for the treatment of infants and children aged 6 months or older, with severe acute undernutrition, who have appetite and do not have medical complications. These health products are nutrient dense, and contain adequate protein and other essential nutrients such as vitamins and minerals. These foods are soft or crushable and can easily be eaten without any additional preparation. They are consumed without adding water, have a low risk of bacterial contamination, require no refrigeration and have a nutritional composition based on the F-100 therapeutic milk used in hospital settings.

² 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 herewith to convey that reference is made to undernutrition only and not to all other types of malnutrition (2).

³ Wasting is a reduction or loss of body weight in relation to height. Acute undernutrition in children aged 6–59 months can be moderate or severe. Severe acute undernutrition is defined as severe wasting (low weight-for-height), and/or mid-upper arm circumference less than 115 mm, and/or bilateral pitting oedema (10).

⁴ Stunting, or being too short for one's age, is defined as being of a height that is more than two standard deviations below the WHO child growth standards median (10).

WHO guidelines recommend the use of RUTFs and F-75 or F-100 as part of the management of severe acute undernutrition; other nutrition-related health products (iron-containing micronutrient powders for point-of-use fortification of foods, iron + folic acid supplements, folic acid supplements) are recommended for the prevention of nutritional anaemias and neural tube defects in women. A high-dose vitamin A supplement is recommended for vitamin A deficiency and to reduce mortality in infants and children, and calcium supplements to reduce the risk of pre-eclampsia during pregnancy (1, 12–15).

A proposed strategy to improve the access of the target population in need to nutrition-related health products is to make them part of the EML. The WHO Department of Essential Medicines and Health Products defines essential medicines as those that satisfy the priority health-care needs of the population. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price that the individual and the community can afford.

The EML serves as a guide for the development of national and institutional essential medicine lists and is updated and revised every 2 years by the WHO Expert Committee on the Selection and Use of Essential Medicines. In 2017, an application to include RUTFs in the EML was made by a nongovernmental organization. This application was reviewed, and the Expert Committee agreed on the need to improve access to RUTFs at the country level for the outpatient treatment of severe acute undernutrition. The Expert Committee considered that including RUTFs in the EML might carry implications to comply with stringent requirements for medicines or pharmaceutical products in some countries and manufacturing sites, and recommended WHO to conduct a comprehensive evaluation of the benefits and trade-offs associated with the potential listing of nutrition-related health products in the EML (16).

On 20–21 September 2018, the WHO Department of Nutrition for Health and Development, in collaboration with the Department of Essential Medicines and Health Products, convened a technical consultation: Nutrition-related health products and the *WHO Model List of Essential Medicines*: practical considerations and feasibility. The two days of technical consultation were used to identify the criteria that define a nutrition-related health product to be considered as a candidate for inclusion in the EML and to determine the advantages, disadvantages and trade-offs that would result from the inclusion of RUTFs and other nutrition-related health products in the EML.

The objectives of the technical consultation were to:

- identify common criteria that characterize a nutrition-related product for potential listing in the EML;
- evaluate advantages and disadvantages of listing RUTFs and other nutrition-related health products in the EML, in particular considering manufacturing standards for foods and pharmaceuticals;
- identify which dimensions and elements (e.g. availability, access, cost, alternative formulations, quality, country preferences) and trade-offs are considered by stakeholders when assessing RUTFs and other nutrition-related health products for improved access in public health;
- discuss country experiences in the regulatory processes that could help to improve access to nutrition-related health products.

The agenda of the first day focused on the *WHO Model List of Essential Medicines* (EML) (9) and mapping of current nutrition-related health products included in the EML. Also, WHO guidelines and food safety considerations related to nutrition-related health products, and other international guidelines and standards, were reviewed. Presentations on stakeholder's perceptions of RUTFs and other nutrition-related health products, and case-studies of adding RUTFs to essential medicines lists, were discussed during the rest of the meeting agenda. Four plenary discussion sessions were planned throughout the meeting.

Participants were selected to have representation of experts and stakeholders from different WHO regions and multiple sectors, including representatives from governmental agencies, intergovernmental agencies, non-state actors in official relations with WHO, and the private sector. Participants were invited as representatives of their organizations.

This meeting followed provisions set in the WHO *Framework of engagement with non-State actors* (17) and the procedures for management of conflicts of interests (18). Compliance assessments were performed by the responsible technical officer and the relevant WHO departments, before the meeting.

This report summarizes the discussions and presents five of the six commissioned papers that served for the discussions in the meeting. The summaries of presentations were sent to presenters for review and validation, and the background papers were peer-reviewed by external experts, who were selected based on their expertise in the field of nutrition and nutrition-related health products. A rapporteur was commissioned for development of the first draft of the report, based on the notes taken at the meeting, recordings and presentation materials. A preliminary version of this meeting report was shared with the meeting participants. Finally, the report underwent the WHO publication clearance process.

This document is not a WHO guideline and does not contain any WHO official recommendations. The named authors of the meeting presentations and background papers alone are responsible for the views expressed in this publication and this does not necessarily all meeting participants agree with the content of the report.

MANAGEMENT OF CONFLICTS OF INTEREST

The provisions set in the *Framework of engagement with non-state actors* (17) were observed in the meeting. This framework endeavours to strengthen WHO engagement with non-state actors (nongovernmental organizations, private-sector entities, philanthropic foundations, academic institutions), while protecting the outcomes of the consultation from potential risks such as conflicts of interest, reputational risks and undue influence. Additionally, the rules in the WHO *Basic documents* (19) require all experts participating in WHO meetings to declare any interest relevant to the meeting before their participation. Statements of the conflicts of interest of all participants were reviewed by the responsible technical officers and the relevant departments before the meeting. The procedures for management of conflicts of interest strictly followed the WHO *Guidelines for declaration of interests (WHO experts)* (18). The potential conflicts of interest declared by the participants attending the meeting are summarized as follows:

- Dr Eva Monterrosa declared being an employee of Sight and Life, a think tank of DSM, which is a pharmaceutical manufacturer of vitamins;
- Dr Stanley Zlotkin declared holding a registered trademark for the term “Sprinkles”, which is used in reference to micronutrient supplements in the United States of America and Canada;
- Professor Kathryn G Dewey declared receiving a research grant from the Bill & Melinda Gates Foundation supporting the work of the International Lipid-Based Nutrient Supplements project. The project focuses on the use of lipid-based nutrient supplements in Africa;
- Ms Patti Rundall declared owning 20 shares in Nestlé SA;
- Mr Thomas Couaillet declared being employed by Nutriset, which is a manufacturer of RUTFs in 11 different countries.

All other participants declared no conflicts of interest.

SUMMARY OF MEETING PRESENTATIONS

The World Health Organization Model List of Essential Medicines and criteria for selection

Presented by Nicola Magrini

The first EML was established by WHO in 1977. The purpose of the EML was to highlight the need for prioritization of essential medicines in health systems, as a guide for Member States. The current version, published in 2017, includes two lists:

- the 20th EML, which contains 433 medicines (9);
- the 6th *WHO Model List of Essential Medicines for Children* (EMLc), which contains 314 medicines (20).

WHO defines essential medicines as those that satisfy the priority health-care needs of the population, which are then incorporated in the EML to facilitate better health care, better medicines management, and lower costs. The selection of essential medicines for inclusion in the EML is guided by established procedures (21):

- disease burden and public health need and relevance;
- sound and adequate data on the efficacy (on relevant outcomes), safety and comparative cost effectiveness;
- WHO good management and oversight of conflicts of interests;
- other considerations, including feasibility, availability, different populations studied, regulatory status (off-label) and guidelines.

The process of inclusion of new medicines and amendment or removal of existing medicines from the EML is managed by the EML Expert Committee. All applications are submitted in a structured format, and the Expert Committee usually seeks early involvement of the relevant WHO technical departments. The format of the application includes a report of the cumulative evidence (e.g. systematic review) and uses the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach (22) for rating the certainty of the evidence and the strength of recommendation. Each application to the EML is evaluated by two or three independent referees previously selected to serve on the expert panel by the WHO Director-General. In addition to the expert peer-review, comments are invited from any interested WHO departments, professional societies, international agencies and academia. The Expert Committee convenes a plenary discussion on all applications and makes a recommendation without voting, in accordance with page 130 of the WHO *Basic documents*, 48th edition (19). For the purposes of transparency and dialogue, all applications, expert reviews, comments, clarification letters and technical reports of the Expert Committee meetings are made public.

Challenges in the process

Several challenges are encountered in the process of updating the EML. The major issues are as follows:

- applications are usually of variable quality and size, with a narrow focus on a single medicine (e.g. formulation, dosage);
- the evidence requires more comprehensive reviews, such as well-conducted systematic reviews;
- there is a need for more explicit priority-setting and horizon-scanning, which is further encumbered by the framework for how these are to be accomplished;
- in the selection and use of essential medicines, the Expert Committee needs to expand its description of the use of essential medicines, with input from Member States.

The EML represents a model list for both selection and implementation by individual countries and is not a regulatory tool. Local selection and reimbursement are the responsibility of individual countries, which fosters greater access to and availability of medicines in each country's essential medicines list.

Review of nutrition-related health products currently listed as essential medicines in the *World Health Organization Model List of Essential Medicines* and *Model List of Essential Medicines for Children*

Presented by Vanessa Garcia Larsen

WHO's 13th General Programme of Work (GPW13) highlights three strategic priorities (7):

- advancing universal health coverage;
- addressing health emergencies;
- promoting healthier populations.

Ensuring access to nutrition-related health products can support these strategic priorities by reducing the risk and burden of health conditions associated with deficiencies in nutritional intake. In view of this, understanding the distribution of deficiencies and their most effective treatment is useful in informing the decision-making process for inclusion of nutrition-related health products in the EML.

Key nutrition-related health products currently included in the EML and EMLc are categorized into four groups: anti-anaemia medicines, medicines for use in diarrhoea, vitamins and minerals. The categorized list of nutrition-related health products currently included in the EML and EMLc is shown in Fig. 1.

Fig. 1. Nutrition-related health products included in the 20th *World Health Organization Model List of Essential Medicines* and 6th *Model List of Essential Medicines for Children*

Anti-anaemia medicines	Diarrhoea	Vitamins	Minerals
<ul style="list-style-type: none"> ■ Iron + folic acid^a ■ Iron (ferrous salt) ■ Folic acid ■ Hydroxocobalamin 	<ul style="list-style-type: none"> ■ Zinc sulfate ■ Oral rehydration salt 	<ul style="list-style-type: none"> ■ Nicotinamide^a ■ Ascorbic acid ■ Ergocalciferol ■ Colecalciferol ■ Pyridoxine ■ Retinol ■ Riboflavin ■ Thiamine 	<ul style="list-style-type: none"> ■ Calcium^a ■ Iodine ■ Sodium fluoride

^a Included in the EML for adults only.

The evidence on efficacy and safety of these nutrition-related health products for the specified outcomes listed varies from being very effective to having no effect, in studies comparing various doses of supplementation with a different dose or placebo. The quality of evidence, as assessed by GRADE criteria (22), is variable, with most systematic reviews rating the quality of evidence as very low or moderate.

Following this review, there is a need for establishment of some minimum criteria for nutrition-related health products to be considered for potential inclusion in the EML or EMLc. These may include:

- the burden of deficiency affecting at least 5% of people (children or adults) in the general population;
- evidence that a deficiency affects specific vulnerable populations (e.g. sub-Saharan Africa, communities affected by war or post-war conflict, displacement, emergency migration);
- deficiency considered to be endemic in a specific population.

While there is a clear need for high-quality evidence from randomized controlled trials on the potential benefit of nutrition-related health products, methodological limitations in randomized-controlled trials might not necessarily account for the burden of disease and potential benefit of supplements in vulnerable populations.

World Health Organization guidelines pertaining to essential nutrition actions that require nutrition-related health products

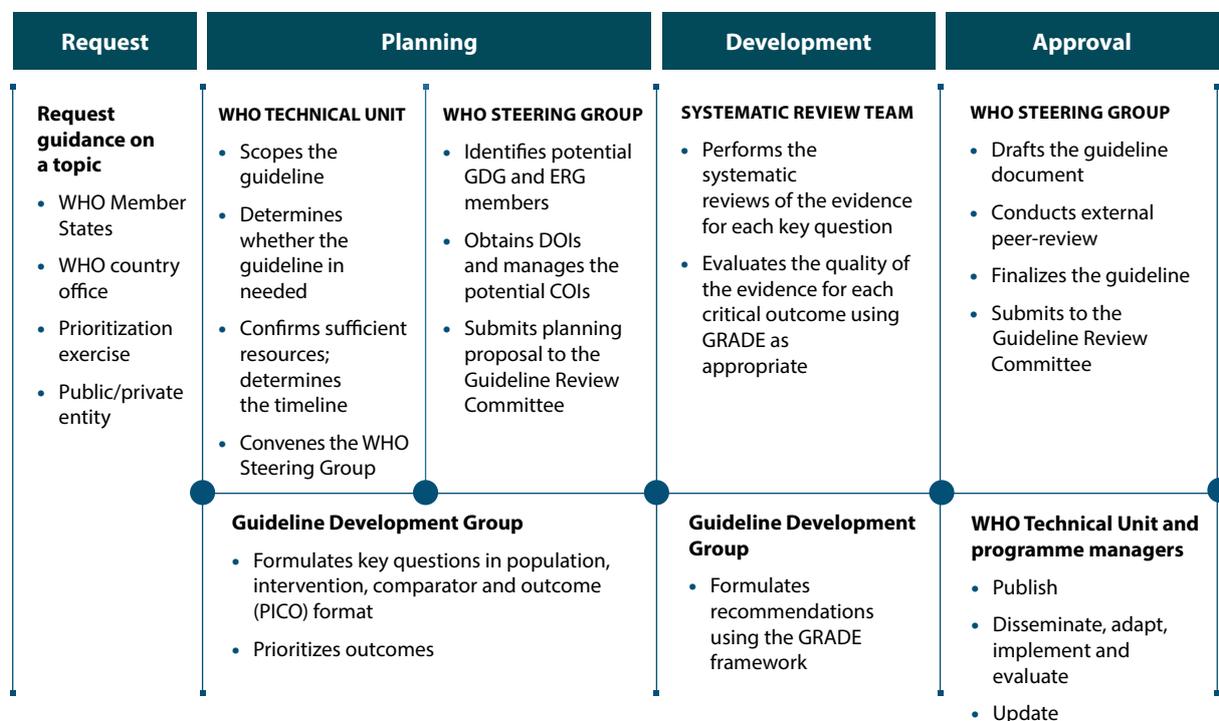
Presented by Pura Rayco-Solon

WHO recommendations for health intervention in clinical care, public health and health policy are published as guidelines. A WHO guideline is any document, whatever its title, that contains WHO recommendations about health interventions, whether they are clinical, public health or policy interventions. The recommendations provide information about what policy-makers, health-care providers or patients should do. It implies a choice between different interventions that have an impact on health and that may have ramifications for the use of resources. In addition to guidelines, WHO produces other documents that are not to be considered as guidelines, for instance information documents that report facts, descriptive evidence, or review of existing practices and interventions. There are also documents that state established principles (e.g. human rights), WHO Secretariat reports and other papers submitted to governing bodies (e.g. World Health Assembly resolutions), standard operating procedures for organizations or systems, operation manuals, and implementation guides.

Guidelines are developed through a process that is outlined in the *WHO handbook for guideline development* (23). This ensures that all WHO guidelines are scoped, evidence-informed, transparent, relevant and usable. There is a quality-assurance process, overseen by the Guidelines Review Committee Secretariat. The guideline development process is summarized in Fig. 2.

WHO has several guidelines for health interventions that include nutrition-related health products (1, 12–15, 24–39) (see Table 1). These guidelines are on a range of topics, such as provision of micronutrients through supplementation and fortification, promotion of preconception and antenatal nutrition, prevention of early pregnancy and poor reproductive outcomes, management of malnutrition, and disease prevention and management. The nutrition-related health products or medicines recommended in these guidelines, except for iron-containing multiple micronutrient powders and intermittent iron + folic acid, are included in the EML and EMLc. WHO also provides a guideline (1) and a technical note (29) for managing acute malnutrition, which recommend the use of therapeutic foods, formula diets and supplementary foods. Other medicines or health products may be used in disease prevention, treatment and management and rehabilitation and palliative care services, and have relevance for nutrition-related conditions throughout the life-course. None of the nutrition-related health products for acute malnutrition are currently included in the EML or EMLc.

Fig. 2. World Health Organization (WHO) guideline development process



COI: conflict of interest; DOI: declaration of interest; ERG: External Review Group; GDG: Guideline Development Group; GRADE: Grading of Recommendations, Assessment, Development and Evaluation.

Table 1. World Health Organization guidelines on health interventions and products recommended in public health and clinical settings^a

Guidelines related to micronutrient supplementation and fortification

Guideline	Target group	Product	EML and EMLc
<i>Guideline: daily iron supplementation in adult women and adolescent girls (24)</i>	Adult women and adolescent girls	Ferrous salt: Tablet equivalent to 60 mg iron	10. Medicines affecting the blood 10.1 Anti-anaemia medicines
<i>Guideline: daily iron supplementation in infants and children (25)</i>	Children	Oral liquid equivalent to 25 mg iron (as sulfate)/mL	
<i>Guideline: vitamin A supplementation for infants and children 6–59 months of age (14)</i>	Children	Retinol: Capsule 50 000 IU, 100 000 IU, 200 000 IU (as palmitate)	27. Vitamins and minerals
<i>Guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries (26)</i>	Infants aged 2 weeks to 6 months	Ferrous salt: Oral liquid equivalent to 25 mg iron (as sulfate)/mL	10. Medicines affecting the blood 10.1 Anti-anaemia medicines
		Colecalciferol: Oral liquid 400 IU/mL	27. Vitamins and minerals
		Ergocalciferol: Oral liquid: 250 µg/mL	

Guideline	Target group	Product	EML and EMLc
<p><i>Guideline: use of multiple micronutrient powders for point-of-use fortification of foods consumed by infants and young children aged 6–23 months and children aged 2–12 years (13)</i></p> <p><i>Preventing and controlling micronutrient deficiencies in emergencies. Multiple vitamin and mineral supplements for pregnant and lactating women, and for children aged 6–59 months (27)</i></p>	Infants and young children	Multiple micronutrient powders	—
<p><i>Vitamin and mineral requirements in human nutrition (28)</i></p>	Infants and young children	Ascorbic acid Hydroxocobalamin Pyridoxine Riboflavin Thiamine	27. Vitamins and minerals
<p><i>Guideline: fortification of rice with vitamins and minerals in public health (29)</i></p> <p><i>WHO guideline: fortification of maize flour and corn meal with vitamins and minerals (30)</i></p> <p><i>Fortification of food-grade salt with iodine for the prevention and control of iodine deficiency disorders (31)</i></p>	Populations	Fortificants Iron Folic acid Vitamin A (rice) Iodate or iodide (salt)	—

Guidelines related to preconception

Guideline	Target group	Product	EML and EMLc
<p><i>Guideline: intermittent iron and folic acid supplementation in menstruating women (12)</i></p> <p><i>Guideline: daily iron supplementation in adult women and adolescent girls (24)</i></p> <p><i>Weekly iron–folic acid supplementation (WIFS) in women of reproductive age; its role in promoting optimal maternal and child health (32)</i></p>	Menstruating women	Iron + folic acid tablets	10. Medicines affecting the blood 10.1 Anti-anaemia medicines

Guidelines related to antenatal care

Guideline	Target group	Product	EML and EMLc
<i>Recommendations on antenatal care for a positive pregnancy experience (33)</i>	Pregnant women	Ferrous salt: Tablet: equivalent to 60 mg iron	10. Medicines affecting the blood 10.1 Anti-anaemia medicines
<i>Integrated Management of Pregnancy and Childbirth. Standards for maternal and neonatal care (34)</i>		Folic acid: Tablet: 400 µg (periconceptual use), 1 mg, 5 mg	
		Iron + folic acid tablets: Tablet: 60 mg iron + 400 µg folic acid	
<i>WHO recommendation: calcium supplementation during pregnancy for prevention of pre-eclampsia and its complications (15)</i>	Pregnant women	Calcium: Tablet: 500 mg (elemental)	27. Vitamins and minerals
<i>Reaching optimal iodine nutrition in pregnant and lactating women and young children (35)</i>	Pregnant or lactating women with active tuberculosis Moderate undernutrition with active tuberculosis	Iodine: Capsule: 200 mg Iodized oil: 1 mL (480 mg iodine), 0.5 mL (240 mg iodine) in ampoule (oral or injectable), 0.57 ml (308 mg iodine) in dispenser bottle	

Guidelines related to management of acute malnutrition

Guideline	Target group	Product	EML and EMLc
<i>Guideline: updates on the management of severe acute malnutrition in infants and children (1)</i>	Children with severe acute malnutrition	Ready-to-use therapeutic foods Therapeutic milks: F-75 F-100	—
<i>Technical note: supplementary food for the management of moderate acute malnutrition in infants and children 6–59 months of age (36)</i>	Children with moderate acute malnutrition	Ready-to-use supplementary foods (proposed nutrient composition)	—

Guidelines related to disease prevention and management

Guideline	Target group	Product	EML and EMLc
<i>Ending preventable child deaths from pneumonia and diarrhoea by 2025: the integrated Global Action Plan for Pneumonia and Diarrhoea (GAPDD) (37)</i>	Children	Zinc sulfate: Solid oral dosage form: 20 mg (in acute diarrhoea) Oral rehydration salts: Powder for dilution in 200 mL, 500 mL, 1 L	17. Gastrointestinal medicines 17.5 Medicines used in diarrhoea 17.5.2 Medicines for diarrhoea 26. Solutions correcting water, electrolyte and acid–base disturbances 26.1 Oral
<i>Guideline: preventive chemotherapy to control soil-transmitted helminth infections in at-risk population groups (38)</i>	Children, non-pregnant adolescent girls and women of reproductive age, pregnant women	Albendazole/mebendazole Albendazole: Tablet (chewable): 400 mg Mebendazole: Tablet (chewable): 500 mg	6. Anti-infective medicines 6.1 Anthelmintics 6.1.1 Intestinal anthelmintics
<i>Guideline: nutritional care and support for patients with tuberculosis (39)</i>	Pregnant or lactating women with active tuberculosis Moderate undernutrition with active tuberculosis	Multiple micronutrient supplements Multiple micronutrient powders	—

EML: WHO Model list of Essential Medicines (9); EMLc: WHO Model list of Essential Medicines for Children (20); IU: international unit.

^a Other medicines or health products not included in this table may be used in disease prevention, treatment, disease-management, rehabilitation and palliative care services, may have relevance for nutrition-related conditions throughout the life course. Some examples include: oxygen as a medical gas for the management of hypoxaemia in severe acute undernutrition, or specific antibiotics as first-choice therapy in use in complicated severe acute malnutrition; or a fixed-dose combination formulation of isoniazid, pyridoxine, sulfamethoxazole and trimethoprim for the prevention of infections in adults and children living with HIV/AIDS.

Panel discussion: Public health sector perspective on the regulatory aspects of nutrition-related health products

Brazil

Presented by João Paulo S Perfeito

The Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA) classifies nutrition-related health products dichotomously as food supplements and medicines. Where classification is considered as food supplements, there is no need for registration; however, nutrition-related health products documented as medicines are subject to registration or notification. Before July 2018 vitamins, minerals, amino acids and proteins for oral use that were within the recommended daily intake levels were considered as foods, while nutrition-related health products that contained more than 100% of the recommended dietary intake for at least one nutrient were classified as medicines.

ANVISA has since published a new regulatory framework with special consideration for food supplements. Within this new framework, nutrition-related health products are classified according to the purpose of use (claim). Products used to supplement the diet of healthy people are classified as food supplements, which are exempt from registration. However, it is required to provide information on composition (e.g. nutrients), quality (e.g. identity, purity, composition specifications), quantity of nutrients, and the minimum and maximum levels; definition of shelf-life; and appropriate labelling for correct identification and differentiation from nutrition-

related health products classified as medicines. Food supplements are mandated to carry the label “food supplement” and “this product is not a medicine”.

In contrast, nutrition-related health products with well-defined therapeutic claims are classified as medicines and require registration (with pre-grant analysis) or notification (without pre-grant analysis). Suppliers of these products must provide evidence of safety and efficacy in the form of clinical trials, preferably randomized, controlled and double blinded. Evidence may also be provided from meta-analysis or systematic reviews. Additionally, the products are subject to the same technical requirements as any other medicine, as outlined by ANVISA.

The current version of the Brazilian essential medicines list, published in 2017, outlines the qualitative and quantitative composition and dosage form of medicines. Nutrition-related health products in the Brazilian list include vitamins and minerals in different dosage forms, and multiple micronutrient powders. It is thought that the addition of nutrition-related health products to the Brazilian list, depending on the agreement of Federation units within the Brazilian Government, would increase the need for nutrition-related health products; increase regulatory demand, availability and competition; and possibly decrease prices. Currently, nutrition-related health products marketed as RUTFs are not available on the Brazilian market and are not part of the Brazilian Government’s strategy to combat malnutrition.

Mexico

Presented by Pamela Suárez Brito

The sanitary regulation, control and promotion of products and services, including nutrition-related health products, are the responsibility of the Federal Commission for Protection against Sanitary Risk (COFEPRIS), a decentralized body of the Mexican Ministry of Health. The Mexican General Law of Health defines food as any substance or product, solid or semi-solid, natural or processed, that provides the body with elements for nutrition (40). The law further defines dietary supplements as products made from herbs, vegetable extracts, traditional foods, or dehydrated or concentrated fruit, added to or not with vitamins or minerals. Dietary supplements could be presented in pharmaceutical dosage, with the purpose being to increase total dietary ingestion or to supplement any of its components. While dietary supplements are regulated, Mexican regulation differs from the Codex Alimentarius (41) in that the content of dietary supplements may or may not contain vitamins or minerals and they do not have to be packaged in a pharmaceutical form. Also, the Regulation of Sanitary Control of Products and Services establishes specific labelling provisions that apply to dietary supplements (42).

A product for prevention of malnutrition can currently be considered as a dietary supplement, with the stated purpose of increasing the intake of nutrients from a normal diet, and is not intended as a meal replacement.

Under the Mexican Regulation of Health Supplies (42), there is a category for formulations for specialized enteral feeding to be used under the supervision of a health professional. The route of administration is oral or enteral, when it is administered somewhere in the digestive tract. These nutrition-related health products differ from dietary supplements as they are designed for treatment of medical conditions and not solely to increase total dietary intake. They require sanitary registration with COFEPRIS.

Overall, Mexico has regulations that make provisions for nutrition-related health products classified as foods, dietary supplements or medicines.

Sudan

Presented by Ali Arabi

There is a growing emergency of severe acute undernutrition in Sudan, with a prevalence ranging from 3% to 20% in the worst-affected localities. In response to this crisis, the nutrition sector in Sudan is actively functioning with 22 sector partners, including local and international nongovernmental organizations. The Government of Sudan's approach to the management of undernutrition in Sudan entails:

- prevention of acute undernutrition through adequate micronutrient supplementation programmes with retinol capsules, folic acid + iron and deworming;
- treatment of severe and moderate acute undernutrition through use of routine medicines (ReSoMal), therapeutic milk formulas, RUTFs and RUSFs.

Essential medicines are regulated by the Sudanese Government and, as part of the national essential medicines list, are distributed at no cost through the health sector. Nutrition-related health products such as RUTFs (produced locally since 2011) are registered as a nutrition commodity with therapeutic effect and included in the national essential medicines list. The registration of therapeutic milk is ongoing. These products have been endorsed by the Sudanese Standards and Metrology Organization, with special national Codex guidelines that facilitate food quality and safety being issued for them. This aspect of ensuring the safety of nutrition-related health products is done through the national public health laboratory. As part of the functions of the Sudanese Standards and Metrology Organization, the sale, use and distribution of therapeutic foods are regulated jointly with the judiciary and consumer protection authorities and ministries of health at the state level.

During emergencies, nutrition-related health products are also regulated through the Humanitarian Aid Commission for appropriate access and transportation.

Availability of RUTFs in Sudan is mainly through international agencies such as the United Nations Children's Fund (UNICEF) but has been reduced in recent years, owing to deterioration of international funding in general. The Sudanese Government invested nearly US\$ 20 million for procurement of RUTFs in 2015–2016. The supply of these commodities is monitored through national systems (e.g. Nutrition Information System) and UNICEF, mainly through mentoring local consultants.

Despite the accomplishments of the Sudanese Government and local and international partners, there are major technical issues associated with the availability and distribution of nutrition-related health products used in the management of undernutrition, including:

- limited technical capacity of partners, especially ministries of health, to lead on supply-chain management;
- warehousing and storage of commodities;
- supply-chain monitoring, particularly during emergencies and in remote areas and up to the end-user level;
- technical support for integrating the nutrition supply system into the broader public health logistic system.

Surmounting these challenges requires inclusion of routine medicines for the management of undernutrition in all proposals to funding agencies, and adherence to guidelines and rationale for use of medicines. Additionally, there is a need to strengthen monitoring capacity and for greater coordination with the medical supply fund, to ensure the sustainability of supplies while including the nutrition-related health products used in community management of acute malnutrition in the expansion of primary health care. Clarity is also needed on segregation of the roles and responsibilities of UNICEF and WHO in managing acute undernutrition in Sudan.

Cameroon

Presented by Thomas Lapnet Moustapha

The first Cameroonian list of essential medicines was finalized in 1992, for standardization of treatment in primary health-care settings. The Cameroonian list has since been revised in 2000, 2007 and 2017 and now serves the entire health system. Coverage is provided at all three levels of the national health system – central, intermediate and peripheral. The use of each medicine in the Cameroonian list is specified for its respective health facility.

The nutrition-related health products included in the Cameroonian list are classified as follows:

- anti-anaemia medicines: folic acid, iron, calcium folinate, iron salts, iron salts + folic acid;
- vitamins: retinol, complex B₁–B₆–B₁₂, multivitamins and minerals, vitamin B₁, vitamin B₁₂, vitamin C, nicotinamide, ergocalciferol and calcium, pyridoxine;
- minerals: magnesium sulfate, calcium gluconate, potassium chloride, sodium chloride;
- oral rehydration salts and zinc.

Other nutrition-related health products such as RUTFs, therapeutic formula diets and multiple micronutrient powders are not included in the Cameroonian list. The classification of nutrition-related health products has not been done systematically. Products classified as medicines are regulated as such, with some advantages related to custom duties but possibly subject to limited distribution. Inclusion in the Cameroonian list would protect these products, and factors enabling availability will need to be clearly discussed and officially approved. Inclusion in the Cameroonian list has some advantages in terms of monitoring and traceability, standardization, predictability, pooled procurement, and interest to potential manufacturers.

Discussion between the nutritional services and the Essential Medicine List Committee has started in Cameroon. Although there are shared interests in the potential advantage of nutrition-related health products for both prevention and treatment, further sensitization and stakeholder involvement are required to move this process forward.

Nigeria

Presented by Ogori Taylor

Undernutrition is a significant problem in Nigeria, with people living in the northern areas being affected disproportionately. The aetiology of undernutrition in Nigeria is multifactorial and contributed to by inadequate dietary intake, poverty, internal displacement of populations, and secondary health conditions such as HIV, AIDS and malaria. Some of the key strategies for implementation of the national nutrition policy include the integration of essential nutrition actions into routine primary health-care services, local production and adequate supply of RUTFs, and school-based feeding programmes.

Access to RUTFs for the treatment of severe acute undernutrition is driven largely by international donor agencies (e.g. UNICEF, Bill & Melinda Gates Foundation). The majority of RUTFs available in Nigeria are imported from other countries, with cost implications and potential restrictions on availability. A major pharmaceutical manufacturer plans to commence RUTF production in Nigeria by the first quarter of 2019.

Regulation of nutrition-related health products in Nigeria is now undergoing review. Some nutrition-related health products are classified as dietary supplements and pre-mixes for food fortification regarded as raw materials. Other nutrition-related health products, such as vitamins and minerals, are classified as medicines and are included in the national essential medicines list. RUTFs have recently been included in the national essential medicines list as a supplement to the sixth edition, classified as nutritional commodities. In contrast to medicines, registration requirements for nutrition-related health products are less stringent and distribution does not require supervision by a pharmacist or other health professional. Distribution is usually done in public

places, including markets and supermarkets. The advantage of registering nutrition-related health products as medicines facilitates a lower import duty of 5%, compared with the 25% duty charged on imported food products.

Efforts to include RUTFs in the Nigerian list may trigger more stringent regulations and restrictions on distribution and trade. Unintended implications, such as competing for scarce government resources, irrational use by health-care workers, and a perception of RUTFs as being nutritionally superior to locally available foods, are likely. This might also erode positive gains in breastfeeding programmes and detract from the promotion of good nutrition with available local foods. While there is consensus that vulnerable populations require RUTFs to manage nutritional imbalances and reduce morbidity and mortality in children under 5 years of age, efforts should be made to promote the use of locally available nutritional products and provide health education to the population. It is also imperative that United Nations agencies such as WHO and the Food and Agriculture Organization of the United Nations (FAO) support countries in the development of quality and safety standards for local production of nutrition-related health products.

India

Presented by Harshpal Singh Sachdev (via web conference)

Undernutrition, in particular severe acute undernutrition, is a major problem in India. Several approaches are being used to tackle this public health concern, including community management of acute malnutrition. Data from India suggest that the survival and recovery benefits of community management of acute malnutrition are overestimated: the case-fatality from severe acute undernutrition is lower than that generally perceived, and some spontaneous improvement occurs in people with severe acute undernutrition (43–45). Unpublished data from a systematic review comparing lipid-based nutrition supplements with specially formulated foods (micronutrients, fortified or non-fortified) or home-based foods for the treatment of severe acute undernutrition showed no difference in terms of recovery or time to recovery in children aged 6–59 months. However, a better recovery profile may support the preferential use of lipid-based nutrient supplements over therapeutic milks (F-100).

Important concerns have been expressed in India regarding the use of RUTFs as the sole nutrition treatment for management of severe acute undernutrition. These arguments propose that RUTFs:

- distort preventive efforts and usual dietary consumption, especially breastfeeding;
- are ultra-processed and high in fat and sugar, which increases the propensity for later-life obesity and the risk of noncommunicable diseases;
- are high in potassium and magnesium;
- consume a large component of the public health budget at the detriment of other, equally important programmes;
- favour multinational over local manufacturers;
- displace local self-help groups and the livelihoods of the people involved.

Regulation of nutrition-related health products, including RUTFs, is an ongoing process, with consideration given for classification by the Food Safety and Standards Authority of India as:

- vitamin and mineral supplements;
- proprietary foods;
- fortified foods (30–50% of recommended daily amount);
- foods for special dietary use;
- foods for special-medical purposes.

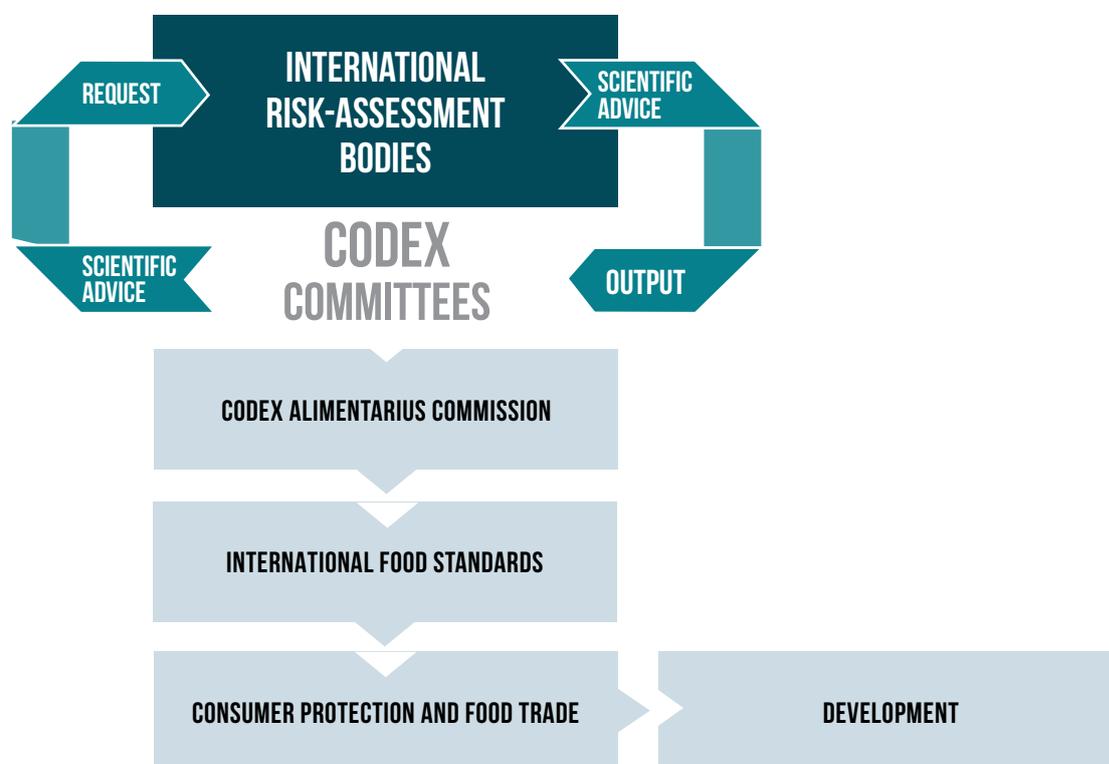
There are two potential regulatory frameworks for approving use of RUTFs, namely the recently introduced Food Safety and Standards Authority of India and the Drugs Controller General of India. The Food Safety and Standards Authority of India framework includes an independent committee that reviews nutrition-related health products for approval as foods for special medical purpose. It also considers Codex standards (41) for quality and safety and evidence of efficacy. Within these two regulatory frameworks, RUTFs would have less stringent requirements than conventional medicines, but their prescription and use would still be under medical supervision, which may vary in the primary health-care setting. The national essential medicines list is formulated by a board under the ambit of the Drugs Controller General of India and is subject to price control. It requires “medically supervised” use, but exceptions exist for public health programmes. Generally, the Drugs Controller General of India and other stakeholders prefer the Food Safety and Standards Authority of India rather than the Drugs Controller General of India regulatory framework for RUTFs. Overall, the inclusion of nutrition-related health products for public health programmes, and probably for the national essential medicines list, would rely on influential input from multiple stakeholders other than the two regulatory frameworks (e.g. Prime Minister’s Office, National Council on Nutrition, National Technical Board on Nutrition). This also represents a challenge to WHO to provide the necessary guidance.

World Health Organization food safety considerations related to nutrition-related health products

Presented by Kim Petersen

The mission of the WHO Department of Food Safety and Zoonoses is “to lower the burden of foodborne disease, thereby strengthening health security and ensuring sustainable development of Member States”. To accomplish this in relation to nutrition-related health products, WHO provides scientific advice and participates in efficient standard-setting through Codex committees. The joint FAO/WHO Scientific Advice Programme that is the scientific basis of the Codex is outlined in Fig. 3 (41). Through specific Codex committees such as the Codex Committee on Nutrition and Foods for Special Dietary Uses and the Codex Committee on Contaminants in Foods, several Codex maximum levels and guidelines have been developed to assure the quality and safety of food for human consumption (e.g. *General Standard for Contaminants and Toxins in Food and Feed* (46)). As part of its risk-assessment responsibilities, the Joint FAO/WHO Expert Committee on Food Additives regularly evaluates mycotoxins such as aflatoxins in foods commonly used as raw materials in nutrition-related health products (e.g. maize, peanuts). This allows the appropriate setting of maximum levels in the Codex standards for aflatoxins and other contaminants that might be present in the raw materials of nutrition-related health products given to particularly vulnerable populations with pre-existing sensitivities.

Fig. 3. Joint Food and Agriculture Organization and World Health Organization Scientific Advice Programme



International guidelines and standards in the production of foods for special dietary uses and foods for special medical purposes

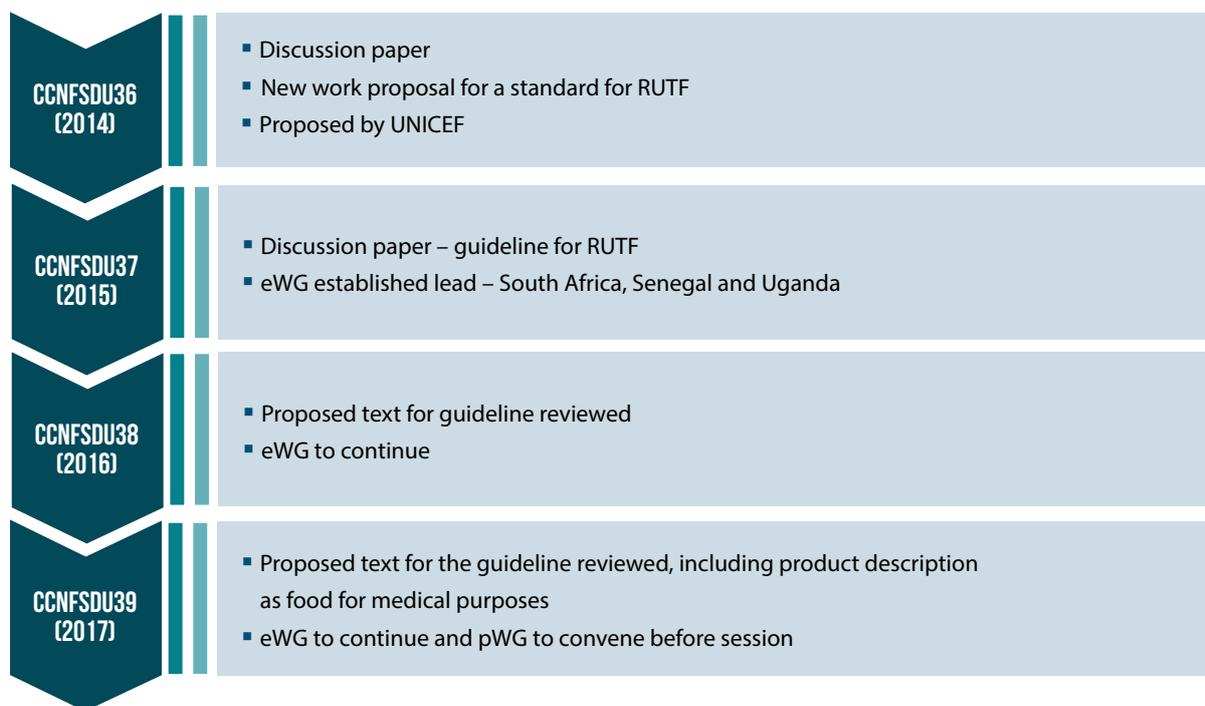
Presented by Pamela Suárez Brito

The Codex Alimentarius includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution to consumers (41).

The Codex Alimentarius has committees that provide standards for foods for special dietary uses (Codex Committee on Food Labelling) and foods for special medical purposes (Codex Committee on Nutrition and Foods for Special Dietary Uses). In the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (47), foods for special dietary uses are those foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of particular physical or physiological conditions or specific diseases and disorders, and that are presented as such. The composition of these foods must differ significantly from the composition of ordinary foods of comparable nature if such ordinary foods exist. The standard for the labelling of and claims for foods for special medical purposes stipulates that foods for special medical purposes are a category of foods for special dietary uses that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of people with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically determined nutrient requirements whose dietary management can be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

The Codex work on RUTFs is ongoing, as outlined in Fig. 4.

Fig. 4. Workflow of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on the guideline for ready-to-use therapeutic food (RUTF)



eWG: electronic working group; pWG: physical working group; RUTF: ready-to-use therapeutic food; UNICEF: United Nations Children's Fund.

Therapeutic and supplementary foods in the management of acute undernutrition

Presented by Zita Weise Prinzo

WHO provides updated guidance on the management of severe acute undernutrition through its published *Guideline: updates on the management of severe acute malnutrition in infants and children (1)*. The joint statement of WHO, the World Food Programme, the United Nations System Standing Committee on Nutrition and UNICEF on *Community-based management of severe acute malnutrition* reflects the endorsement of the outpatient management of severe acute undernutrition and gives recommendations on the nutrient composition of RUTFs (48). Severe acute malnutrition is clearly defined by the WHO *International classification of diseases*, eleventh revision (1, 49).

Children diagnosed as having severe acute undernutrition are assessed for medical complications and lack of appetite, in which case they are referred for inpatient medical care. These children, usually representing 10–30% of people with severe acute undernutrition, are considered at high risk of death, often from hypoglycaemia, hypothermia, cardiac failure or infection.

Therapeutic foods for inpatient treatment

WHO recommends therapeutic milk F-75 as treatment during the stabilization phase. The nutritional composition of F-75 is outlined in the *Management of severe malnutrition: a manual for physicians and other senior health workers (50)*. During this phase, refeeding with F-75 is usually provided for 3–5 days, at a rate of

75 kcal/100 mL. The main aim of the stabilization phase is to ensure rehydration and treatment of underlying medical conditions. During this time, continued breastfeeding, where possible, is recommended. WHO also recommends a transition from F-75 to F-100 therapeutic milk, which is the therapeutic diet in the rehabilitation phase of severe acute undernutrition. The introduction of F-100 is dependent on the stabilization of infections, the metabolic efficiency of the liver, and whether the child has regained an appetite. In the rehabilitation phase, breastfeeding is supported and F-100 is given at 150–200 kcal/kg/day, with the aim of weight gain.

Therapeutic foods for outpatient treatment

Historically, children were kept as inpatients for managing severe acute undernutrition, owing to the hygiene risk (bacterial proliferation) associated with preparation and provision of milk-based formula outside the hospital setting, particularly at home. This issue resulted in the innovation of RUTFs. RUTFs are developed as foods that are ready to use without preparation at home, with a low risk of bacterial contamination, and with a nutritional composition based on the F-100 milk used in rehabilitation of children with severe acute undernutrition without medical complications. While WHO does not have any guidelines related to the ingredient types used, it recommends that at least 50% of the protein source should be from animal products and that they should not be used in children under 6 months of age.

For moderate acute malnutrition, WHO published a *Technical note: supplementary foods for the management of moderate acute malnutrition* (38). The document outlines that the nutritional requirements of children with moderate acute undernutrition are higher than those of non-undernourished children. The dietary management in moderate acute undernutrition should ideally be based on optimal use of locally available nutrient-dense foods. However, there are certain contexts where family foods are not available, such as emergency or food-insecure settings, where these children would require supplementary foods.

Supplementary foods

Supplementary foods are specially formulated foods in ready-to-eat or milled form that are modified in their energy density and protein, fat and micronutrient composition, to help meet the nutritional requirements of specific populations. These foods are not intended to be the only source of nutrients and are different from complementary foods. They are also different from food supplements, which refer to vitamin and mineral supplements in unit dose forms, such as capsules, tablets, powders or solutions. Supplementary foods meeting the nutritional composition as outlined in the WHO technical note (51), have been used for rehabilitation of children with moderate acute undernutrition, and evidence shows benefit in weight gain as recovery.

The WHO *Guideline: assessing and managing children at primary health-care facilities to prevent overweight and obesity in the context of the double burden of malnutrition* was published in 2018 (52). There is a recommendation on supplementary foods in this guideline that stipulates that they should not be routinely given to all children who attend primary health-care clinics and are classified as having moderate acute undernutrition. There has been a need for clarification on what is meant by “not routinely”, which was explained further in an implementation note by WHO, the World Food Programme and UNICEF in May 2018, on the use of supplementary foods in the management of moderate acute undernutrition. The note states that every child with moderate acute undernutrition deserves treatment, and that treatment includes medical interventions where necessary, and counselling, dietary interventions and other complementary interventions where indicated. There is currently no WHO guideline for the use of these products in the prevention of undernutrition, but WHO has commissioned systematic reviews investigating this and will be convening a guideline development group meeting to develop guidelines that also look at prevention.

Expert assessments of the inclusion of ready-to-use therapeutic foods in the World Health Organization Model List of Essential Medicines: lessons learnt from a qualitative evaluation

Presented by **María Cecilia Dedios**

Nutrition-related health products are a fundamental part of nutrition interventions. While nutrition-related health products comprise a coherent group, products in this category vary in their intended use, their composition, and the quality of evidence supporting their use, which greatly complicates classification and legislation by regulatory agencies around the world. RUTFs exemplify this problem well, as they have a dual status as medicines and foods. The proposal to include RUTFs in the EML brings about a need to clarify where these products fit within the category of nutrition-related health products, and a need to assess the consequences, both intended and unintended, of their inclusion in the list. Results from a desk review and two waves of in-depth interviews with experts across five sectors were presented, exploring where RUTFs fit within the category of nutrition-related health products, and the advantages, disadvantages and trade-offs that key stakeholders would face if RUTFs were included in the EML. The participants and agencies were identified through existing lists of experts compiled by WHO.

The results show that nutrition-related health products are not classified consistently by regulatory agencies around the world, and that experts use various criteria to decide which class of nutrition-related health products RUTFs belong to. RUTFs were generally thought of as both foods and medicines, depending on the purpose of use, which resulted in some stakeholders defining RUTFs as foods for special use and others classifying them as medical foods.

In considering the advantages, disadvantages and trade-offs for including RUTFs in the EML, the most cited argument for their inclusion was that it would make the inclusion of RUTFs in national essential medicines lists more likely. Interviewees explained that this is so because many countries use the EML as guidance for their own lists of essential medicines. However, there was an overall lack of consensus, with divergent views on the benefits and trade-offs of inclusion.

Cost and availability were factors identified by stakeholders from all sectors as a challenge in relation to the current use of RUTFs to treat severe acute undernutrition. Experts considered that the products have a high cost, and that the availability of RUTFs in countries could be improved. However, experts did not agree on whether the inclusion of RUTFs in the EML would help or aggravate these challenges. The article (53) summarizes the experts' considerations on challenges to the use of RUTFs by stakeholders across five sectors in WHO Member States. The complete study assessing other aspects of nutrition-related health products is presented in [Annex 3.1](#).

Stakeholder perceptions of adding ready-to-use therapeutic foods and other nutrition-related products to the World Health Organization Model List of Essential Medicines

Presented by **Katherine P Adams**

Access to nutrition-related products in low- and middle-income countries with high burdens of severe acute undernutrition, anaemia and other nutrition-related conditions is often low, and adding RUTFs and other nutrition-related products to the EML has been proposed as one strategy for improving access. The presentation synthesized input from a diverse set of stakeholders on the potential impacts of adding these products to the EML. Stakeholders' perspectives were elicited separately for RUTFs and for other nutrition-related products, and their perspectives were synthesized according to themes emerging from the survey responses.

Although there were some areas of relative consensus among stakeholders, their perceptions varied substantially about the likely impacts on product regulation and cost and on how in-country perceptions of these products might change if they are added to the EML or national essential medicines lists. Stakeholders also differed in their views of whether the addition of RUTFs to the EML would inhibit or support local production.

Stakeholders' perspectives on the inclusion of RUTFs in the EML were divergent regarding development of alternative formulations, whether the cost of the products would be affected, the impact on local procurement and the supply chain, and budget implications for governments, especially in developing economies.

Considering the differing views of stakeholders and the varying degrees of uncertainty on the effect on many potential areas of impact, the authors suggested, as proposed by a United Nations agency, that a rigorous risk assessment be undertaken to evaluate the primary concerns raised by stakeholders. A summary of stakeholders' support, or not, for adding RUTFs to the EML is presented in the article in [Annex 3.2](#) (54). The authors conclude that the decision to add RUTFs and other nutrition-related products to the EML should be contingent upon demonstrating, with reasonable confidence, that the cumulative effect of adding RUTFs and other nutrition-related products to the EML on these factors would result in improved access among the populations most in need, while providing sufficient latitude for local production and for the development and testing of alternative formulations. For more information, see [Annex 3.2](#).

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

Presented by Aurélie du Châtelet

Severe acute undernutrition is a global public health concern, with only one in four children with this condition being treated. WHO has highlighted the need to prioritize treatment of this condition through one of the strategic priorities in the GPW13 (7). The objective was to analyse the outcomes and risks of adding RUTFs to national essential medicines lists. The methodological approach included a literature review, country-specific case-studies, and interviews with key informants. Table A3.3.1 (see [Annex 3.3](#)) summarizes the status of RUTFs in relation to national essential medicines lists in 36 countries, as assessed by a desk review between January and March 2015 and updated in August 2018. Countries that have included RUTFs in their national essential medicines lists, have registered them variously in their local regulatory frameworks as medicines, foods or nutrition commodities (55).

The country case-studies were conducted with information retrieved from reports and interviews with key informants in the eight included countries in this assessment. The impact in Nigeria and Zimbabwe varied and included a change in perception of RUTFs, increased funding for procurement, development of local production, improved stock management and distribution (supply-chain management), and significant availability of the products in targeted areas.

The key informant interviews provided arguments both for and against inclusion of RUTFs in national essential medicines lists and the EML. The arguments in favour suggested that inclusion in the EML would:

- create political commitment to address acute undernutrition;
- improve integration of nutrition within health systems;
- increase financial resources available for, and decrease the cost of production of, RUTFs;
- improve the use of RUTFs in public health;
- lead to easier procurement processes.

The arguments against inclusion in the EML included:

- issues with quality control of production of RUTFs related to pharmaceutical and microbiological standards;
- the risk of reinforcing existing trends around commodification of RUTFs and jeopardizing food-based preventive approaches;

- overemphasis on a medical approach to community management of acute undernutrition, which poses a threat to breastfeeding practices;
- low capacity of some national health systems and fragile systems unable to cope with increased demands.

Overall, the authors concluded that adding RUTFs to national essential medicines lists and the EML is likely to mobilize political commitment to improve the treatment of severe acute undernutrition, to facilitate use, to improve availability and procurement, and to reduce costs. This is largely hinged on the need for clarification on the safety of RUTFs and perhaps an established standard for RUTFs. More research is needed to quantify the impact of inclusion, particularly in countries where RUTFs are already included in the national essential medicines lists. Full details of the study (55) are presented in [Annex 3.3](#).

Public health relevance of including specialized nutrition-related health products in the South Sudan Essential Medicine List 2018

Presented by Charles Ocan and Marina Adrianopoli

The presentation described the South Sudanese context and the processes of reviewing the *South Sudan Essential Medicine List* (SSEML), including stakeholder engagements, collaboration, and assessment of the inclusion of RUTFs in the SSEML; the rationale for including nutrition-related health products in the SSEML; stakeholders' considerations, which can be seen as replicable criteria in other contexts; the use of specialized nutrition-related health products in the guidelines; and expected results, impacts, resources and barriers in the context of South Sudan.

The prevailing health conditions and the need to ensure appropriate procurement of safe, efficacious and good-quality essential medicines, including specialized nutrition-related health products, formed a large part of the context for reviewing and updating the *South Sudan Essential Medicine List 2018* (SSEML 2018). This process, which began in 2015, was influenced by the overall recommendations from health professionals and experts within the South Sudanese Government and international partners. The SSEML 2018 was modelled on the 2017 EML. The process included a comprehensive desk review and stakeholder consultations. The process was unduly affected by a resurgence in violence in 2016. In 2017, through the work of the Pharmaceutical Technical Working Group, an expert committee was formed to work with the lead consultant reviewing the 2007 SSEML. Among the applications was the request for inclusion of RUTFs submitted by the Department of Nutrition in the South Sudanese Ministry of Health, UNICEF, the WHO Health Emergencies Programme, and other stakeholders implementing programmes with nutrition interventions. The main rationale for inclusion of RUTFs in the SSEML was to improve access to RUTFs for community management of acute undernutrition and the management of severe acute undernutrition. Issues regarding supply-chain management and financing were discussed extensively. Some stakeholders felt that adding RUTFs to the SSEML could imply that the products are medicines and therefore liable for stringent quality-assurance processes. Following further consultation in July 2018, RUTFs were added to the SSEML 2018, with a clear view of measuring the impact of the product. The framework that was set forth to accomplish this was based on three main elements:

- the public health relevance of including specialized nutrition-related health products for the treatment of acute undernutrition in infants and children in the SSEML 2018;
- the efficacy and safety of these products and their recommended use, as outlined by the national guidelines for community management of acute malnutrition;
- procurement and supply-chain management of RUTFs.

The authors concluded that, while the case of South Sudan provides important lessons on how this approach can be replicated in similar contexts, considerations must be given to prospective challenges, such as:

- government health-system capacity and expenditure;
- gaps in the evidence documenting the effectiveness of specialized nutrition-related health products for the treatment of acute undernutrition;
- undermining of or distracting from other preventive or mitigating interventions, such as promotion of breastfeeding, which may result when specialized nutrition-related health products are included in the essential medicines list;
- misuse of specialized nutrition-related health products by family members.

Full details of the study (56) are presented in [Annex 3.4](#).

The road to sustainable availability of ready-to-use therapeutic foods for the management of acute undernutrition in the Plurinational State of Bolivia

Presented by Ana Maria Aguilar

The process of adding RUTFs to the list of essential medicines for the management of moderate and severe acute malnutrition in the Plurinational State of Bolivia was described. The study used a timeline analysis tool for in-depth interviews with key informants and revision of selected documents. Also, a specific database of the logistics of RUTFs was reviewed and an electronic survey was conducted to illustrate current use. The initial process of adding RUTFs to the list was reconstructed with information provided by key informants, which was verified with available documentation. In the Bolivian context, the verification of RUTFs by the National Pharmacological Commission was an important step, which was facilitated by the nutrition-related product being part of a nationally prioritized programme. This process is documented in the article (57), highlighting factors such as the existing legal framework, public health insurance, and implementation of the Programa Multisectorial Desnutrición Cero (Zero Malnutrition Programme) (58), which seems to have facilitated the process and ensured the sustainability of the use of RUTFs. RUTFs remained on the 2018 list and are currently available and used in primary health facilities.

In summary, the process of incorporating RUTFs in the Bolivian essential medicines list, from inception to expansion, was a positive experience, was done in a timely manner, and is regarded to have contributed to the reduction of the infant mortality rate. Full details of the study (57) are presented in [Annex 3.5](#).

Panel discussion: Challenges at the country level in access to nutrition-related health products, with a focus on purchasing and production

Manufacturer perspective: PlumpyField network

Presented by Thomas Couaillet

The PlumpyField network has conducted a study examining the impact of including RUTFs in the national essential medicines lists of countries where the PlumpyField network has producers. For the majority of these countries, RUTFs are included in the national essential medicines list and registered as foods, food supplements, nutritional inputs or food–medicines, or given a miscellaneous categorization.

RUTFs are produced using high safety and quality standards. These standards are guided by the Codex Alimentarius (41) and the UNICEF specifications, UNICEF being one of the largest global purchasers of RUTFs. In instances where RUTFs have been included in national essential medicines lists, this has not resulted in any change of production standards. However, it is noted that if RUTFs are to be considered as medicines, then there might be implications for adapting pharmaceutical production standards. This would have a direct impact on the production costs and feasibility of local production.

The majority of RUTF sales at the country level are attributed to international agencies such as UNICEF, with less than 10% of sales between January 2016 and June 2018 related to government sales. The potential benefits of including RUTFs in the EML are linked closely to improved access in countries where there is a high burden of severe acute undernutrition. Any such inclusion might:

- result in prioritization of treatment for severe acute undernutrition by governments and covering supply of RUTFs in their national health-care systems;
- contribute to regulatory harmonization and better recognition of RUTFs;
- lead to a reduction in market prices, directly through competition in production, and indirectly through removal of value-added tax and custom duty, which also applies to raw materials used in the production of RUTFs.

International governmental agency perspective: United States Agency for International Development

Presented by Rufino Perez

Management of acute undernutrition in challenged regions of the world is a priority for the United States Agency for International Development (USAID), building local capacity through local production of nutritious food products or specialized nutritious foods. In relation to the effort to incorporate RUTFs in the EML, USAID made the comments listed next.

- It is likely that some countries will treat RUTFs as a pharmaceutical product, which already occurs with micronutrient supplements in many countries, and therefore may impose an unnecessary burden (e.g. overly strict production standards, pharmacological-type storage requirements, specialized transportation, medicine-like regulatory compliance).
- The use of pharmaceutical regulatory standards that are not applicable to RUTFs may be required. RUTFs are already produced under the strictest standards for food safety and quality, and any new regulations may affect countries' and donors' capacity and responsiveness in current global programmes for the treatment and management of acute undernutrition.
- Overly stringent and unnecessary regulations may displace local manufacturers. Large corporations and international producers are more likely to meet potential upgraded pharmaceutical standards and requirements, negatively impacting on local producers and therefore access to RUTFs.
- Potential inclusion of nutritious food products as medicines may negatively impact on USAID's ability to fund programmes where RUTFs are needed in the fight against undernutrition.

USAID therefore considers that:

- RUTFs should not be included in the EML because of the stated concerns;
- developing a unique category or list for essential specialized nutritious food products for the treatment of severe or moderate acute undernutrition within the WHO framework would lead to better recognition of their importance, in terms of increasing access and enabling adequate regulatory frameworks;
- production and handling of essential specialized nutritious food products should use Codex standards and guidelines, and thus including RUTFs in a list of medicines would lead to confusion;
- if there is consensus for a WHO list or food category to be created, then products included in the list should be comprehensively assessed for efficacy and safety in the management of severe and moderate acute undernutrition.

Intergovernmental agency perspective: World Food Programme

Presented by Shane Prigge

The United Nations' World Food Programme provides support to countries affected by undernutrition, through development, sourcing and provision of specially formulated foods. RUSFs are provided for the treatment of moderate acute undernutrition.

These nutrition-related health products are sourced from suppliers around the world. In 2017 the World Food Programme sourced a total of approximately 25 000 tonnes of RUSFs from different origins, including Europe (over 55%), Asia (about 20%), Africa (about 15%) and North America (about 10%). In 2017, the World Food Programme sourced approximately 125 000 tonnes of Super Cereal Plus.

The specifications for RUSFs and Super Cereal Plus procured by the World Food Programme are guided by the WHO *Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age* (36). Currently, the specifications used for procurement of RUSFs, RUSFs and Super Cereal Plus are set by the buying agencies, as there are no Codex standards for these foods (51, 59).

The buying agencies prequalify suppliers according to food production standards, such as good manufacturing practices and hazard analysis critical control point. The World Food Programme, USAID, UNICEF and Médecins Sans Frontières have aligned their specifications and auditing criteria; each agency applies its own criteria to approve suppliers. Recently, Action Against Hunger International and the International Committee of the Red Cross have also joined the interagency group.

The World Food Programme does not recommend the inclusion of foods for the treatment of acute undernutrition in the EML until the following are evaluated by countries:

- classification (medicine, miscellaneous or special food, including whether it is considered a food, a food for dietary use, a food for medical purpose, or a medicine) and the EML formulation that would be used to define it;
- impact on the regulatory mechanisms that would be used, and may have to be adapted, to regulate foods in the EML;
- assessment of the possible impact, in different countries, on the distribution channels that may be used to store, handle, transport and provide these foods to consumers, if they were included in the EML. There is concern that distribution may become more restricted, which would limit rather than stimulate availability and access to this life-saving treatment at the community level.

International nongovernmental organization perspective: Nutrition International

Presented by Alison Greig

The inclusion of nutrition-related health products in the EML can improve access to such products, but it requires some careful consideration. It can impact positively or negatively on a variety of important components of supply, such as standards and specifications; access, if it causes it to influence prescription practices; procurement laws and guidelines; and integration into the national supply-chain systems. Currently, most nutrition-related health products are listed in the EML, owing to their role as medicines. If a product is then registered as a pharmaceutical in country, this has been shown in some cases to impose restrictions on manufacturing, because pharmaceutical products must be manufactured in accordance with pharmacopoeia monographs such as the United States Pharmacopoeia, the British Pharmacopoeia and the WHO International Pharmacopoeia. Such designation and the accompanying quality and safety requirements may limit local manufacturing and present inequity in the production landscape, favouring larger companies. Inclusion in the EML, however, does not necessarily mean the nutrition-related health products need to be registered as pharmaceutical products. To improve access to nutrition-related health

products, inclusion of the products in the EML is only one part of a multifactorial strategy, which also includes the following elements:

- *policy and guidelines*: there should be a WHO recommendation for use of the products, supported by robust evidence for the dosage, target group and associated health outcomes, and national guidelines adapted to the local context for greater efficiency;
- *products*: the willingness of governments to procure or accept donations from international partners and the balance between local and imported supplies;
- *regulatory framework*: it is a country-level decision to register nutrition-related health products as foods, food supplements or medicines, and from Nutrition International's experience, it is this registration classification that influences the standards set for manufacturing, importation, procurement practices, supply chain and access by the population. There can also be limitations in the capacity of government to enforce these regulations;
- *adoption of the EML*: the EML serves as a model for Member States, but it is a country decision to adopt it. Inclusion of medicines in a national essential medicines list may allow products to be part of national forecasting, increase their availability through the public health system, and act to incentivize local manufacturing; in some instances, it can mean lower import taxes.

Where nutrition-related health products are clearly categorized as medicines because of their dosage form (e.g. high-dose vitamin A supplements, dispersible zinc tablets for treating childhood diarrhoea), their medicinal use can help inform the decision process for other nutrition-related health products being included in the EML. However, some products are not so clearly identifiable as medicines, and their function and therefore their status as foods, food supplements or other designation is less obvious and requires broader consultation. Although important, global guidance will require further actions that include advocacy and technical assistance to translate guidance and improve adoption or inclusion into national policy, regulatory frameworks and local essential medicines lists.

International agencies play a key role in supporting countries by:

- advocating for the adoption of international standards at the local level;
- providing technical assistance to improve the congruence between global guidance and local options;
- assisting with forecasting and procurement;
- in some cases, being brokers in procurement, owing to having a lower conflict of interest than the private sector and other agencies.

GENERAL DISCUSSIONS

This section presents some of the more recurrent discussions during the meeting. These comments represent those of individual stakeholders and entities and do not reflect the WHO position.

Public health importance and efficacy of ready-to-use therapeutic foods

Some stakeholders were of the view that since WHO currently recommends RUTFs as a treatment option for uncomplicated severe acute undernutrition, they should be available in the EML. It was also noted that there is a need for a comprehensive programme integrating the prevention and treatment approaches for children with acute undernutrition. To this end, it was pointed out that this is the primary objective of the Innovative Approaches for the Prevention of Childhood Malnutrition project now under way in Burkina Faso and Mali.

Access to, availability of and prioritization of ready-to-use therapeutic foods

The views on inclusion of RUTFs in the EML were diverse. Some stakeholders posited that it may lead to increased health budgets to accommodate the cost of RUTFs, while others argued that this is unlikely if governments are not committed to the process. It was felt by some stakeholders that prioritization of RUTFs on national essential medicines lists may result in a reduction in expenditure on other essential medicines, because increasing the list does not equate to increased financial resources. It was noted that many countries have already included RUTFs in their national essential medicines lists, which prompted the view from some stakeholders that non-inclusion of RUTFs in the EML does not prevent a country from listing them in its own essential medicines list. Further, inclusion of RUTFs in the EML does not interfere with Member States' ability to procure and distribute in countries where RUTFs are already on the national essential medicines lists. The view suggesting that countries are able to lead on the decision of RUTFs and their own essential medicines lists was counteracted by some stakeholders, particularly because it was felt that non-inclusion in the EML sends a message to Member States that the issue may not be a priority. At this point, the members of the EML Secretariat emphasized that the EML is simply a model list for countries to use as a guide.

Some stakeholders felt that addition of RUTFs to the EML is not the best solution; rather, advocacy to governments to increase allocation in the local budget for the procurement of RUTFs should be given greater priority. One intergovernmental organization recommended that WHO should test the suppositions on the benefits and costs of adding RUTFs and other nutrition-related health products to the EML, based on findings from the background papers.

Regulation and product quality of ready-to-use therapeutic foods

While some presentations brought out the inconsistencies in regulation of RUTFs in various countries, almost all stakeholders at the technical consultation agreed that nutrition-related health products should be classified not as medicines but as specialized foods for medical use, or food commodities. There was much discussion around product regulations and the need for a framework used to weight the evidence on RUTFs coming from the different stakeholders. Most participants felt that, in addition to the outline criteria for considering the addition of new products to the EML, this would allow a transparent method for how these views are used by the WHO Expert Committee for considering RUTFs and the EML.

There was consensus on the need for guidelines outlining the definition and specifications of RUTFs. Many stakeholders agreed that the work being done by the Codex Committee on Nutrition and Foods for Special Dietary Uses to develop standards for RUTFs will contribute greatly to the decision-making process. At least one stakeholder felt that the Codex was not the most appropriate body to lead this process and that it should be led by WHO, particularly because of the more health-focused nature of the standard.

While at least one concern was raised regarding the standards used in the production of RUTFs by manufacturers, it was felt by the major intergovernmental organizations and governmental agencies involved in procurement and distribution that manufacturers followed good manufacturing practices and hazard analysis critical control point procedures.

An intergovernmental organization posited that a possible solution to the ongoing discussion would be an option for a different list of specialized nutritious foods or products for the prevention and management of undernutrition.

Stakeholders felt that, although the evidence forthcoming from reviews is important and more reviews might be needed, the growing mortality in infants and children around the world requires immediate action. An intergovernmental agency, with the support of other stakeholders, noted its readiness to contribute, but requires some conclusions out of the current dialogue on the solutions to reach the target population regarding RUTFs.

FINAL DISCUSSION ON PRACTICAL CONSIDERATIONS AND FEASIBILITY OF INCLUDING NUTRITION-RELATED HEALTH PRODUCTS IN ESSENTIAL MEDICINES LISTS

Nutrition-related health products are already included in the EML and EMLc and in various national essential medicines lists. These include different health products, such as vitamin and mineral supplements with diverse uses. The process of considering the feasibility and practicality of including nutrition-related health products with a food matrix could represent a different challenge. The case raised by the application of RUTF can be used as an index case to develop the needed framework that may be applicable to additional nutrition-related health products in the future, and the feasibility of creating a new list for nutrition-related health products or a new section for nutrition-related health products in the EML.

There is high variability among countries on how RUTFs are classified in their regulatory frameworks, and they are variously considered as foods, food supplements or medicines. Most countries have developed their own approach, irrespective of the EML.

There was clarity on the position of multiple stakeholders and description of the multiple purposes and indications for RUTFs as foods, medicines or both. There remain positive and negative perceptions on the benefits of including RUTFs in the EML.

There is a relevant standing recommendation from WHO that children with severe acute undernutrition and without complications can be managed as outpatients by providing appropriate amounts of RUTF.

There is the potential for new applications for listing nutrition-related health products in the EML, in which case the Expert Committee will evaluate the applications and provide the subsequent recommendations and listings. Any changes in the listing should support the malnutrition programmes of WHO and other United Nations agencies and be endorsed by WHO and other United Nations agencies and technical departments. The listing should rely on WHO guideline recommendations.

The EML serves as a guide for the development of national and institutional essential medicine lists. Moreover, the inclusion of RUTFs in the EML does not appear to interfere with the Member States' ability to procure and distribute in countries where RUTF is already on the national EML.

Overall, the presentations and discussions covered the proposed meeting objectives. On the way forward, WHO can provide technical assistance to countries to ensure that responsible use and access to nutrition-related health products, including RUTFs, are reinforced to guarantee their appropriate use in health programmes.

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ANNEX 2. AGENDA

A2

Thursday 20 September 2018

08:30–09:00	Registration
09:00–09:30	Welcome, introductions and opening remarks Department of Nutrition for Health and Development Department of Essential Medicines and Health Products
09:30–10:00	Objectives and expected outcomes of the meeting Introduction of the participants and verbal declarations of interests
10:00–10:30	The <i>World Health Organization Model List of Essential Medicines</i> and criteria for selection
10:30–11:00	Review of nutrition-related health products currently listed as essential medicines in the <i>World Health Organization Model List of Essential Medicines</i> and <i>Model List of Essential Medicines for Children</i>
11:00–11:30	Break and group photo
11:30–12:00	World Health Organization guidelines pertaining to essential nutrition actions that require nutrition-related health products
12:00–12:30	Discussion
12:30–13:30	Lunch
13:30–15:00	Panel discussion: Public health sector perspective on the regulatory aspects of nutrition-related health products
15:00–15:30	Break
15:30–16:00	World Health Organization food safety considerations related to nutrition-related health products
16:00–16:30	International guidelines and standards in the production of foods for special dietary uses and foods for special medical purposes
16:30–17:00	Discussion

Friday 21 September 2018

09:00–09:15	Welcome Summary of day 1 and objectives for day 2
09:15–09:45	Therapeutic and supplementary foods in the management of acute undernutrition
09:45–10:15	Expert assessments of the inclusion of ready-to-use therapeutic foods in the <i>World Health Organization Model List of Essential Medicines</i> : lessons learnt from a qualitative evaluation (Annex 3.1)
10:15–10:45	Discussion
10:45–11:10	Break
11:10–11:30	Stakeholder perceptions of adding ready-to-use therapeutic foods and other nutrition-related products to the <i>World Health Organization Model List of Essential Medicines</i> (Annex 3.2)
11:30–11:50	Process and impact of integration of ready-to-use therapeutic foods in national essential medicines lists (Annex 3.3)
11:50–12:20	Discussion
12:20–13:20	Lunch
13:20–13:40	Public health relevance of including specialized nutrition-related health products in the <i>South Sudan Essential Medicine List 2018</i> (Annex 3.4)
13:40–14:00	The road to sustainable availability of ready-to-use therapeutic foods for the management of acute malnutrition in the Plurinational State of Bolivia (Annex 3.5)
14:00–14:30	Discussion
14:30–15:00	Break
15:00–16:30	Panel discussion: Challenges at the country level in access to nutrition-related health products, with a focus on purchasing and production
16:30–17:15	Final discussion on practical considerations and feasibility of including nutrition-related health products in essential medicines lists
17:15–17:30	Closing remarks and next steps

Expert assessments of the inclusion of ready-to-use therapeutic foods in the *World Health Organization Model List of Essential Medicines*: lessons learnt from a qualitative evaluation

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Abstract

Nutrition-related health products are a fundamental part of nutrition interventions. While nutrition-related health products comprise a coherent group, products in this category vary in the quality of evidence supporting their use, intended use and composition, which greatly complicates classification and legislation for these products by regulatory agencies around the world. Ready-to-use therapeutic foods (RUTFs) exemplify this problem well, as they have a dual status as medicines and foods. The current proposal to include RUTFs in the WHO [World Health Organization] *Model List of Essential Medicines* (EML) brings about a need to clarify where RUTFs fit within the category of nutrition-related health products, and a need to assess the consequences of their inclusion in the list. Drawing from in-depth interviews with experts working in the field of nutrition across different sectors, this study explores where RUTFs fit within the category of nutrition-related health products, and the advantages, disadvantages and trade-offs that key stakeholders would face if RUTFs were included in the EML. The results show that nutrition-related health products are not classified consistently by regulatory agencies around the world, and that experts use various criteria to decide which class of nutrition-related health products RUTFs belong to. There is no consensus among experts about the appropriateness or benefit of including RUTFs in the EML. The advantages and disadvantages, consequences and trade-offs of including RUTFs in the EML are examined and discussed.

Keywords: essential medicines; nutrition products; ready-to-use therapeutic foods; RUTFs; undernutrition

Introduction

Undernutrition creates a substantial burden of disease globally through four main conditions: wasting, stunting, underweight and deficiencies in vitamins and minerals (1, 2). Malnourished children, particularly those with severe undernutrition, have a higher risk of death from common childhood illnesses, such as diarrhoea,

pneumonia and malaria (2). Iodine, vitamin A and iron are the most important micronutrient deficiencies in global public health terms; their deficiency represents a major threat to the health and development of populations worldwide, particularly children and pregnant women in low-income countries (2, 3). Further, for World Health Organization (WHO) Member States committed to achieving the 2030 Sustainable Development Goals, nutrition plays an important role in many of them (4–6), as it is evident that it plays a key role in the healthy and productive development of the population.

There are various evidence-informed interventions to improve nutrition around the world. Many of these essential nutrition actions are recommended by WHO for different population groups across settings and conditions, and nutrition-related health products are a fundamental part of them (1, 7–10).¹

Nutrition-related health products include products for particular nutrition-related requirements resulting from physical or physiological conditions, which assist, improve or modify the normal physiological growth, development and functions of the body, as well as products that play a role in preventing, treating or curing diseases (10–14). While nutrition-related health products are a coherent group, the category is broad, and contains products with different intended uses, indications, compositions and degrees of evidence supporting their effectiveness (13, 15). Further, nutrition-related health products come in various dosage forms, such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop-dispensing bottles, and other similar forms of liquids and powders (16, 17). These differences complicate a single, straightforward definition of nutrition-related health products,² creating confusion and fuelling inconsistent nomenclatures and classifications by regulatory agencies around the world.

Many nutrition-related health products are what the Codex Alimentarius (Codex) calls “foods for special dietary uses”. Several standards relating to foods for special dietary uses have been established by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) (11, 12, 18–27). Other foods for special dietary uses may exist and are recognized in some national regulations but are not necessarily defined at Codex Alimentarius level. The CCNFSDU defines foods for special dietary uses as:

Those foods specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.³ The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist (12, 15, 23).

They are also called “foodstuffs intended for particular nutritional uses” by the European Union (28). Definitions of foods for special dietary uses vary slightly across countries and regions (29).

Other nutrition-related health products with therapeutic uses are considered “foods for special medical purposes”. According to the CCNFSDU, these are:

A category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two (13).

¹ This study has focused on nutrition-related health products included in health-related actions with an impact on nutrition, or what are also known as “specific nutrition interventions”. Many other health interventions and non-health-related interventions outside the health sector can also have an important impact on nutrition but were not included in the scope of this study.

² For this study, nutrition-related health products were defined as those that aim to cover particular nutritional needs of the target population and impact the health status of this population by modifying priority health outcomes.

³ This includes foods for infants and young children.

They are also called “medical foods” by the United States Food and Drug Administration (US FDA) and “dietary foods for special medical purposes” by the European Union (EU) (30–32). Nutrition-related health products in this category need to meet regulatory requirements for use in chronic conditions (30).

The regulatory framework that defines nutrition-related health products as foods, medicines or foods for special medical purposes varies across countries. Despite the challenges in classification at country level, it is clear that nutrition-related health products are a fundamental part of nutrition interventions. Over the past years, a myriad of nutrition-related health products have been recommended by WHO as part of nutrition interventions, including multiple micronutrient supplements; food fortification with micronutrients or point-of-use fortification with multiple micronutrient powders, iron and folic acid supplements, vitamin A supplements or calcium supplements; and other products such as lipid-based nutrient supplements and therapeutic milks. Some of these interventions, such as the Integrated Management of Childhood Illnesses (33), routine antenatal care (34), and management of severe acute undernutrition (1, 35)¹ are part of integrated public health programmes and have been employed successfully in the management of undernutrition around the world.

An important aspect for the successful use of nutrition-related health products is that nutrition interventions integrated into public health programmes are associated with issues surrounding the accessibility and cost of these products in-country. The inclusion of a medicine in the *WHO Model List of Essential Medicines* (EML) (36) conveys the message that some medicines are more important than others, which can facilitate Member States in assuring the availability of these products (37, 38). It is in this context, that the Evidence and Programme Guidance Unit in Department of Nutrition for Health and Development at WHO seeks to understand how nutrition-related health products are defined and classified by experts working on nutrition intervention and programmes. The issues of definition and classification of nutrition-related health products have fundamental implications for how any given product is regulated within countries, which in turn impacts the product availability, cost and specification for use in each country (39).

Owing to this, there is a need to develop a shared understanding of the category of nutrition-related health products and relevant subgroups, and how ready-to-use therapeutic foods (RUTFs)² in particular fit into this category. This study conveys perspectives of experts working in the field of nutrition across different sectors about the definition of nutrition-related health products and the criteria they use in their daily work to classify them into subgroups, and inquires further about how RUTFs fit into the broad category of nutrition-related health products.

A key example of this issue is the definition and classification of RUTFs. In 2017, the international nongovernmental organization Action Against Hunger submitted an application to WHO proposing the inclusion of RUTFs in the EML and in the *Model List of Essential Medicines for Children* (EMLc) (40). RUTFs are high-energy, fortified, ready-to-eat foods for special medical purposes (1, 41, 42) that have a status bordering between foods and medicines. The application to include RUTFs in the EML draws on existing evidence of the efficacy of RUTFs in the management of severe acute undernutrition in children aged 6–59 months (41, 43). The United Nations Children’s Fund, the United States Agency for International Development, and several ministries of health and civil society organizations in Member States supported the inclusion of RUTFs in the EML, citing the body of evidence, practical knowledge and specialist endorsement of these products to treat severe acute undernutrition using a community and integrated model (7, 44–47).

In the application, it is argued that the inclusion of RUTFs in the EML could help alleviate some of the challenges related to the current use of RUTFs to treat severe acute undernutrition around the world, including

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 herewith to convey that reference is made to undernutrition only and not to all other types of malnutrition (2).

² RUTFs are specially-formulated foods for the treatment of infants and children 6 months of age or older, with severe acute undernutrition, who have appetite and do not have medical complications. These health products are nutrient dense, and contain adequate protein and other essential nutrients such as vitamins and minerals. These foods are soft or crushable and can easily be eaten without any additional preparation. They are consumed without adding water, have a low risk of bacterial contamination, require no refrigeration and have a nutritional composition based on the F-100 therapeutic milk used in hospital settings.

challenges related to their availability, accessibility, distribution and cost. This is because the inclusion of RUTFs in the EML can encourage Member States to include them in their national lists of essential medicines, which in turn facilitates the incorporation of RUTFs into national guidelines and public health policies, and their assimilation into the routine delivery system (39, 47). However, the potential inclusion of RUTFs in the EML brings about important considerations about how RUTFs are to be classified and regulated by Member States. One key consideration relates to the bordering status of RUTFs as foods and medicines. While the application to include RUTFs in the EML asked to classify them under the miscellaneous category, this ambiguous status can complicate their classification and approval by country-level regulatory agencies (44). A second key issue is to consider the trade-offs and potential unintended consequences of including these products in the EML.

The overall aim of the project was two-fold. First, it sought to determine the experts' definitions of nutrition-related health products and the criteria they use to organize products into subgroups; to explore whether they find the category of nutrition-related health products useful; and to understand how they define and classify RUTFs within the category of nutrition-related health products. Second, it sought to evaluate the advantages, disadvantages, and trade-offs key stakeholders would face if RUTFs were included in the EML. Accordingly, the present study asks the following questions:

1. How do RUTFs fit into the conceptual criteria that define nutrition-related health products?
2. What are the advantages and disadvantages of including RUTFs in the EML?
3. What are the criteria and trade-offs considered by stakeholders in their assessment of RUTFs as candidate essential medicines?

Materials and methods

Participants

A total of 18 participants were interviewed across two waves of interviews. Both waves were conducted with experts on nutrition; participants in wave 1 ($n = 6$) were experts on nutrition products and nutrition programmes, while participants in wave 2 ($n = 12$) were experts on nutrition programmes and the use of RUTFs in the management of severe acute undernutrition.

Participants were selected using purposive sampling (48). The main sampling criterion was heterogeneity. The researchers sought to interview people with expertise in different domains of the research questions (technical expertise, practical knowledge, decision-makers) and who worked in different sectors. The interviewees were identified through existing lists of experts compiled by the WHO Evidence and Programme Guidance Unit. The experts from these lists are external experts, partners from United Nations agencies or international organizations, or donors with which WHO has been working on the development of undernutrition guidelines, technical notes, and in emergencies. In addition, a small proportion of interviewees were identified via review of publications. The interviewees worked in the following sectors: regulatory agencies, nongovernmental organizations and humanitarian organizations, United Nations agencies and programmes, academia, and private-sector stakeholders that produce RUTFs.

Wave 1 interviewees worked in regulatory agencies ($n = 3$), United Nations agencies ($n = 1$), the private sector ($n = 1$) and nongovernmental organizations and humanitarian organizations ($n = 1$). Wave 2 interviewees were experts from regulatory agencies ($n = 2$), nongovernmental organizations and humanitarian organizations ($n = 2$), United Nations agencies ($n = 4$), the private sector ($n = 1$) and academia ($n = 3$).

Procedure

Semi-structured interviews were conducted to gather information on the experts' definition of the category of nutrition-related health products and how they classify RUTFs within it (wave 1) and to explore the advantages, disadvantages and trade-offs faced by stakeholders in relation to the inclusion of RUTFs in the EML (wave 2).

Informed consent was obtained before collecting any data. This included consent to audio-record the interview. Participants were informed of the evaluation aims and interview objectives, and it was explained to them that participation in the interview was voluntary. All interviews were conducted over Skype and were anonymous and confidential. An identification number (ID) was assigned to each participant to preserve anonymity. This ID, rather than the participant's name, was used in all study documents and during the data analysis. The interviews lasted between 30 and 45 minutes. Interviews were audio-recorded and transcribed verbatim for analysis.

Instrument

Semi-structured interview guides were developed for each wave of interviews. The process for development of interview guides was informed by a desk review, which was conducted in the preliminary phase of the study. Questions in the semi-structured interview guides were designed specifically to gather the informants' perspectives in a non-leading fashion and help them engage in an exercise of description and reflection of their own practical experience and expert knowledge of the topic of interest in each wave of the interviews. A series of follow-up probing questions were included to expand on the information provided during the interviews, and to give participants the opportunity to elaborate where necessary (49).

The semi-structured interview guide for wave 1 focused on the experts' definitions of the category of nutrition-related health products; criteria used to classify nutrition-related health products into subgroups; the usefulness and meaningfulness of the category of nutrition-related health products; definition of RUTFs; and classification of RUTFs in the category of nutrition-related health products.

The semi-structured interview guide in wave 2 was designed to identify the potential advantages, disadvantages, domains and trade-offs of including RUTFs in the EML. Based on the desk review, the following criteria were explored: cost and budget impact of RUTFs; cost effectiveness of RUTFs; equity considerations; effectiveness and quality of the evidence available on RUTFs; prioritization of severe acute undernutrition versus other conditions; prioritization of the population group; issues related to the supply chain, particularly product availability and shortages; use of local versus global commercial formulas; and preferences of the target population versus preferences of RUTF experts. The guide also included questions about the management of potential conflicts of interest resulting from the inclusion of RUTFs in the EML, and questions on products that are similar to RUTFs that could be considered for inclusion in the EML. The semi-structured interview guides can be found in [Appendices A3.1.1](#) and [A3.1.2](#).

Data analysis

The qualitative data in wave 1 were analysed using thematic analysis, through the following predefined themes: definition of nutrition-related health products; criteria used to classify nutrition-related health products; and classification of RUTFs in the category of nutrition-related health products. Examples of codes are "definition of nutrition-related health products", "criteria" and "RUTF medicine". The first code focused on the definition of nutrition-related health products, and explored whether the experts' definitions of nutrition-related health products included or excluded various groups of products such as supplementary nutrition products, dietary supplements, fortified blended foods, lipid-based nutrient supplements, and others. The second code focused on the criteria experts use to organize the various nutrition-related health products into subgroups. The third code captured the experts' opinions on the usefulness and meaningfulness of the category of nutrition-related health products, and explored some of the other terms they use to refer to this group of products. The fourth code focused on the definition of RUTFs, exploring any additions experts would make to the definition that was presented to them. The fifth and last code focused on understanding how RUTFs fit into the category of nutrition-related health products.

The qualitative data in wave 2 were analysed using thematic analysis, through the following predefined themes: advantages of including RUTFs in the EML; disadvantages of including RUTFs in the EML; and criteria and trade-offs of including RUTFs in the EML. A coding frame was developed, based on the research questions

and conceptual framework. An example of a code is “current use of RUTFs”; examples of subcodes are “cost” and “availability”.

Data were analysed using thematic analysis, with the qualitative software NVivo. The evaluator tagged each section of the transcribed interviews with codes (themes) and subcodes (subthemes). The software was used to group together paragraphs tagged with the same code. Viewing the data side by side facilitated the analysis of common elements across all interviews. Next, the data were analysed to identify differences in the answers of participants, by sector.

Results

This section presents the results of the qualitative interviews organized by the themes explored. The section begins with the findings on the definition of nutrition-related health products, the criteria experts use to classify nutrition-related health products into subcategories, and the perceived usefulness of the category of nutrition-related health products. Next, it focuses on the definition of RUTFs and the experts’ assessments of how to classify RUTFs in the category of nutrition-related health products.

Definition of nutrition-related health products

When asked what the term “Nutrition-related health products” means, most experts converged in saying that it refers to products made of nutritious ingredients that are to be consumed for a specific health reason.

[nutrition-related health products] makes me think of manufactured products containing nutritious ingredients. They are to be consumed for a reason, as part of a healthy diet, or maybe even for treating certain conditions or preventing certain conditions, or expecting nutritional benefits. (W101, United Nations agency)

All experts considered that the category of nutrition-related health products is quite broad and that it includes multiple products with different uses. However, differences across sectors were made evident through the specific “reason” or the use of nutrition-related health products. Experts from nongovernmental organizations and humanitarian organizations and from United Nations agencies tended to include products aimed at improving the quality of nutrition as part of the category of nutrition-related health products. Therefore, products to supplement a healthy diet were considered nutrition-related health products. The category was broadly defined; it included supplements for a healthy diet and products used for the management of health conditions.

The [nutrition-related health products] category, in my mind, would include products across an axis, yes. The diet quality improvement all the way through therapy. And obviously that’s not a black and white classification, there is some grey area. (W103, nongovernmental organization and humanitarian organization)

In contrast, experts from regulatory agencies tended to include in the category of nutrition-related health products only those products that are aimed at preventing or managing health conditions. When prompted, they would accept the idea of a product aimed at aiding a healthy diet as technically being a nutrition-related product, but this was somewhat counterintuitive to them, as they were much more focused on the regulatory framework of their agencies. Such frameworks require stringent assessments of evidence and complex regulations that leave supplements and other nutrition-related products out of the categories they work with. These experts discussed products that often require a formulation by a medical doctor and that are commonly provided to the intended population as part of social, educational or health programmes.

In my mind, nutrition-related products have a medical purpose or a treatment purpose. These include foods for special medical uses. These products include those that are administered through an enteral or parenteral route. Most, but not all of them, are covered by the national health insurance, so we pay particular attention to supporting evidence, cost and safety. (W104, regulatory agency)

In summary, experts from different sectors understand nutrition-related health products to mean slightly different things. While experts across sectors include in the category of nutrition-related health products those nutritious products for the management of health conditions, experts outside the regulatory sector tend to define the category more broadly, to include products aimed at supplementing a healthy diet that are to be consumed by healthy individuals.

Criteria used to classify nutrition-related health products and usefulness of the category

Experts used a combination of criteria to classify nutrition-related health products into subgroups. One prominent criterion was the differential use of products associated with therapeutic or preventive efforts. Nutrition-related health products used to treat or manage disease are different from those used to prevent health conditions. Experts added that nutrition-related health products used by healthy individuals to achieve or support healthy nutrition comprise a third subgroup, but this group was less clearly defined, and experts had more trouble determining the boundaries of this classification. Within the nutrition-related health products with therapeutic or preventive uses, condition-specific use was employed by all experts to classify nutrition-related health products into subgroups.

The [nutrition-related health products] category basically refers to a processed fortified food. And then, there are different types for different uses. You have RUTF for SAM [severe acute undernutrition], RUSF [ready-to-use supplementary food] for MAM [moderate acute undernutrition], and then you've got fortified blended foods, which have a special variant for children. There are powdered complementary food supplements and micronutrient powders to be added to food to provide essential nutrients to a diet that is likely low in those nutrients. (W101, United Nations agency)

A second criterion was nutritional composition. Participants considered the composition of the product to categorize different nutrition-related health products, as conveyed in the following quote,

The second way [of classifying nutrition-related health products] is where you have single nutrient versus the complete diet replacement (...) so, there is an objective of what you are trying to accomplish and then there is the problem that underpins the objective that you are trying to accomplish. Is it failure of the entire diet? Energy, micronutrients, macronutrients, or is it an inadequacy of some or several components of that diet? (W103, nongovernmental organization and humanitarian organization)

The quality of evidence supporting the nutrition-related health products, while considered important, was not a criterion used to classify nutrition-related health products into subgroups. This evidence should usually be of high quality, commonly resulting from randomized controlled trials and found in the published literature on the topic. However, none of the experts interviewed considered that nutrition-related health products should be divided into groups according to the amount of evidence supporting them.

It is important to note that all experts relied on a combination of criteria to delineate subgroups of nutrition-related health products, and that these criteria are not mutually exclusive. Therefore, a fixed taxonomy of nutrition-related health products was not present in participants' answers, although differences across sectors emerged. Experts from regulatory agencies tended to draw from the official or national-level classification of these products. These classifications vary slightly across countries, as has been reported by previous research (30, 50).

I know these terms are kind of confusing, but we are trying to make a clear distinction between products to be used by healthy people and products to be used for health-specific conditions, that being preventing or treating something. If you are sick or have a health condition, and you need a product intended at mitigating or preventing some kind of osteoporosis for example, we are talking about nutrition-related health products that are classified and regulated as medicines as per the country classification system. (W102, regulatory agency)

When asked about how their country had developed a classification system for nutrition-related health products, experts from regulatory agencies explained that the taxonomy was developed drawing from the various classification systems around the world, including Codex, the US FDA and the classification system of the EU, but also the classification system of New Zealand, which was mentioned as a comprehensive classification system for nutrition-related health products. In general, the distinction between nutrition-related health products with therapeutic use and nutrition-related health products aiming to aid diet among healthy people was clear across sectors, yet there was variation in how classification systems dealt with products falling in between these two categories. In various countries, products with “dual status” as foods and medicines (such as RUTFs) tended to be regulated as medicines, since they are meant to be used by people with a health condition.

Lastly, when asked about the usefulness and meaningfulness of the category of nutrition-related health products, experts seemed to agree that the wording “nutrition-related health products” is not that commonly used but it is not hard to understand. However, they pondered whether the non-specificity of the concept could create confusion, given the different names people in the nutrition field already use to refer to these products.

Typically SNF, special nutritious food, which is a name you will most often hear. Partly we have to go with how people already refer to these products. So that's why we say special nutritious food, which at least [is] sort of an overarching category. (W101, United Nations agency)

To me [nutrition-related health products] is not a terminology that I've come across, but it is clear and it communicates the point but I am somebody who has worked in this field for a really long time, so to me it's not necessarily common use but it's not a complex terminology to understand. Although maybe I can see some complexities because, if I were a high-performance athlete I could call some of those supplements that I'm taking nutrition-related health products. And if I'm a health food fanatic and I'm taking alfalfa oil, I might call it nutrition-related health products. I suppose it is for me, who works in the field, I have my own conceptual framework that I would put around that term but probably it's so open that depending on where you're coming from you could make it mean what you want it to mean. I suppose there is some risk in that. (W103, nongovernmental organization and humanitarian organization)

Therefore, while the category of nutrition-related health products is not a complex term to understand, the lack of specificity of the term could potentially create more confusion among people working in the nutrition field. This is because there are already various names being used to describe this group of products. Another expert explained that most of these names come from the pharmacists, but they lose or change their original meaning as they travel from the medical field to applied work. The expert recommended trying to build some consensus around how these terms are used, and that this is work that needs to be done from the ground up, taking into account how these terms are being used at present.

Definition of ready-to-use therapeutic foods

Respondents did not agree on one single definition of RUTFs, but all agreed that they belong to the category of nutrition-related health products. Some experts defined RUTFs as therapeutic foods, as these are products to be used for the management of acute undernutrition, a health condition. This was most often the case for participants in the regulatory sector. In this line of reasoning, experts emphasized that RUTFs are meant to be used for unhealthy children, meaning they are closer to being a medicine than being a food. Participants from outside the regulatory sector found the definition of RUTFs more difficult, given their dual status as foods and medicines. In general, they defined RUTFs as special foods, aimed at the management of a health condition, and they were not considered as medicines. Some experts used concepts such as food for special dietary uses and medical foods. One participant considered RUTFs to be foods, as they are produced in the same manufacturing units where chocolate or peanut butter are produced, with no additional requirements.

It should not be seen as a medicine because it is still a food but is a therapeutic food, because [it] is a food that should not be consumed by the normal population. [It] should really be targeted to those children, during rehabilitation, which is a very short period of time and for a relatively small number of children compared to the whole population of children. So it is really for a period of two months during rehabilitation. (W202 United Nations agency)

While most experts agreed with the provisional definition of RUTFs provided by Codex, some raised concerns about the risk of ending with a fixed description once RUTFs are included in the EML. This would constrain innovations in the ingredients and the product recipe. It was argued that innovation of ingredients can help reduce the cost of RUTFs (e.g. by using proteins from fish instead of milk). It was also argued that some flexibility in ingredients would enable the development of recipes that are better received by the target population (e.g. replacing peanuts with local ingredients such as rice). This would not be possible if the description of RUTFs is not flexible. All experts agreed on the importance of maintaining the same nutritional composition regardless of the ingredients used.

Classification and regulation of ready-to-use therapeutic foods as nutrition-related health products

Experts were asked about where RUTFs fit in the category of nutrition-related health products. Their answers were slightly different from those for the question about the definition of RUTFs. Experts pondered about the dual status of RUTFs as foods and medicines, but took a pragmatic approach to the question of classification, beyond abstract definitional considerations.

There are pros and cons of classifying each way, so if it's classified as a medicine then within countries the whole process to get it included and approved to be used in nutrition programmes is much different, it will need to go through a much more complex and sometimes time-consuming process to have approval. (W105, private sector)

Therefore, when deciding how to classify RUTFs within the category of nutrition-related health products, all experts weighed the regulatory implications of classifying RUTFs as medicines on the one hand, and as foods on the other. Experts working in regulatory agencies thought that RUTFs should be classified and regulated as medicines, which would help to assure adequate standards of production and monitoring of administration to the intended population. Experts working in other sectors considered that RUTFs should be classified in an in-between category, being “foods for special dietary uses”, “foods for special medical uses”, or “foods for special medical purposes”. Such a categorization would be adequate, as it allows control of the quality of the product without hampering the distribution and availability of RUTFs to be used in nutrition programmes led by Member States. Experts explained that RUTFs should not be classified as medicines or as

any medical product category requiring medical regulations, as this would create various complications at the country level, with several potential unintended consequences.

I would always advocate for the lighter one, I would advocate for special dietary purposes, if it had to go one way or the other. I don't think a lot of the governments that use this food would have the capacity to do the risk assessment required, I think they are going to follow the guidelines issued by WHO very closely. I think it's very much a matter of how WHO is actually defining RUTF and how WHO is advising on the classification. (W206 United Nations agency)

Potential consequences of classifying RUTFs as medicines or any medical product category that would trigger medical regulations included increases in cost, restrictions of access, hampering of local production of RUTFs, and a cascade effect of classifying other products such as RUSFs as medicines, with all the aforementioned potential consequences. In fact, the possibility of medical regulations was the most cited concern about the potential inclusion of RUTFs in the EML.

If RUTF is classified as being the same as conventional medicines, there is a risk that a whole range of new higher standards and demands – which frankly would be unnecessary – they would add no value to consumer safety but they would add to the cost of the product. The biggest barrier probably at the moment to further treatment is the cost of product. (W205, private sector)

However, a minority of participants- all from regulatory agencies- considered that classification of RUTFs as medical products would have the benefit of governments having more control, supervision, and accountability in how the products are used and produced. In evaluating the trade-off between classification as food or medicine, two experts from regulatory agencies in wave 2 agreed that a classification as medical products is better.

It would be important to classify them as medicine. For example, in a country like mine, the risk of counterfeit products is high, so you want regulations and assurance that the product you are using is of good quality. (W210, regulatory agencies)

Advantages, disadvantages, and trade-offs of including ready-to-use therapeutic foods in the WHO Model List of Essential Medicines

The most cited argument for the inclusion of RUTFs in the EML was that it would make the inclusion of RUTFs in national essential medicines lists more likely. Interviewees explained that this is so because many countries use the EML as guidance for their own list of essential medicines. Inclusion in the country-level list would, in turn, increase the accessibility and availability of RUTFs. Lastly, the inclusion of RUTFs in the EML could increase awareness about severe acute undernutrition and aid its prioritization in countries with a high prevalence of the condition.

If you include [RUTFs] in the list of the country, it obviously will create awareness on the [severe acute undernutrition] condition, investment of the government, responsibility, and it comes with mutual sustainability, it could help to improve access and also acceptance from the population. (W201, United Nations agency)

Yet, experts also expressed a number of concerns about the inclusion of RUTFs in the EML. As mentioned before, the most common concern was that it would trigger medical regulations, which would aggravate current challenges related to accessibility and cost, while potentially creating new challenges such as harming smaller companies that could produce RUTFs locally.

There were other arguments against the inclusion of RUTFs in the EML. One pertained to the risk of medicalizing child feeding. Participants considered that including RUTFs could create incentives for these products to be used as replacement for real food (both on the part of parents and on the part of the industry), and that prevention efforts targeting severe acute undernutrition would see their budget strained as the result of the resources' need to provide RUTFs as essential medicines. In particular, concerning the idea of including a food (if RUTF is defined as a food) in the EML:

It's a dangerous precedent where we are putting a food onto the EML and I think that could lead, rightly or wrongly, to interpretation, it could still change how they're regulated, how they're made available. I think it's very easy to assume that would happen for the RUSF and potentially for all the [lipid-based nutrient supplements] product categories and then I would become extremely concerned if that started happening for all complementary foods. (W206, United Nations agency)

A second argument was about the lack of conclusive evidence that RUTFs are indeed the best approach to manage severe acute undernutrition. One expert argued that the current estimates of RUTFs' effectiveness are inflated, and that RUTFs are not necessarily better than other interventions. In particular, this expert argued that RUTFs have not been proven to be better than preventive efforts against severe acute undernutrition. In this line of reasoning, pushing RUTFs into the EML alongside country-level essential medicines lists, would put governments in a position where they need to prioritize RUTFs over other essential medicines or other public health problems. In addition, and in open contradiction with the main argument for the inclusion of RUTFs expressed by other experts, participants from academia and the private sector converged in considering that the health system would face an unnecessary burden, which, combined with budget constraints in countries with a high prevalence of severe acute undernutrition, would have the consequence of decreasing the accessibility of RUTFs.

Putting it on the EML, people think that is going to increase access, think that somehow health budgets are going to automatically increase by doing so and that's simply not the case. Health budgets are going to remain constant and now the people within that sector are going to take prioritization decisions. So with the budget that exists in that sector, they are going to have to now prioritize RUTF versus other essential medicines. (W206, private sector)

Criteria and trade-offs related to the inclusion of ready-to-use therapeutic foods in the WHO Model List of Essential Medicines

The interviews were designed to explore the criteria involved in the trade-offs stakeholders would face should RUTFs be included in the EML. These criteria relate to the current use of RUTFs and inform about the strengths and challenges faced by stakeholders in using RUTFs. Table A3.1.1 shows the factors considered to be a challenge in relation to the current use of RUTFs, broken up by sector. The findings suggest some commonalities across sectors, most notably that availability and cost are current challenges in relation to RUTFs.

In general, respondents mentioned that RUTFs are expensive; this was true for experts across all sectors. All experts discussing this challenge agreed on the need to seek ways to reduce the cost of RUTFs. However, there was no consensus about the type of impact that the inclusion of RUTFs in the EML would have on cost. Most respondents thought that the inclusion in the EML would increase the cost of RUTFs, most likely as a result of stringent, medicine-like regulations and more complex requirements of production, alongside a hampering of locally produced RUTFs. Because RUTFs are perceived as costly products, experts expressed concern about potential consequences of prioritizing RUTFs over other strategies to manage severe acute undernutrition. In addition, they doubted that currently strained health systems would increase their budgets to prioritize and cover the costs of RUTFs, if they were included in the country-level essential medicines lists.

Table A3.1.1. Challenges in the current use of ready-to-use therapeutic foods, by sector

Factor	Nongovernmental organizations and humanitarian organizations	United Nations agencies	Private sector	Academia	Regulatory agencies
Availability	×	×			×
Accessibility		×		×	
Distribution				×	×
Cost	×	×	×	×	×
Manufacturing	×		×		×
Cost effectiveness				×	
Regulation				×	×
Requirements for medicines					
National registration					
Other considerations		×		×	
Equity					

A second criterion perceived as a current challenge was the availability of RUTFs. Experts in nongovernmental organizations and humanitarian organizations, and those working in United Nations agencies and country-level regulatory agencies, thought that the availability of RUTFs needs to be improved to assure treatment of severe acute undernutrition around the world, particularly in those countries with the highest prevalence of severe acute undernutrition and in emergency situations.

[The inclusion in the country EML] will increase national government involvement and the appropriation of the management of SAM and RUTF that is used for treatment, it will mean that the government will increase the awareness, and the acceptance from the population will increase the accessibility and availability of the product, if we talk about availability, that means that we are going to have more coverage of the programme. W201, United Nations Agency)

United Nations agency experts discussed the benefit of having governments rather than international agencies take on the responsibility to assure the provision and availability of RUTFs in contexts where they are needed. An important trade-off involved balancing the cost and availability of RUTFs. If RUTFs were to be included in the essential package, then experts would expect this to bring about an increase in funding to assure their availability. However, some experts were not sure that an increase in funding would necessarily result from the inclusion of RUTFs in the EML or in national essential medicines lists. An industry stakeholder expressed concern about the inclusion of RUTFs in the EML negatively affecting the availability of the products. This participant cited the trade-off between channelling distribution through the health system and through other routes such as community programmes, and ways of distributing RUTFs that run in parallel to the health system. In this case, the expert argued, the inclusion of RUTFs in the EML would restrict their availability to channels belonging to the health system and would have the effect of decreasing the availability of RUTFs through other channels.

Discussion

This article has sought to explore how experts define the category of nutrition-related health products, and the criteria they use to classify nutrition-related health products into subgroups. In addition, the study has sought to understand how RUTFs fit in the broader category of nutrition-related health products, as well as experts' perspectives on the advantages, disadvantages and trade-offs of including RUTFs in the EML.

The study findings indicate that nutrition-related health products are a broad category that means slightly different things to experts across sectors. Those from the regulatory sector had a narrow definition of nutrition-related health products comprising nutritious products to manage health conditions. Experts from other sectors included in the category nutritious products to aid a healthy diet to be consumed by healthy people.

Experts draw from three main criteria to classify nutrition-related health products into subgroups. They determine whether the product is aimed at treating or preventing conditions. Nutrition-related health products to treat or manage conditions are different from those used to prevent health conditions. Within this broad division, experts consider the intended use for specific conditions, such as RUTFs for severe acute undernutrition and RUSFs for moderate acute undernutrition. A third criterion is nutritional composition, which goes from single nutrient to replacement of the whole diet. Importantly, these criteria were not described as mutually exclusive, rather, participants draw from all of them to classify nutrition-related health products.

In relation to RUTFs, most experts highlighted the dual status of these products as foods and medicines and, therefore, were inclined to think that RUTFs belong to a middle-ground category such as foods for special dietary uses or foods for special medical uses. Since a final definition of RUTFs is currently being developed (42), the majority of participants in this study considered that such definition should focus on composition but be flexible otherwise, to allow innovation in the ingredients used to produce RUTFs. This would allow consistency in the nutrient composition of RUTFs across manufacturers, while allowing global and local manufacturers to try new ingredients that could help to reduce the cost of RUTFs. Regarding how RUTFs should be classified in the EML, most experts thought that they should be classified in the "miscellaneous" category. However, they stressed that this classification could lead to inconsistencies in how RUTFs are classified across Member States.

All experts took a pragmatic approach to answering the question of classification and regulation of RUTFs, beyond its conceptual definition. There was no consensus among experts with regard to how RUTFs should be classified and regulated in-country. Some experts considered RUTFs to be foods and thought they should be regulated as such. Other participants stated that RUTFs should be classified and regulated as foods for special dietary uses, as this reflects the fact that RUTFs are meant to be used by a certain population, to treat severe acute undernutrition, and for a specific period of time. Experts outside the regulatory sector considered that RUTFs should not be classified as medicines, as this would bring about complex regulations with the unintended consequence of decreasing their availability and accessibility, and probably increasing their cost. However, experts from regulatory agencies, particularly from low- and middle-income countries, considered it important to classify RUTFs as medicines, to assure stringent and reliable regulation by countries.

In general, the qualitative interviews on the experts' definitions of nutrition-related health products show that the category is thought of as a broad category comprising a myriad of products. Some key criteria used by experts to classify nutrition-related health products into subgroups are the nutritional composition, the intended use, and the division between therapeutic and preventive products. RUTFs belong to the category of nutrition-related health products, but the way in which experts classify them into a subgroup depends on whether experts are concerned with taxonomy or with the regulatory consequences of classifying RUTFs as foods or as medicines.

The experts' assessments of the advantages and disadvantages of including RUTFs in the EML varied according to their expectations of how RUTFs would be classified by regulatory agencies at the country level. The large majority of experts considered that the inclusion of RUTFs in the EML would facilitate their inclusion

in national essential medicines lists. However, there was no consensus among experts about the direction of the consequences (advantages or disadvantages) that this would bring about. Two important considerations in this regard were the issues of regulation and quality of evidence supporting RUTFs, as discussed in the results section. Finally, the potential trade-offs resulting from the inclusion of RUTFs in the EML depended on how experts evaluated the current use of RUTFs, particularly the challenges in relation to the current use of RUTFs in the treatment of severe acute undernutrition. There was a large consensus about cost being a current challenge in relation to RUTFs. Experts agreed that RUTFs are costly, but they also thought that they afford cost-effective interventions. Importantly, the availability of RUTFs was perceived as a current challenge, mostly by experts working in nongovernmental organizations and United Nations agencies. Most cited trade-offs around the issues of cost and the prioritization of RUTFs against other products or interventions to manage severe acute undernutrition, and trade-offs relating to the capacity of strained health systems and the modifications they would have to implement in order to assure the availability of RUTFs if they were included in national essential medicines lists.

In general, the qualitative interviews on the experts' perspectives on the advantages, disadvantages and trade-offs of including RUTFs in the EML were plural and sometimes contradictory. Most of the divergences found in the experts' assessments are explained by the lack of a commonly agreed definition of RUTFs and the uncertainties about how RUTFs will be classified and regulated at the country level. Case-studies of countries where RUTFs have been included in their national essential medicines list should be carried out, to learn how different classifications and regulations of these products play out in real life. The present study on the experts' assessment of the advantages, disadvantages and trade-offs of including RUTFs in the EML shows that this inclusion would probably facilitate adoption of the products in national essential medicines lists, but that the effect of this on cost and availability is deeply entangled with the question of how RUTFs are classified by each country.

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Appendix 3.1.1

Semi-structured interview guide (wave 1)

The purpose of this interview is to identify the criteria that define nutrition-related products. As you probably know, there isn't a consensus on what this category of products entails, nor is there a unified nomenclature to refer to them. In this interview, I will be asking a variety of questions that will help me to better understand the *criteria you use to define nutrition-related products* and which products fall into this category. I will also be asking questions about ready-to-use therapeutic foods that will help me understand how they fit your definition of nutrition-related products.

How this interview will work

I will be asking general questions about nutrition-related products. After each question, there will be some time for you to respond. To begin the interview, I would like to ask for your consent to record our conversation today.

YES

NO

[Turn the recorder on]

State the date and participant code

Definition of the category

- In your own words, what are “nutrition-related products”?
- Are there any subcategories of “nutrition-related products”?
- Is the category “nutrition-related products” different from “supplementary nutrition products”? If so, how is it different?
- Do you consider dietary supplements to be “nutrition-related products”? Why?
- Do you consider fortified blended foods to be “nutrition-related products”? Why?
- Do you consider lipid-based nutrient supplements (LNS) products to be “nutrition-related products”? Why?
- Is the category “nutrition-related products” different from “foods for special dietary uses”? If yes, how is it different?
- Lastly, is the category “nutrition-related products” different from “foods for special medical purposes”? If so, how is it different?
- Does the classification of these products in your country differ from the classification provided by the United States Food and Drug Administration and the European Union?
- If so, what are the main differences?

Criteria used to define the category

- In your work, what term do you use to refer to “nutrition-related products”?
- Please list the nutrition products you consider within this category

_____	_____
_____	_____
_____	_____
_____	_____

- Thinking of the products you just listed, what criterion (or criteria) did you use to decide which product belongs to the category [name the nomenclature used by the interviewee]?
- Thinking of the products you just listed, were there any products that you ruled out of this list? If so, what criteria did you use to rule them out?

Usefulness of the category

- Do you find the category of nutrition-related health products meaningful? Why/why not?
- Do you find the category of nutrition-related health products useful? Why/why not?
- Do you find the category of nutrition-related health products problematic? Why/why not?
- What would be a good criterion to organize these products?
 - What about condition-specific intended use?
 - What about therapeutic or preventive use?
 - What about nutritional composition?
 - What about the quality of evidence supporting claims?
 - Do you use any other criterion? Please explain.

Ready-to-use therapeutic foods (RUTFs)

I would like to ask you a few questions about ready-to-use therapeutic foods. We define ready-to-use therapeutic foods as:

“High-energy, fortified, ready-to-eat foods for special medical purposes suitable for the dietary management of children from 6 to 59 months with SAM [severe acute undernutrition], typically made from full-fat milk powder, sugar, peanut butter, vegetable oil, and vitamins and minerals.”

- Do you think this definition is sufficient? Why/why not?
- Would you include any other product characteristic in this definition?
- Please list the names of RUTF products you are familiar with:

_____	_____
-------	-------

_____	_____
_____	_____
_____	_____
_____	_____

- When you think of RUTFs, do you include F-100 and F-75 in this category? [Please remember these are milk-based therapeutic formulas.] Why/why not?
- Do you consider RUTFs to be nutrition-related health products? Why?
- Do you consider RUTFs to be foods for special dietary uses or medical foods? Why?

Thank you for your participation in the interview!

[Turn the recorder off]

Appendix 3.1.2

Interview guide (wave 2)

The purpose of this interview is to discuss the potential inclusion of ready-to-use therapeutic foods (RUTFs) in the WHO [World Health Organization] *Model List of Essential Medicines* (EML). As you probably know, there is an initiative to include RUTFs in the EML. In this interview, I would like to get your perspective on this. I will be asking you about the potential advantages and disadvantages (intended and unintended) of including RUTFs in the list. I will also be asking questions to better understand the trade-offs that key actors across sectors would face should this initiative move forward.

How this interview will work

I will be asking general questions about nutrition-related products. After each question, there will be some time for you to respond. To begin the interview, I would like to ask for your consent to record our conversation today.

YES

NO

[Turn the recorder on]

State the date and participant code

Ready-to-use therapeutic foods (RUTFs)

I would like to ask you a few questions about ready-to-use therapeutic foods. We define ready-to-use therapeutic foods as:

“High-energy, fortified, ready-to-eat foods for special medical purposes suitable for the dietary management of children from 6 to 59 months with SAM [severe acute undernutrition], typically made from full-fat milk powder, sugar, peanut butter, vegetable oil, and vitamins and minerals.”

[ONLY IF REQUESTED BY INTERVIEWEE, SAM criteria: Child has a mid-upper arm circumference <115 mm or a weight-for-height/length <-3 z-scores below the median of the WHO growth standards, or has bilateral oedema.] Following WHO recommendations, RUTFs are intended to treat uncomplicated cases of SAM in phase two of recovery or at home.

RUTFs have a *status bordering between foods and medicines*. RUTFs may potentially be included in the EML under the “miscellaneous” category. In relation to this application:

- Do you consider RUTFs to be foods for special dietary uses or medical foods? Why?
- What would be your main argument for the inclusion of RUTFs in the EML?
- What would be your main concern about the inclusion of RUTFs in the EML?
- What would be your main argument against the inclusion of RUTFs in the EML?
- What potential conflict of interest do you see resulting from the inclusion of RUTFs in the EML?
- How would you manage the potential conflict of interest you mentioned?

Regarding the current use of RUTFs:

- From your perspective, what are the main advantages of using RUTFs to treat SAM?
- From your perspective, what are the main challenges related to the use of RUTFs to treat SAM?
- Is availability a challenge? If yes: Would the inclusion of RUTFs in the EML help?
- Is accessibility a challenge? If yes: Would the inclusion of RUTFs in the EML help?
- Is distribution a challenge? If yes: Would the inclusion of RUTFs in the EML help?
- Is the cost of these products a challenge? If yes: Would the inclusion of RUTFs in the EML help?
- Is manufacturing a challenge? If yes: Would the inclusion of RUTFs in the EML help?
- Is regulation/classification of these products a challenge? If yes: Would the inclusion of RUTFs in the EML help?
- Do you think that the requirements for medicines/pharmaceutical products should be applied to RUTFs? Why?
- For national registration: Are there any special or additional regulatory requirements that a medicine or pharmaceutical product must comply with in comparison with a food product?
- Would you have any other consideration in relation to the inclusion of RUTFs in the EML? Please explain.
- Overall, do you think use of RUTFs is a cost-effective intervention to treat SAM? Why?
- Do you have any equity-related concerns regarding RUTFs?
- Is there any other product similar to RUTFs that you think should be included in the EML? Please explain

Thank you for your participation in the interview!

[Turn the recorder off]

Stakeholder perceptions of adding ready-to-use therapeutic foods and other nutrition-related products to the *World Health Organization Model List of Essential Medicines*

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Abstract

The WHO [World Health Organization] *Model List of Essential Medicines* (EML) serves as a guide for national medicines lists aimed at prioritizing effective, safe and cost-effective medicines to meet a population's health-care needs. Access to nutrition-related products in low- and middle-income countries with high burdens of severe acute undernutrition, anaemia and other nutrition-related conditions is often low, and adding ready-to-use therapeutic foods (RUTFs) and other nutrition-related products to the EML has been proposed as one strategy to improve access. This paper synthesizes input from a diverse set of stakeholders on the potential impacts of adding these products to the EML. Although there were some areas of relative consensus among stakeholders, their perceptions varied substantially regarding the likely impacts on product regulation and cost, and how in-country perceptions of these products might change if they are added to the EML or national essential medicines lists. Stakeholders also differed in their views of whether the addition of RUTFs to the EML would inhibit or support local production of these products, and how the scope for development of alternative formulations would be affected. The variation in stakeholder perceptions, which stems largely from uncertain categorization and regulation at county level if nutrition-related products are added to the EML or national essential medicines lists, illuminates uncertainty about whether and how access to these products would change in different settings. Considering this uncertainty, the need for a risk assessment is suggested, to evaluate the primary concerns raised by stakeholders.

Keywords: *essential medicines list; nutritional products; ready-to-use therapeutic foods; RUTFs; trade-offs*

Introduction

Essential medicines, as defined by the World Health Organization (WHO), are the collection of medicines that best meet a population's priority health-care needs (1). To meet those needs, essential medicines must be continuously available with adequate supply, quality and affordability. Disease prevalence and public health relevance, evidence on clinical efficacy and safety, and cost effectiveness are therefore key considerations in the selection of essential medicines. The *WHO Model List of Essential Medicines* (EML) and the *WHO Model List of Essential Medicines for Children* (EMLc) were established and are maintained with the intention of guiding the contents of national and institutional essential medicines lists (2). Nearly all low- and middle-income countries maintain a national essential medicines list (or equivalent), guided by the EML but adapted to fit the local

conditions, including prevalent diseases, availability of medicines, health facilities and workforce, affordability, and demographic and environmental factors (3).

WHO guidelines on the management of severe acute undernutrition in children aged 6–59 months recommend that F-75, F-100 and ready-to-use therapeutic foods (RUTFs) be used as part of the inpatient management of this condition (4), and that RUTFs be provided as therapeutic feeding for the community-based management of uncomplicated wasting (4, 5). Other nutrition-related products, including iron-containing micronutrient powders for point-of-use fortification of foods (6), are recommended by WHO to prevent nutritional anaemias in infants aged 6–23 months and children aged 2–12 years in areas where the prevalence of anaemia is 20% or higher. Daily or intermittent iron + folic acid supplements are also recommended as part of routine antenatal care (7).¹ RUTFs and other nutrition-related products, such as the intermittent iron + folic acid dosage for use in pregnancy, are not currently included in the EML, but it has been proposed that adding them to the list may improve the access of target populations to these products.

The EML and EMLc undergo review every 2 years (2). During the review process, the Expert Committee on the Selection and Use of Essential Medicines reviews applications and takes decisions about deleting existing medicines from the list; revising the indications of existing medicines; and adding new products. The addition of RUTFs to the EML was first proposed in March 2017, when the Expert Committee reviewed an application put forward by Action Against Hunger to add RUTFs to the miscellaneous category of the EML and EMLc, for dietary management of uncomplicated severe acute undernutrition (8). The miscellaneous category is a subsection of Section 26 of the current EML, entitled “Solutions correcting water, electrolyte and acid–base disturbances”. Listing RUTFs and, possibly, other nutrition-related products under this subsection has been proposed as a way to discourage the application of pharmaceutical standards to these products (9).

Action Against Hunger’s decision to put forward the application was based on its findings from a literature review, two case-studies and interviews with key informants to explore the arguments for and against adding RUTFs to the EML and national essential medicines lists, and the potential impacts of doing so (9). Action Against Hunger found a substantial public health need for access to RUTFs in low- and middle-income countries. The assessment suggested that the EML could play an important role in accelerating access to RUTFs for the dietary management of uncomplicated severe acute undernutrition and could contribute to improving public health outcomes and reducing morbidity and mortality.

The Expert Committee did not recommend the addition of RUTFs to the EMLc, and considered that listing RUTFs in the EML “may have implications for the availability of alternative products or formulations”. The Expert Committee further stated that “in some countries and for some manufacturers, inclusion of RUTF in the EML may carry implications about the need to comply with requirements for pharmaceutical products and thus potentially have an impact on cost and access” (10). Nevertheless, the Expert Committee recognized that adding RUTFs and other nutrition-related products to the EML may improve access to these products for populations in need. The Expert Committee recommended further analysis of the implications and impacts of including RUTFs in the EMLc, and requested the WHO Department of Nutrition for Health and Development to prepare a report for the next Expert Committee meeting, addressing various aspects, including country requirements if RUTFs were included in national essential medicines lists; costs and access implications; progress of the Codex guidelines on RUTFs by the Codex Committee on Nutrition and Foods for Special Dietary Uses; and the systematic reviews being prepared on the effectiveness and safety of RUTFs (9).

The Department of Nutrition for Health and Development, in collaboration with the Department of Essential Medicines and Health Products, convened a technical consultation in Geneva, Switzerland in September 2018. In preparation for the technical consultation, WHO extended a call for authors for the preparation of review papers on diverse topics related to the criteria and implications of listing nutrition-related products in the EML.

¹ Ferrous salt + folic acid in tablet form equivalent to 60 mg iron and 400 µg folic acid for use as a nutritional supplement during pregnancy already appears in the EML.

This paper presents the potential impacts, as perceived by stakeholders, of adding RUTFs and other nutrition-related products to the EML. Stakeholder perceptions of potential impacts cover regulation; product quality; development of alternative formulations; local production; cost, procurement and budgetary implications; and other country-level considerations. Informed by a synthesis of the perceptions of stakeholders, the paper reflects on whether or not RUTFs and other nutrition-related products should be added to the EML.

Materials and methods

Stakeholders along the whole supply chain for RUTFs, including local and international RUTF producers, United Nations agencies, bilateral aid agencies, nongovernmental organizations, governmental organizations, and other international organizations engaged in addressing undernutrition, were contacted via email in June–July 2018 and asked to participate in a survey to provide their perspectives on the potential trade-offs associated with adding RUTFs and other nutrition-related products to the EML. The survey consisted of a series of qualitative questions (see [Appendices A3.2.1](#) and [A3.2.2](#)) on different dimensions of potential impact. Questions about RUTFs were posed separately from questions about other nutrition-related products but each set culminated in a question asking whether the stakeholder would support adding RUTFs or other nutrition-related products to the EML.

The same survey was given to all stakeholders, but they were told that they were free to skip any particular questions that covered issues on which they did not care to comment. All stakeholders were told that their names, positions and organizations might appear in this paper.

Completed surveys were compiled by question and by stakeholder type, to facilitate comparison across and within stakeholder types in perceptions of the potential effects of adding nutrition-related products to the EML. By gradually aggregating the survey responses, perceived positive and negative impacts were identified within each dimension of potential impact.

Results

Stakeholders

A total of 43 stakeholders were contacted, and completed surveys were received from 18 stakeholders (41.9% response rate). [Appendix A3.2.3](#) lists the stakeholders who provided their perspectives. It is relevant to note that the majority of participating stakeholders were engaged in providing RUTFs for children with uncomplicated severe acute undernutrition, via RUTF production or programmatically, or they were involved from a research standpoint. One nongovernmental organization not engaged in the provision of RUTFs also participated.

Stakeholder perceptions: ready-to-use therapeutic foods

Regulation

As the EML is a model list that serves as a guide for the development of national and institutional essential medicines lists, the listing of a product in the EML does not carry with it any legal or regulatory requirements. However, almost all stakeholders anticipated that the regulation of RUTFs will change if they are added to the EML. A number of stakeholders (several RUTF producers, participants from a United Nations agency, stakeholders at a bilateral aid agency, and several participants from nongovernmental organizations) noted that the likely impacts of adding RUTFs to the EML on how the products are regulated will be country specific. In particular, many stakeholders noted that, depending on how individual countries would classify RUTFs if they are added to the EML, it may be more likely that they are treated as medicines, and therefore local regulation of RUTFs could become more stringent and inhibit the availability and accessibility of the products. On this issue, participants from a United Nations agency noted:

It will be important to assess how food, food for specialized medical purposes and medicines are regulated in different countries ... It will be especially important to find out how they would classify RUTF when it is placed in the miscellaneous category of the EML, and whether there would be specific restrictions to the manufacturing (e.g. only in a facility that is qualified to produce drugs) and/or distribution (e.g. can only be provided by registered health professionals) and/or consumption (e.g. must be under clinical/controlled conditions).

The importance of clarity on this issue cannot be overstated. If the inclusion on the [essential medicines list] in a specific country requires RUTF to meet pharmaceutical standards for manufacturing, importation and distribution, this could effectively eliminate the accessibility of RUTF in some contexts. Where this would not be the case, the inclusion on the EML is much more acceptable. A key question is whether inclusion on the EML could make this point of conditionality very clearly.

A participant from a nongovernmental organization stated:

... addition of RUTF on [the] EML, even in the category miscellaneous ... could bring confusion with the pharmaceutical standards which are not applicable for RUTF. This might result in higher standard requirements that cannot be reached by current manufacturers, blockade in import at country level and, as a result, shortage of RUTF availability.

A participant from a governmental organization noted that some manufacturers may not be able to meet more stringent regulatory requirements, and, coupled with more rigorous monitoring, this could have negative impacts on availability.

Input from a participant from another governmental organization highlights the potential for divergence in how different stakeholders may perceive the most appropriate categorization for RUTFs:

It is my opinion that the addition of RUTF to the EML will help improve the emphasis on the importance of RUTF as a medication and not as a food commodity. In many countries, RUTF is seen as just a food commodity and this downplays the importance of the commodity in the treatment of malnutrition. It may also be the foundation of the reason why misuse of RUTF is so notorious.

A participant from an international organization argued:

Regulatory, monitoring and enforcement systems are weak in many low- and middle-income countries, which have the highest prevalence of severe acute malnutrition. The inclusion of RUTF into the EML would put added costs in governing these products to ensure their quality, safety, use and access are adequately managed. Spill over, inappropriate distribution and use ... and the monitoring of these risks can be a considerable problem.

Other stakeholders foresaw that the likely changes in the regulation of RUTFs would positively impact access to the products. A RUTF producer perceives:

[Addition of RUTFs to the EML] will help the international and local producers to meet the need as per the specifications of the regulatory norms. In other words, more regulatory systems will accept RUTF as a legitimate remedy for [severe acute undernutrition] amelioration, and the production and thus the availability of RUTF [will] improve drastically.

A participant from a nongovernmental organization foresaw that the addition of RUTFs to the EML would be catalytic in engaging the global community in addressing RUTF regulation outside procurement and regulation primarily by United Nations agencies. In particular, they felt that it would lead to a process that addresses issues of regulation and procurement in a way that accounts for the needs of national governments and other national stakeholders, which would result in a more “viable/open ecosystem for RUTF production and distribution” and ultimately improve access:

At present, the procurement via [United Nations] agencies means that regulation is solely determined by the [United Nations] agencies involved (mostly UNICEF [United Nations Children’s Fund]). This is conducive neither to government ownership nor to a transparent discussion about regulation from a government-led perspective. The debate about RUTF regulation will not advance if this continues to be managed as a conversation about how to regulate the [United Nations]-managed system. Only when national governments become accountable for sourcing the product will the regulatory framework be assessed outside of the current parameters.

Finally, drawing a parallel with the history of oral rehydration solution, participants from an international organization foresaw that changes in the regulation of RUTFs under the EML would foster an environment in many countries in which there is scope for all types of companies to produce RUTFs (e.g. local, regional, multinational, small and medium-sized enterprises, dairy cooperatives):

We can learn from the success of the [oral rehydration solution] model, where we see different types of producers, which led to [oral rehydration solution] becoming affordable, convenient to procure and use and easily accessible/available even in remote rural areas. Clear regulations on standards and labelling support a level playing field. This requires a strong regulatory monitoring capacity of governments, however.

Product quality

Almost all stakeholders anticipated that adding RUTFs to the EML would either improve or have no impact on product quality. Among those who anticipated improvements in quality, participants from an international organization, a nongovernmental organization, two governmental organizations and a RUTF producer all emphasized that quality might improve as the result of development of a common set of standards and guidelines that are applied to all RUTF producers and are used by all buyers, whether they are governments, nongovernmental organizations or United Nations agencies. A participant from a governmental organization, for example, noted:

Being placed in the EML/EMLc provides basis for governments to include this in the national formulary and also be one of those to be registered at the Food and Drug Regulatory Office. As such, [by] being registered or licensed in a country, through existing regulatory bodies, quality of the product is thereby assured.

Several stakeholders also mentioned the relevance of the Codex standard¹ in ensuring high-quality products. A stakeholder from a nongovernmental organization noted: “Quality will, I think, mainly improve as a result of clear Codex standards and enforcement of product specifications, which is why it is imperative that these process[es] continue in parallel”. Another participant from a nongovernmental organization emphasized that RUTF should meet food quality standards under the Codex.

¹ Work is currently under way to establish guidelines for RUTFs under the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) (9). The development of a new Codex guideline involves an eight-step process (11). The 40th session of the CCNFSDU on 26–30 November 2018 reviewed the proposed draft guideline for RUTFs and agreed to hold the text at Step 4 and to consider the remaining recommendations of the physical working group at its next session and to continue developing Sections 5.2.2 and 6.2 for circulation for comments and consideration at the next session in 2019 (12). From there, comments from member countries and other interested parties are again solicited and finalized by the CCNFSDU, and the draft is submitted to the 5/8 Step (conclusion).

Among stakeholders that anticipated there would be no change in product quality, two RUTF producers stated that RUTFs already meet very high quality standards and they are highly regulated by the interagency group of the United Nations Children's Fund, the World Food Programme, the United States Agency for International Development, Médecins Sans Frontières and national authorities. Stakeholders at a bilateral aid agency noted recent improvements by the interagency group to the process for auditing approved suppliers, adding that, although the addition of RUTFs to the EML may improve some food-safety testing procedures, they did not believe the overall quality of the products procured by members of this interagency group would be impacted.

Development of alternative formulations

Stakeholder perceptions of the effects of adding RUTFs to the EML on the development of alternative formulations varied across and within stakeholder types. Stakeholders participating in the survey noted that this is an important issue, since developing alternative formulations for RUTFs has the potential to reduce costs and improve efficacy and acceptability (e.g. development of RUTFs with organoleptic properties that are preferred by a particular target population) in some settings.

Beginning with perceived negative impacts, participants from a United Nations agency, a bilateral aid agency, several nongovernmental organizations and several RUTF producers perceived that adding RUTFs to the EML could introduce prohibitive barriers to the development of alternative formulations, including a standard that is very specific (e.g. a list of ingredients) or very rigid, or stipulations that a new formulation would require (potentially lengthy) approval for modifications to the standard. A participant from a nongovernmental organization noted:

If the standard is too specific, then potentially it could hinder innovation. Reducing the cost of RUTF has been a public health priority, which requires innovation related to RUTF formulation, including the use of ingredients that could lower overall product cost. Much research has already been conducted and is ongoing, related to alternative formulations. It will also be important that there is some flexibility or understanding that testing of alternative formulations to treat severe acute malnutrition is possible.

On the other hand, other participants, including a RUTF producer, an international organization and several governmental organizations, expected advances in the development of alternative formulations if RUTFs are added to the EML. These stakeholders contended that the addition of RUTFs to the EML may increase support for RUTFs (from policy-makers, governments, donors and private-sector food manufacturers) and attract more investments in research and development for the development of alternative formulations. However, one participant from a nongovernmental organization felt that the development of alternative formulations should be bound by Codex guidelines:

The question of alternative formulations should not be left open, but rather, clear references to [the] Codex should be made to ensure that whilst governments are given space to explore alternative sources, there remains a minimum framework of what is considered to be acceptable deviations from the standard formula and global sourcing from patent holders.

Finally, a participant from an international organization felt that investments in the development of alternative formulations for RUTF are, in general, misplaced:

Product innovation should be based on independent scientific evidence that any change in product formulation is effective for the treatment of [severe acute malnutrition] ... Product "innovations" in RUTF, which [are] costly and usually done to increase markets for these products, should not be a priority over long-term, sustainable and culturally appropriate approaches to reduce the prevalence [of severe acute malnutrition] and [for] the prevention of [severe acute malnutrition] and the underlying causes of malnutrition.

This participant was also concerned that adding RUTFs to the EML would give unwarranted credibility to the single-recipe globally traded products that need to have a long shelf-life:

We also understood that there has been general agreement that the focus should be on locally made, culturally appropriate products, rather than on single-recipe, globally traded products – especially those that have a long shelf-life, and contain high levels of added sugar and other ingredients – that manufacturers claim are needed to improve palatability. It seems highly likely that listing RUTF on the EML will undermine any move to home or local preparation/production and will disproportionately promote single-recipe globally traded products.

Local production

While the vast majority of RUTFs are produced by international companies, local production is expanding and is being promoted as a way to improve sustainability (13, 14). Among stakeholders participating in the survey who had a perception of negative implications for local production, several mentioned that if adding RUTFs to the EML creates the perception that they are medicines, then local production could be restricted to pharmaceutical companies instead of food manufacturers, effectively curtailing local production. It was also mentioned by some participants that it may be harder and more costly for smaller local producers to meet more stringent requirements, particularly in countries with limited laboratory capacity, again discouraging local production. Moreover, some noted that local producers already face significant costs in the form of importation taxes on raw materials and registration, and additional fees for registering a new pharmaceutical product, if applied, could constrain local production, which, as noted by a participant from a nongovernmental organization, “runs contrary to some recent initiatives to encourage local production of RUTF [among other nutrition commodities]”.

Other participants, however, indicated that they expected that adding RUTFs to the EML would boost local production. Some noted that adding RUTFs to the EML may lead to a stable market for the products, which would help expand local production. In particular, participants from an international organization noted:

Local producers typically find it difficult to attract investment to produce, expand or for [research and development on] alternative formulas, have high local cost of capital and rely on expensive external labs for quality tests. They are likely to benefit the most once RUTF is considered as an essential medicine.

Others foresaw that adding RUTFs to the EML may lead to increased roles for national governments in determining RUTF suppliers, probably resulting in increased demand for and production of locally produced RUTFs. Moreover, a participant from a nongovernmental organization noted that “inclusion in the EML might accelerate local and regional production, as governments seek to tap into domestic/regional producers in part to reduce transport-associated costs”.

Cost, procurement and budget implications

In general, stakeholders were uncertain about the likely impacts of adding RUTFs to the EML on the cost and procurement of RUTFs and the likely budget implications. Some stakeholders raised concerns that the cost of RUTFs, which accounts for a large portion of the total cost of managing uncomplicated severe acute undernutrition and is often cited as a barrier to increased coverage (15, 16), may rise as a consequence of being added to the EML. In particular, many stakeholders mentioned concerns that stricter regulatory standards and more required clearances for producers and distributors will raise the cost of production and distribution, and, as a result, access to RUTFs will decline. According to a participant from an international organization:

It is therefore essential that inclusion in the EML does not inadvertently lead to an irrational/non-evidence-based raising of standard. Provided RUTF is added in a way that does not inadvertently lead to senseless additional production standards (e.g. as a “miscellaneous” item and distinct from conventional medicines), inclusion in the EML is likely to be positive and lead to greater access to treatment and therefore save lives. If inclusion inadvertently raises production standards, it is likely to be negative, reducing access to treatment and therefore resulting in avoidable child deaths.

Participants from several nongovernmental organizations also noted the potential for increases in RUTF transport and storage costs if the products are added to the EML. One of these nongovernmental organization participants noted that transport and storage costs may rise if local production is curtailed and procurement is limited to international producers, while another cited existing challenges with adequate infrastructure for the transport and storage of RUTFs in some countries, which could be compounded if adding RUTFs to the EML increases the supply of RUTFs in such countries.

On the other hand, other stakeholders predicted that the price of RUTFs will decrease as a result of increased competition and economies of scale. For example, participants from an international organization noted:

Standards for RUTF will support competition and more competition can lead to lower price points, as well as through economy of scale if/when demand/use of RUTF increases.

A RUTF producer similarly noted:

What is likely to happen is that EML addition [will] lead to widespread adoption and production of RUTF. This in turn is likely to lead to massive economies of scale (scale procurement of milk powder, and peanut for instance). This, in turn, is likely to put a downward pressure on prices.

A stakeholder from a nongovernmental organization saw potential improvements in predictability and planning around procurement and transport:

Procurement and transport will likely become more predictable and can be better planned, which currently is a major disadvantage. Funding waves determine procurement. If EML can strengthen the budgeting for RUTF from domestic budgets, then procurement and transport will be smoother and more predictable.

Several governmental organizations also anticipated positive implications for national-level budgeting. A participant from one governmental organization noted:

Adding RUTF to the EML will serve as a way of showing all stakeholders the importance of the product and its availability. As a result, this might also, in turn, influence the decision of stakeholders in committing to support the procurement and transportation of the product to ensure availability like other products on the EML.

A participant from another governmental organization observed:

Regulatory agencies and policy-makers use the EML/EMLC as a basis for resource management planning and also for programme commodity alignment as well. National policies on managing severe acute malnutrition will benefit from [an] official [essential medicines list] that will reflect RUTF in it.

Other country-level considerations

Several additional questions were posed to stakeholders that were specific to national-level effects of the inclusion of RUTFs in the EML. Most stakeholders, including all participants from governmental organizations, were in agreement that individual countries would be more likely to add RUTFs to their national essential medicines lists if they were listed in the EML, although some noted that the process could take time.¹ A participant from a governmental organization noted that in recognition of reductions in morbidity and mortality after RUTFs were introduced for the management of severe acute undernutrition, their country's department of health had applied for RUTFs to be added to the country's medical catalogue. Meanwhile, a participant from an international organization raised concerns that if RUTFs were added to the EML, then they would be more likely to be added to national essential medicines lists, owing to "pressure from manufacturers, aid organizations, researchers and those who receive funding from these industries, to add these products to the EML".

Stakeholders had varying viewpoints on the effect of adding RUTFs to the EML on in-country perceptions of the purpose of the product from the perspective of ministries of health, health-care providers and households. Some foresaw positive impacts. A RUTF producer, for example, noted:

RUTF addition to [the] EML would give more clarity, visibility and authentic acceptance to the role of RUTF as a therapeutic treatment for [children with uncomplicated severe acute malnutrition] ... It would also facilitate product acceptance and a significant shift in the perspective of [the] ministry of health, health-care providers and consumers.

Similarly, a participant from a nongovernmental organization noted that "It would help frame the condition it is meant to address [acute malnutrition] as a governmental responsibility, not just a civil society/[United Nations] responsibility." Finally, participants from a United Nations agency noted that if, as a result of being added to the EML, RUTFs became viewed more as foods with a medical purpose, then sharing and use by unintended consumers may be reduced. On the other hand, participants from this United Nations agency and several other stakeholders cautioned that it could also result in a return to a more medicalized approach to the treatment of severe acute undernutrition, where distribution is limited to pharmaceutical channels, and community-based distribution via unskilled or less skilled health workers is restricted. In particular, a participant from a nongovernmental organization noted:

The risk is that some countries would specify that RUTF can only be used as a medicine by trained and registered medical staff or only in health structure – this could call into question the model of community-based management of acute malnutrition, which is the raison d'être of RUTF.

Finally, a participant from an international organization felt that there was not sufficient evidence on the efficacy of RUTFs to justify their addition to the EML and cautioned that adding RUTFs to the EML would lead to unwarranted perception of the efficacy of these products and increase pressure on countries to "accept these products, including countries that have spent considerable time deliberating the best way to tackle malnutrition and have decided not to use these products".

Most stakeholders, including each governmental organization, also perceived that adding RUTFs to the EML may be catalytic in the integration of treatment of severe acute undernutrition, generally, into country-level health systems. However, some stakeholders felt that, while this is a possibility, the potential risks of negative impacts are not worth the potential benefits of greater integration of the treatment of severe acute undernutrition in health systems.

¹ One participant noted that, although adding RUTFs to the EML may accelerate the addition to national essential medicines lists in countries already committed to using RUTFs, it is unlikely to have an effect in countries that are reluctant to adopt and use RUTFs.

Assessment of adding ready-to-use therapeutic foods to the WHO Model List of Essential Medicines

Table A3.2.1 presents stakeholders' assessments of whether or not they would support adding RUTFs to the EML.

Among RUTF producers, one supported and two did not support the addition of RUTFs to the EML. Participants from a United Nations agency chose not to make an expression of support but suggested that a more detailed risk assessment be undertaken to ensure that manufacturing, distribution and use will not be restricted compared with continued classification of RUTFs as foods with a medical purpose.

Table A3.2.1. Stakeholders' assessments of adding ready-to-use therapeutic foods to the World Health Organization Model List of Essential Medicines

Stakeholder type ^a	Support adding RUTFs to the EML	Do not support adding RUTFs to the EML	Other	Conditions, caveats and comments ^b
RUTF producers (n = 3)	1	2		Must be done considering the most stringent manufacturing and product quality standards, to ensure the safety of children with severe acute undernutrition
United Nations agencies ^c (n = 1)			1	More detailed risk assessment is required, to ensure manufacturing, distribution and use will not be restricted compared with continued classification of RUTFs as foods with a medical purpose (not as medicines), and when standards provide sufficient room for innovation on product formulation and for formulation of buyer specifications that also enable smaller (local) manufacturers to enter the market
Bilateral aid agencies (n = 2)	2			Support is conditional on RUTFs being added in a category that does not refer to medicines, pharmaceutical items or medicinal food items. Prefer a new category of "therapeutic foods" or "special dietary foods", but categorization as a "miscellaneous" item is also acceptable. Supply-chain and procurement planning and last-mile delivery must be addressed for EML as a whole; Supportive unless strong evidence is presented by relevant stakeholders to support their hypotheses around the likely net effect on health and nutrition outcomes being negative
Nongovernmental organizations (n = 5)	4	1		Supportive, but as foods or essential commodities, and not necessarily as medicines. Appropriate categorization depends on country-specific regulatory environments and the implications of classification in that context on the ability of international and local suppliers to operate production of safe products according to existing international specifications; It will institutionalize RUTFs and allow countries to take full ownership, include RUTFs in budget decisions, and better integrate RUTFs and management of severe acute malnutrition into health systems. On the production and supply side, predictability will improve, leading to better planning and more stable production, quality and price; No value added, and the risk of confusion with pharmaceutical products and standards is too high. Importation would be blocked, resulting in a shortage of RUTFs. Innovation and local manufacturing could also be negatively impacted

Stakeholder type ^a	Support adding RUTFs to the EML	Do not support adding RUTFs to the EML	Other	Conditions, caveats and comments ^b
International organizations (n = 3)	1	1	1	<p>Fully support but recommend deferring addition of RUTFs to the EML until a Codex guideline is available. Treating severe acute undernutrition with RUTFs must not be viewed as conflicting with investments to improve access to high-quality food. Treating the millions of severely undernourished children, many of whom die every day, is as pressing a need as prevention of further undernutrition through improved access to food;</p> <p>RUTFs are food products that should be subject to regulatory and other guidelines for foods. Even if classified as medicines, they should not be added to the EML as such, since efficacy and safety must be established before medicines are added to the EML. The International Baby Food Action Network has serious reservations about the use of RUTFs in management of severe acute malnutrition (as either foods or medicines) because (i) existing evidence does not unequivocally support use of RUTFs for recovery from and prevention of mortality from severe acute malnutrition in programme settings; and (ii) there is potential for harmful long-term effects on health;</p> <p>Addition to the EML as a miscellaneous item may be positive step</p>
Governmental organizations (n = 4)	4			<p>Serious resource mobilization must be undertaken by WHO, to support countries to procure RUTFs in a more sustainable manner</p>

EML: WHO Model List of Essential Medicines; RUTF: ready-to-use therapeutic food; WHO: World Health Organization.

^a The numbers in each row represent the number of stakeholders whose response fell within each category. Stakeholders that did not respond to this question have been omitted.

^b Individual stakeholders' comments are separated by a semicolon.

^c Participants chose not to make an expression of support.

Participants from both bilateral aid agencies conditionally supported adding RUTFs to the EML. For participants from one agency, support was conditional on RUTFs being added in a category that does not refer to medicines, pharmaceutical items or medicinal food items; they also noted that if RUTFs were added to the EML, then supply-chain and procurement planning and last-mile delivery must be addressed for the EML as a whole. The participant from the other bilateral aid agency supported adding RUTFs to the EML, unless there was strong evidence showing that the likely net effect on health and nutrition outcomes would be negative.

Among participants from nongovernmental organizations, four supported and one did not support inclusion of RUTFs in the EML. Among the nongovernmental organization supporters, one participant supported inclusion of RUTFs, but only as foods or essential commodities, and not necessarily as medicines, adding that the appropriate categorization depended on country-specific regulatory frameworks and the implications of classification in that context on the ability of international and local suppliers to operate the production of a safe product according to existing international specifications. The participants from the non-supporting nongovernmental organization noted that they saw no value added and a high risk of confusion with pharmaceutical products and standards.

Among participants from international organizations, one felt that adding RUTFs to the EML may be a positive step; another supported their inclusion but recommended deferring until the Codex guidelines for RUTFs are available; a third did not support adding RUTFs to the EML.

All participants from governmental organizations supported adding RUTFs to the EML, although a participant from one governmental organization noted that it will require resource mobilization by WHO to support countries to procure RUTFs in a more sustainable manner.

Stakeholder perceptions: other nutrition-related products

In general, stakeholders were more engaged with questions about RUTFs compared with questions about other nutrition-related products. Moreover, some perceived impacts of adding RUTFs to the EML, such as the risk that product distribution might be limited to pharmacies, health facilities or trained health workers, or the projection that countries would be more likely to place RUTFs on their national essential medicines lists, were very similar to stakeholders' perceptions about other nutrition-related products. Differences in expected impacts that were mentioned by stakeholders are discussed next.

Specifically, several stakeholders perceived that for some nutrition-related products that currently suffer from poor or inconsistent quality, the development and enforcement of common standards could result in quality improvements. Participants from an international organization echoed the importance of enforcement, noting:

Standard-setting benefits everyone, from the producer to the citizen. But standards are only as effective as their monitoring and enforcement system. If audits are not conducted on a regular basis, you can increase the risk for counterfeit products. For food-type products, standards would go beyond formulation and shelf-life to include quality such as hygiene, microbial content, [and] nutritional content.

In terms of impacts on how nutrition-related products would be perceived by ministries of health, health-care providers, households and consumers if they were added to the EML, participants from a nongovernmental organization noted that the addition of F-75, F-100 and iron + folic acid would demonstrate that these are important commodities for treating serious conditions (severe acute undernutrition with complications and iron-deficiency anaemia); but for other products that are used for a variety of purposes, both preventive and curative, adding them to the EML could be interpreted as those products being indicated to treat a single or limited conditions, therefore discouraging their procurement for other conditions. These participants additionally noted:

From the perspective of the government or ministry of health, there is a likelihood that putting these products on the EML will promote the perception of products as a silver bullet for treating a single condition, and therefore discourage other important, complementary preventive interventions presently provided alongside distribution of these commodities, such as social and behaviour-change communication for improved dietary intake, water, sanitation and hygiene messages.

Finally, these participants warned of potential negative programmatic impacts and reductions in coverage, if adding nutrition-related products that are commonly distributed at the community level by front-line development workers (such as ready-to-use supplementary foods [RUSFs], micronutrient powders, lipid-based nutrient supplements and iron + folic acid) to the EML, limited their distribution to health facilities or by trained health workers.

Participants from an international organization perceived that adding nutrition-related products to the EML "would force health-care providers to be more knowledgeable about nutrition, including appropriate training on the causes and use of the nutrition-related products". Moreover:

At the very least it would prompt government review into how these products are delivered through various service mechanisms ... It would also prompt a more careful surveillance of the public health problems (e.g. anaemia) that are to be address[ed] through nutrition-related products at the health centres.

One participant from a governmental organization reported that many of these other nutrition-related products are already in the process of being included in national medical catalogues, which will allow for funding for procurement. A participant from another governmental organization foresaw that the “addition of these products to the EML may serve as a springboard for governments in taking ownership and making their personal commitment in funding the procurement, storage and supply-chain management issues of these products”.

Finally, several stakeholders perceived that nutrition-related products that are typically delivered through the health system might, as a result of being added to the EML, become more integrated into national health systems. Participants from an international organization also noted the potential for further integration and coordination between health systems and national food and drug administration-type regulatory bodies, and predicted that the most critical issues associated with food-type nutritional products (e.g. label requirements, shelf-life, good manufacturing practices) already exist in most countries and can be strengthened further through meeting EML standards.

Assessment of adding other nutrition-related products to the WHO Model List of Essential Medicines

Table A3.2.2 presents stakeholders’ assessments of whether or not they would support adding other nutrition-related products to the EML.¹

Neither of the RUTF producers that responded to this question supported adding other nutrition-related products to the EML. Participants from a United Nations agency supported adding products such as F-75, F-100, RUSFs and iron + folic acid, as these products are not available through non-health-sector channels, but they did not support adding products that can also be distributed through markets or schools. These participants also urged that RUTFs and RUSFs be considered jointly:

... we should avoid situations where there would be two separate pipelines for products for the treatment of severe versus moderate acute malnutrition, where RUTF would be available from the health clinic and RUSF would have to be sourced differently. Related to this, it would also be important that in case of a simplified/harmonized protocol, where RUTF is used for treatment of both [severe and moderate acute malnutrition], that this is possible, i.e. use of RUTF does not become restricted only to [severe acute undernutrition] when it would be placed on the EML.

¹ Owing to an oversight, it was not made clear to stakeholders that ferrous salt + folic acid in tablet form for use as a nutritional supplement during pregnancy already appears in the EML. Although intermittent iron + folic acid supplements for menstruating women are not currently in the EML, this distinction in target population and regimen was not made explicit to stakeholders. Support for adding iron + folic acid to the EML should thus be interpreted with this in mind.

Table A3.2.2. Stakeholder support for inclusion of other nutrition-related products in the *World Health Organization Model List of Essential Medicines*

Stakeholder type ^a	Support inclusion of other nutrition-related products in general in the EML	Do not support inclusion of other nutrition-related products in the EML	Support inclusion of only specific other nutrition-related products in the EML ^b	Comments ^c
RUTF producers (n = 3)		2		
United Nations agencies (n = 1)			1 Only products that are not (to be made) available through non-health-sector channels (F-75, F-100, RUSFs, iron + folic acid)	Nutrition-related products that can also be distributed through markets or schools, and those that should be part of a normal dietary pattern (e.g. complementary feeding) should not be in the EML. Adding them would give a wrong message about these foods and would probably reduce innovation and limit efforts to scale up availability, access and consumption
Bilateral aid agencies (n = 2)	1		1 F-75 and F-100	Since F-75 and F-100 are a complete therapeutic diet, considerations around adding RUTFs to the EML also apply to these products; Supportive unless other commissioned papers put forward strong arguments, supported by empirical data, showing negative impacts on supply and prioritization of good-quality nutrition-related products at national and subnational level are likely
Nongovernmental organizations (n = 5)	0	2	2 Micronutrient powders, iron + folic acid; F-75, F-100, iron + folic acid	Use experiences and implications of adding RUTFs to EML before adding other nutrition-related products; Iron + folic acid and micronutrient powders are fully developed and ready for scale at programme level, but this is not case for lipid-based nutrient supplements. Corn-soya blends are food products used for supplementary rations; Supportive of F-75, F-100, and iron + folic acid for specific purposes. Unsure about other nutrition-related products; Strongly disagree with addition of other nutrition-related products unless a specific list is created for nutritional products

Stakeholder type ^a	Support inclusion of other nutrition-related products in general in the EML	Do not support inclusion of other nutrition-related products in the EML	Support inclusion of only specific other nutrition-related products in the EML ^b	Comments ^c
International organizations (n = 3)	0	1	1 Iron + folic acid, micronutrient powders, Super Cereal Plus	<p>Adding other nutrition-related products to the EML would be premature, unhelpful and distracting from high-priority need to further establish the efficacy and effectiveness of these products;</p> <p>Support adding iron + folic acid, micronutrient powders and Super Cereal Plus, but the supply chain (from production to procurement) should be clearly understood, and inclusion in the EML should facilitate rather than impair access. Robust supply-chain monitoring systems would be required to ensure adherence to standards, so products received by end-users are safe and efficacious</p>
Governmental organizations (n = 4)	1	0	1 F-75, F-100, RUSFs, micronutrient powders, iron + folic acid	Support addition of these products because they are required and should be readily available for treatment of complicated malnutrition (F-75, F100), stunting (RUSFs) and other nutrition-related conditions such as anaemia

EML: WHO Model List of Essential Medicines; RUSF: ready-to-use supplementary food; RUTF: ready-to-use therapeutic food; WHO: World Health Organization.

^a The numbers in each row represent the number of stakeholders whose response fell within each category. Stakeholders that did not respond to this question have been omitted.

^b For support expressed only for specific other nutrition-related products.

^c Individual stakeholders' comments are separated by a semicolon.

Among participants from bilateral aid agencies, one conditionally supported the addition of nutrition-related products, while the other supported only the inclusion of F-75 and F-100, as they considered these to be a complete therapeutic diet with similar considerations to those of RUTFs.

Among participants from nongovernmental organizations, one supported adding micronutrient powders and iron + folic acid, and another was supportive of adding F-75, F-100 and iron + folic acid. A third was not supportive but rather recommended deferring the consideration of other products so that the experiences and implications of adding RUTFs to the EML could be applied. Finally, one participant from a nongovernmental organization strongly opposed adding other nutrition-related products unless a list specific to nutritional products was created. Among participants from international organizations, one supported adding iron + folic acid, micronutrient powders and Super Cereal Plus but cautioned that a clear understanding of the supply chain (from production to procurement) is needed and that the inclusion of these products should facilitate rather than impair access. Another did not support adding other nutrition-related products at this time and felt that their addition would be premature and distracting from the high-priority need to further establish the efficacy and effectiveness of these products.

Finally, among participants from governmental organizations, one supported adding nutrition-related products in general to the EML, while the other supported adding F-75, F-100, RUSFs, micronutrient powders and iron + folic acid, citing that these products should be readily available for the treatment of complicated undernutrition, stunting and other nutrition-related conditions such as anaemia.

Discussion

All stakeholders were told that their names, positions and organizations might appear in this paper. A majority of stakeholders consented to being quoted with attribution. Ultimately, it was decided to anonymize all stakeholders and their perceptions. It is possible, however, that asking stakeholders to provide their input under the assumption that they might be identified and quoted with attribution (if consenting) may have introduced bias in their reported perceptions.

The perceptions of a diverse group of stakeholders on the potential impacts of adding RUTFs and other nutrition-related products to the EML were varied, highlighting the uncertainty around the potential implications for access. For some issues, there was some consensus among stakeholders about the likely impacts. In particular, most stakeholders foresaw changes in how RUTFs are regulated, with many stakeholders noting that changes could be country specific. Most stakeholders also perceived likely improvements in the quality of RUTFs if they are added to the EML, with some noting that quality standards should be set by (or be in parallel with) Codex guidelines. Most stakeholders predicted that if RUTFs and other nutrition-related products are added to the EML, then individual countries will be more likely to add them to their national essential medicines lists. Many stakeholders also perceived that in-country decision-making and funding for RUTFs for the management of severe acute undernutrition, and integration of the treatment of severe acute undernutrition into national health systems, would improve with the addition of RUTFs to the EML.

However, there were many dimensions in which stakeholder perceptions about the likely impacts were in stark contrast to one another. Stakeholder perceptions about the implications of likely changes in the way RUTFs are regulated range from RUTFs (and some other nutrition-related products) being treated as medicines and therefore subject to prohibitively stringent pharmaceutical standards, to expectations that a more formal regulatory framework will lead to greater acceptability and facilitate production by a broader range of producers. Stakeholders also disagreed on the likely impacts on local production and the development of alternative formulations, with some predicting that innovation will be stifled and others foreseeing an environment that fosters local production and developments of alternative formulations. While many stakeholders raised concerns that more stringent regulation of nutrition-related products could result in higher costs, other foresaw greater competition and economies of scale leading to lower costs. Stakeholders also had very different views on how in-country perceptions of RUTFs and other nutrition-related products might change if added to the EML, including cultivating greater acceptance of RUTFs, to concerns over a more “medicalized” approach to treating severe acute undernutrition and other nutrition-related conditions.

In light of the contrasting perceptions about many of the impacts of adding RUTFs and other nutrition-related products to the EML, it is not surprising that stakeholders varied, within and across stakeholder types, in whether or not they supported adding RUTFs and other nutrition-related products to the EML. Considering the differing views of stakeholders and the varying degrees of uncertainty in the effects on many potential areas of impact, we suggest, as proposed by participants from a United Nations agency, that a rigorous risk assessment be undertaken to evaluate the primary concerns raised by stakeholders. In particular, the decision to add RUTFs and other nutrition-related products to the EML should be based upon a firmer understanding of (i) how the products would probably be categorized and regulated in individual countries; (ii) the associated implications for production, cost and distribution; and (iii) the effect on the scope for the development of alternative formulations and local production. In the authors’ view, the decision to add RUTFs and other nutrition-related products to the EML should be contingent upon demonstrating, with reasonable confidence, that the cumulative effect of adding RUTFs and other nutrition-related products to the EML on these factors would result in improved access among the populations most in need, while providing sufficient latitude for local production and for the development and testing of alternative formulations.

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Appendix A3.2.1

Stakeholder questions on ready-to-use therapeutic foods (RUTFs) and the WHO [World Health Organization] Model List of Essential Medicines (EML)^a

1. How do you think the addition of RUTFs to the EML would affect product quality? Do you have specific concerns about potential negative impacts on product quality or expectations about potential positive impacts on product quality? To the extent possible, please provide explanations for your perceptions about the potential effects on product quality.
2. Do you think the addition of RUTFs to the EML would impact the standards of formulation for RUTFs? If yes, in what ways? If no, why not?
3. Do you think the addition of RUTFs to the EML would impact product innovation, including both local production and the development of alternative formulations? If yes, in what ways? If no, why not?
4. How do you think the addition of RUTFs to the EML would affect the regulatory environment for RUTFs? Please include consideration of how the ability of international and local producers of RUTFs may be impacted by regulatory changes and, subsequently, the likely implications for the availability of RUTFs.
5. If you expect that adding RUTFs to the EML might impact the regulatory environment or formulation standards, what would be the likely implications for the cost of production, transport and storage of RUTFs? How might access to RUTFs be impacted by potential changes in these costs?
6. In what ways might the procurement and transport of RUTFs, at both international and country levels, be impacted by adding RUTFs to the EML?
7. If RUTFs are added to the EML, do you think it is likely that individual countries would then add RUTFs to their national essential medicines lists?
8. If RUTFs are added to the EML, how might in-country perceptions of these products be impacted? In particular, how might views regarding the purpose or function of RUTFs, from the perspective of the ministry of health, health-care providers, households and consumers, change as a result of adding RUTFs to the EML? Similarly, how would these perceptions potentially change if countries also added RUTFs to their national essential medicines lists?
9. If RUTFs are added to the EML, how might in-country decision-making around and funding for the treatment of uncomplicated severe acute malnutrition be affected? That is, would you anticipate that adding RUTFs to the EML might spur greater governmental prioritization of ensuring RUTFs are continuously available for treating uncomplicated severe acute malnutrition (including addressing procurement, storage, and supply-chain management issues)? Would decision-making and funding decisions around RUTFs for the treatment of severe acute malnutrition be contingent upon RUTFs being added to the national essential medicines list?
10. Related, do you anticipate that adding RUTFs to the EML might be catalytic in the integration of severe acute malnutrition treatment into country-level health systems?
11. Given all the considerations above, would you support adding RUTFs to the EML? If your support is conditional, please specify the conditions.

^a Questions were also available in French.

Appendix A3.2.2

Stakeholder questions on other nutrition-related products and the WHO [World Health Organization] Model List of Essential Medicines (EML)^a

This set of questions pertains to nutrition-related products other than ready-to-use therapeutic foods (RUTFs), including F-75, F-100, ready-to-use supplementary foods (RUSFs), fortified blended foods (e.g. Super Cereal, Super Cereal Plus), small-quantity lipid-based nutrient supplements, micronutrient powders and iron + folic acid supplements. Your answers can apply generally to these other nutrition-related products, or you can provide input for specific products as you see fit.

1. How do you think the addition of other nutrition-related products to the EML would affect product quality?
2. Do you think the addition of other nutrition-related products to the EML would impact the standards of formulation for these products? If yes, in what ways? If no, why not?
3. Do you think the addition of other nutrition-related products to the EML would impact product innovation, including both local production and the development of alternative formulations? If yes, in what ways? If no, why not?
4. How do you think the addition of other nutrition-related products to the EML would affect the regulatory environment for these products? Please include consideration of how the ability of international and local producers of these products may be impacted by regulatory changes and, subsequently, the likely implications for the availability of these products, if applicable.
5. If you expect that adding other nutrition-related products to the EML might impact the regulatory environment or formulation standards, what would be the likely implications for the cost of production, transport and storage of these products? How might access to these products be impacted by potential changes in these costs?
6. In what ways might the procurement and transport of other nutrition-related products, at both international and country levels, be impacted by adding these products to the EML?
7. If other nutrition-related products are added to the EML, do you think it is likely that individual countries would then add these products to their national essential medicines lists?
8. If other nutrition-related products are added to the EML, how might in-country perceptions of these products be impacted? In particular, how might views regarding the purpose or function of these products, from the perspective of the ministry of health, health-care providers, households and consumers, change as a result of adding them to the EML? Similarly, how would these perceptions potentially change if countries also added these products to their national essential medicines lists?
9. If other nutrition-related products are added to the EML, how might in-country decision-making around and funding of the use of these products for the treatment of severe acute malnutrition and prevention of stunting and other nutrition-related outcomes (e.g. anaemia) be affected? That is, would you anticipate that their addition to the EML might spur greater governmental prioritization of ensuring these products are continuously available (including addressing procurement, storage, and supply-chain management issues)? Would decision-making and funding decisions be contingent upon these products also being added to national essential medicines lists?
10. Related, do you anticipate that adding other nutrition-related products to the EML might be catalytic in their integration into country-level health systems?
11. Given all the considerations above, would you support adding other nutrition-related products to the EML? If your support is conditional or extends only to specific products, please specify the conditions or products.

^a Questions were also available in French.

Appendix A3.2.3 Participating stakeholders

Stakeholder type	Context	Position of participant(s)	Personal or official organization input
Local RUTF producer	India	Director; Chief Executive Officer	Personal
Local RUTF producer	Sub-Saharan Africa	Executive Director	Official
International RUTF producer	United States of America	Chief Operating Officer	Official
United Nations agency	Italy	Senior Technical Adviser; Nutrition Adviser; Food Technologist; Commodity Specialist	Official
Bilateral aid agency	United States of America	Nutrition Advisor	Personal
Bilateral aid agency	United Kingdom of Great Britain and Northern Ireland	Nutrition Adviser	Personal
Nongovernmental organization	United States of America	Technical Director	Official
Nongovernmental organization	N/A	Technical Director	Personal
Nongovernmental organization	Switzerland	Director	Personal
Nongovernmental organization	Hellen Keller International	Regional Nutrition Adviser; Regional Nutrition Director; Regional Programme Director; Vice President of Nutrition	Official
Nongovernmental organization	Switzerland	Food Quality Assurance Coordinator; Nutrition Working Group Lead; International Medical Coordinator	Official
International organization	N/A	Chief Executive	Official
International organization	Switzerland	Scientific Manager; Global Lead; Managing Director	Official
International organization	United Kingdom of Great Britain and Northern Ireland	Policy Director	Official
Governmental organization	Papua New Guinea	Technical Adviser	Official
Governmental organization	Philippines	Officer	Official
Governmental organization	Gambia	Director	Official
Governmental organization	Sierra Leone	Director	Official

N/A: not applicable; RUTF: ready-to-use therapeutic food.

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

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 herewith 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)^a

Country	References	National essential medicines list		Local regulatory framework			Comments
		RUTFs included	RUTFs not included	RUTFs registered as medicines	RUTFs registered as foods	RUTFs registered as commodities	
Plurinational State of Bolivia	Lista Nacional de Medicamentos Esenciales Liname. La Paz: Ministerio de Salud, Bolivia; 2011	×					
Haiti	Liste Nationale des Médicaments Essentiels. Port-au-Prince: Ministère de la Santé Publique et de la Population, Haiti; 2012 (http://www.who.int/selection_medicines/country_lists/Haiti_LNME_2012.pdf?ua=1)	×		×	×		
Burkina Faso, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Liberia, Malawi, Sierra Leone, South Sudan, Sudan, Uganda	Liste Nationale des Médicaments et Consommables Médicaux Essentiels, édition 2014. Ougadougou: Ministère de la Santé, Burkina Faso; 2014 (http://apps.who.int/medicinedocs/documents/s23267fr/s23267fr.pdf) Liste Nationale de Médicaments Essentiels. N'Djamena: Ministère de la Santé, Chad, 2000 Liste Nationale des Médicaments Essentiels. Yamoussoukro: Ministère de la Santé et de l'Hygiène publique, Côte d'Ivoire; 2013 Liste Nationale des Médicaments Essentiels. Kinshasa: Ministère de la Santé Publique, République Démocratique du Congo; 2010 (http://apps.who.int/medicinedocs/documents/s18817fr/s18817fr.pdf) National Standard Therapeutic Guidelines and Essential Medicines List – Liberia, 2nd ed. Monrovia: Ministry of Health, Liberia; 2017 (http://moh.gov.lr/wp-content/uploads/2017/12/Liberia-NSTG-EML_2nd-Edition_2017.pdf)	×					

Country	References	National essential medicines list		Local regulatory framework			Comments
		RUTFs included	RUTFs not included	RUTFs registered as medicines	RUTFs registered as foods	RUTFs registered as commodities	
	Standard Treatment Guidelines, 5th ed. Ministry of Health, Lilongwe: Malawi; 2015 (https://tinyurl.com/y8oblne6)						
	Essential Medicines List. Freetown: Ministry of Health, Sierra Leone; 2012						
	Essential Medicines List. Juba: Ministry of Health, South Sudan; 2018						
	Essential Medicines List. Khartoum: Ministry of Health, Sudan; 2018						
	Essential Medicines and Health Supplies List. Kampala: Ministry of Health, Uganda; 2016						
Nigeria	Essential Medicines List, 8th ed. Abuja: Ministry of Health, Nigeria; 2018	×				×	
Zimbabwe	Essential Medicines List. Harare: Ministry of Health, Zimbabwe; 2015	×		×	×		
Kenya	Kenya Essential Medicines List. Nairobi: Ministry of Health, Kenya; 2016 (http://apps.who.int/medicinedocs/documents/s23035en/s23035en.pdf)	×				×	Registered as part of the Specialist List for Managing Severe Acute Malnutrition
Niger	Liste des Médicaments essentiels. Niamey: Ministère de la Santé, Niger; 2004	×		×	×		Registration by the Department of Pharmaceutical and Medical Products
Ethiopia	National Essential Medicine List, 5th ed. Food, Medicine and Healthcare Administration and Control authority of Addis Ababa: Ethiopia; 2014 (http://apps.who.int/medicinedocs/documents/s22351en/s22351en.pdf)		×			×	

Country	References	National essential medicines list		Local regulatory framework			Comments
		RUTFs included	RUTFs not included	RUTFs registered as medicines	RUTFs registered as foods	RUTFs registered as commodities	
United Republic of Tanzania, Viet Nam	Standard Treatment Guidelines and Essential Medicines List, 4th ed. Dodoma: Ministry of Health, United Republic of Tanzania; 2013 (http://www.who.int/selection_medicines/country_lists/Tanzania_STG_052013.pdf) List of Essential Medicines. Hanoi: Ministry of Health, Viet Nam; 2008 (http://apps.who.int/medicinedocs/documents/s19532vi/s19532vi.pdf?ua=1)		×	×			
Guinea	Guide Thérapeutique National. Conakry: Ministère de la Santé et de l'Hygiène Publique, Guinée-Conakry; 2013 (http://www.who.int/selection_medicines/country_lists/GuineeConakry_STG_2013.pdf?ua=1)		×				In the Guide Thérapeutique National (synthesis of Model List of Essential Medicines and national pharmaceutical protocols)
Afghanistan, Bangladesh, Cambodia, India, Indonesia, Malaysia, Myanmar, Nepal, Pakistan, Philippines, Sri Lanka	National Essential Drugs List. Kabul: Ministry of Public Health, Afghanistan; 2007 (http://www.who.int/selection_medicines/country_lists/AFG_EML_07.pdf?ua=1) Shafiquzzaman AHM. List of Essential Drugs. Bangladesh Gazette. 22 May 2008 (http://www.who.int/selection_medicines/country_lists/bgd_eml_2008.pdf?ua=1) Essential drugs. Basic information for health center staff and drug sellers. Phnomh Penh: Ministry of Health of Cambodia; 2003 (http://www.who.int/selection_medicines/country_lists/khm_essentialdrugs_2003.pdf?ua=1) National List of Essential Medicines of India. New Delhi: Ministry of Health and Family Welfare, India; 2011 (http://www.who.int/selection_medicines/country_lists/India_NLME_2011.pdf?ua=1)		×				

Country	References	National essential medicines list		Local regulatory framework			Comments
		RUTFs included	RUTFs not included	RUTFs registered as medicines	RUTFs registered as foods	RUTFs registered as commodities	
	National List of Essential Medicines. Ministry of Health, Jakarta: Indonesia; 2008 (http://www.who.int/selection_medicines/country_lists/idn_eml_2008.pdf?ua=1)						
	National Essential Drug List, 2nd ed. Kuala Lumpur: Ministry of Health, Malaysia; 2008 (http://www.who.int/selection_medicines/country_lists/mys_nedl_2008.pdf?ua=1)						
	List of Essential Medicines. Nay Pyi Taw: Ministry of Health, Myanmar; 2016 (http://www.who.int/selection_medicines/country_lists/mmr_eml.pdf?ua=1)						
	National List of Essential Medicines Nepal. Kathmandu: Ministry of Health and Population, Nepal; 2009 (http://www.who.int/selection_medicines/country_lists/npl_eml.pdf?ua=1)						
	National Essential Medicines List of Pakistan. Islamabad: Ministry of Health, Pakistan; 2007 (http://www.who.int/selection_medicines/country_lists/pak_EML_2007.pdf?ua=1)						
	Essential Drug List. Manila: Ministry of Health, Philippines; 2007						
	National List of Essential Medicines Sri Lanka. Colombo: Ministry of Health Care and Nutrition, Sri Lanka; 2009 (http://www.who.int/selection_medicines/country_lists/lka_eml_2009.pdf?ua=1)						

Country	References	National essential medicines list		Local regulatory framework			Comments
		RUTFs included	RUTFs not included	RUTFs registered as medicines	RUTFs registered as foods	RUTFs registered as commodities	
Cameroon, Djibouti, Madagascar, Somalia, Yemen	<p>Liste Nationale des Médicaments Essentiels: Cameroun. Yaoundé: Ministère de la Santé, Cameroun; 2017</p> <p>Liste des Médicaments et Matériels Essentiels. Djibouti: Ministère de la Santé; 2007 (http://www.who.int/selection_medicines/country_lists/dji_Liste_2007.pdf?ua=1)</p> <p>Antananarivo: Ministry of Health, Madagascar</p> <p>Somalia standard treatment guidelines and training manual on rational management and use of health care level, 2nd ed. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2006 (WHO-EM/EDB/073/E; http://www.who.int/selection_medicines/country_lists/som_stg_2007.pdf?ua=1)</p> <p>Essential Drug List, 4th ed. Sana'a: Ministry of Health, Yemen; 2007 (http://www.who.int/selection_medicines/country_lists/yem_EDL_FINAL_2007.pdf?ua=1)</p>		×				

^a 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; an increase in levels of government funding dedicated to RUTF procurement was recorded in Burkina Faso and Zimbabwe (24); facilitation of local production of RUTFs with the expected impact of decreased cost was noted in Nigeria; integration of RUTFs in supply chains was recorded in Burkina Faso and Zimbabwe; there was a self-assessed improvement in the management of supply chains by the Ministry of Health 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 (4) are to hold RUTFs to standards set by the Codex Alimentarius (29, 30). 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 RUTFs in national essential medicines lists] is part of a larger movement for better integration of nutrition and stronger health systems and to achieve sustainable results”.

- *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.

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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?*)

Public health relevance of including specialized nutrition-related health products in the *South Sudan Essential Medicine List 2018*

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Abstract

South Sudan is experiencing a deteriorating nutrition situation, owing to the conflict, severe food insecurity, high prevalence of infectious diseases, limited access to health services, mass displacement and economic crisis. The burden of acute undernutrition remains significantly high in 2018, with over 1 million children under the age of 5 years acutely undernourished; of these, 261 424 have severe acute undernutrition. This paper focuses on the processes undertaken by the Ministry of Health of the Republic of South Sudan, the World Health Organization (WHO) and other partners, to update the *South Sudan Essential Medicine List 2018* to include specialized nutrition-related health products. The overarching goal was to include all medicines needed to treat common conditions and to define the level of care at which they should be available in South Sudan. This was achieved through a bottom-up inclusive policy dialogue and the process led to alignment with and contribution to the World Health Organization (WHO) Thirteenth General Programme of Work 2019–2023, for advancing universal health coverage and addressing health emergencies and well-being; strengthened integration for the management in the health-care system of severe acute undernutrition in infants and children, through improved procurement of supplies; and alignment with the national guidelines and description of the use of specialized nutrition-related health products.

Keywords: *undernutrition; essential medicines; malnutrition; ready-to-use therapeutic foods; RUTFs*

Introduction

Since 2014, South Sudan has experienced a deteriorating nutrition situation, owing to unprecedented levels of food insecurity, spread of communicable diseases, poor infant and child feeding practices, a fragile health system, protracted conflict and economic crisis. The cost of living has continued to escalate. The humanitarian outlook for 2018 remained alarming, with over seven million people in need of humanitarian assistance (1).

The Integrated Food Security Phase Classification showed that from February to April 2018, 6.3 million people in South Sudan (57% of the population) experienced severe food insecurity (2, 3).¹ The burden of acute malnutrition remained significantly high in 2018, with 1 082 414 infants and children under 5 years of age acutely

¹ Severe food insecurity is based on the Integrated Food Security Phase Classification (3). Acute food insecurity occurs in a specific location when at least 20% of households have significant food consumption gaps OR are marginally able to meet minimum food needs only with irreversible coping strategies such as liquidating livelihood assets. Levels of acute malnutrition are high and above normal. Emergency food insecurity occurs in a specific location when at least 20% of households face extreme food-consumption gaps, resulting in very high levels of acute undernutrition and excess mortality; OR households face an extreme loss of livelihood assets that will probably lead to food-consumption gaps. Humanitarian catastrophe occurs in a specific location when at least 20% of households face a complete lack of food and/or other basic needs; starvation, death and destitution are evident; the prevalence of acute malnutrition exceeds 30%; and mortality rates exceed 2/10 000/day (3).

undernourished,¹ and 261 424 of these with severe acute undernutrition (1). These figures indicate an extremely serious situation, where acute undernutrition remains a major public health problem and cause of morbidity and mortality among infants and children aged under 5 years. In this scenario, improved child survival depends on preventing wasting² and on ensuring that timely and appropriate life-saving actions are available.

The health and nutrition supply system, led by partners, has periodically suffered stockouts and gaps. A community perception assessment showed that 73% of responders reported that health facilities are open in their communities, but only 54% of these facilities have the capacity to deliver services; 73% had perceptions that health facilities experience critical gaps such as shortages of essential medicines; and 54% had perceptions that there was no adequate equipment (6).

This paper describes a case-study of South Sudan, focusing on the processes undertaken by the Ministry of Health, WHO and other partners to review and update the *South Sudan Essential Medicine List 2018* (SSEML 2018), to include specialized nutrition-related health products. The specific objectives of the case-study are (i) to describe the South Sudanese context and the processes of reviewing the SSEML, including stakeholders' engagement, and assessment of the inclusion of specialized nutrition-related health products in the SSEML; (ii) to describe the rationale for including nutrition-related health products in the SSEML 2018 (i.e. evidence of benefits and safety, intended use, availability and procurement, and public health relevance); (iii) to consider stakeholders' perspectives, which can be seen as replicable criteria in other contexts; (iv) to describe the use of specialized nutrition-related health products in the South Sudan health guidelines; and (v) to summarize the expected results, impacts, resources and barriers in the process.

Ensuring the inclusion of specialized nutrition-related health products in the SSEML 2018 is therefore a key strategy to improve access to and availability of treatment for acute undernutrition. The SSEML 2018 is a South Sudanese Government policy document to ensure provision of cost-effective, safe and efficacious treatment for the majority of communicable and noncommunicable diseases in South Sudan. It is the South Sudanese Government-approved selection list of medicines and other commodities that guides their procurement and supply to the public sector and medicine donations.

The SSEML 2018 builds on the public health concept of essential medicines, which has been defined to include the following tenets: essential medicines are those that satisfy the priority health-care needs of the population, selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Given the dynamic nature of therapeutic products, standard and prevention-treatment guidelines and essential lists need to be updated regularly to maintain their credibility and relevance. In South Sudan, new guidelines for the treatment and prevention of acute undernutrition have been developed and others have been revised by different Ministry of Health programmes, including the nutrition programme; new commodities, nutrition-related health products and medicines suitable for children with undernutrition have subsequently been added into therapeutic practice. The classification of medicines by level of health-care facility utilization has changed in light of the adoption of "The Boma Health Initiative" (7),³ and the *National Health Policy 2016–2026* (8) in South Sudan.

Therapeutic nutrition-related health products were not included in the SSEML 2007 (9). The rationale built on to include specialized nutrition-related health products in the SSEML 2018 is outlined in the Methodology section of this document.

Methodology

Review and update process for the South Sudan Essential Medicine List 2018

The National Health Policy 2016–2026 (7) and the *Health Sector Strategic Plan 2017–2022* for South Sudan (10) have

¹ The term used that is used in some documents is "severe acute malnutrition", although with the World Health Organization (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 herewith to convey that reference is made to undernutrition only and not to all other types of malnutrition (4). The terms malnutrition or undernutrition are used interchangeably in this article.

² Wasting refers to a child who is too thin for his or her height. Wasting is the result of recent rapid weight loss or failure to gain weight. A child who is moderately or severely wasted is at increased risk of death, but treatment is possible (5).

³ "The Boma Health Initiative" is a newly launched flagship community health programme of the Ministry of Health of South Sudan, to be delivered through community-health workers (called boma health teams), based in bomas, the smallest administrative unit in South Sudan (7).

articulated the priority of the Government and the Ministry of Health to tackle undernutrition as a major public health problem. Under these national frameworks, the national *Community management of acute malnutrition [CMAM] guidelines (11)* were developed in South Sudan in 2017–2018, to ensure delivery of quality nutrition services at community and health-care-facility levels. Underlying the provision of appropriate, equitable and good-quality health care is the consistent availability of essential medicines at every health service delivery point, combined with an efficient monitoring and evaluation system.

The Ministry of Health, cognisant of the role that an updated evidence-based essential medicines list plays in ensuring cost-effective use of resources; appropriate management of medicines, commodities and supplies; and enhanced quality of care, initiated the process of reviewing the essential medicines list in 2016. This is part of the process for improving medicines, commodities and supply availability, and their proper use within the health-care system in public and private health facilities. The SSEML 2018 was compiled based on recommendations from a multidisciplinary group of health professionals and experts at the Ministry of Health or their partners, and within the health facilities across different states in South Sudan. Consideration was given to the recommendations in the 20th *WHO Model List of Essential Medicines (EML)* and 6th *Model List of Essential Medicines for Children*, published in 2017 (12). The overarching goal was to include all medicines needed to treat or prevent common conditions and to define the level of care at which they should be available in South Sudan. Given the burden of childhood wasting in South Sudan, and the need to provide life-saving nutritional treatments to address this condition on a very large scale, the policy of the Ministry of Health aimed to ensure appropriate procurement of safe, efficacious and quality essential medicines in public institutions, through the inclusion of key therapeutic nutrition-related health products in the SSEML 2018.

The review and update of the SSEML 2007 commenced in 2016, when the Ministry of Health, in collaboration with WHO, the Health Pooled Fund¹ and the United Nations Population Fund, revived earlier efforts made by the United States Agency for International Development to support the review of the SSEML 2018. Forms for inclusion, change or deletion of products from the essential medicines list were sent to health facilities in the counties and states (13). The review and update of the SSEML was achieved through a bottom-up policy dialogue, with participatory and inclusive processes. The latter included extensive desk review of global, regional and in-country documents and the EML 2017; technical consultative processes with national and international experts and stakeholders; and technical assistance from the WHO Country Office, the WHO Regional Office for Africa, the Intercountry Support Team for East and Southern Africa and WHO headquarters. The Pharmaceutical Technical Working Group (PTWG)² led the review and the consultative and validation processes, following the overarching principle that selecting key medicines that meet the majority needs of the population ensures that health workers are trained better on how to use them; the pharmaceutical supply-chain processes are optimized; and the purchaser can negotiate for lower prices because of the higher quantities involved.

In 2016, the Ministry of Health, with technical assistance from WHO, an extensive desk review of relevant grey and published literature on the EML and the SSEML 2007, was conducted. Case-studies from other countries, reflecting experiences on the inclusion of ready-to-use therapeutic food (RUTFs) in the SSEML, were sought. This was followed by meetings with key Ministry of Health authorities and health-sector partners, with a view to identifying 46 key informants, who were interviewed at the state and national levels. This process was put on hold, owing to a resurgence of conflict in 2016.

With return to normalcy in 2017, the process was resumed. The Ministry of Health convened a meeting with participants from the PTWG, a technical advisory group of the Ministry of Health, with the aim of accelerating the process, which had already taken a long time. A committee was formed from PTWG members, to work

¹ The Health Pooled Fund is a fund that aims to improve the access to, use and quality of primary health-care services and emergency obstetric and neonatal care services in South Sudan.

² The Pharmaceutical Technical Working Group (PTWG) is one of the coordination platforms (technical working groups) created by Ministry of Health and partners at the national level. It meets monthly and it is chaired by the Director-General of Pharmaceuticals and Medical Supplies. It has the Ministry of Health and partners (including WHO) as its members. Its objective is to discuss technical and programmatic issues regarding essential medicines, supplies and other commodities in the country.

with an external lead consultant reviewing the SSEML. The lead (external) consultant was hired by WHO and the Ministry of Health, in order to support the review of the SSEML. A series of consultative meetings were scheduled with various stakeholders, who procured, distributed and prescribed essential medicines. Of the 510 essential medicines proposal forms received from health facilities, 349 (requested items) were for inclusion in the SSEML 2018. Some of the items that were requested included addition of specialized nutrition-related health products. These were requested by the Department of Nutrition in the Ministry of Health, the United Nations Children's Fund (UNICEF), the WHO Health Emergencies Programme (WHE), and other stakeholders implementing programmes with nutrition interventions. It was considered an important mechanism for future integration of specialized nutrition-related health products in the supply chains.

One proposed strategy for improving access to RUTFs was to include them in the SSEML (14). Furthermore, community-based management of acute undernutrition delivered by community health workers and using RUTFs is a cost-effective strategy compared with inpatient treatment, and compares well with the cost effectiveness of other common child survival interventions (15). These arguments were presented by major stakeholders providing nutrition-related health services. A meeting with a large group of clinical specialists (46 key informants), in Juba Teaching Hospital in November 2017, was convened to discuss the merits of including new products and removing those that were obsolete (i.e. no longer essential). Whereas discussions on medicines were straightforward, addition of RUTFs was debated extensively. The main issues for discussion were related to supply-chain management and financing issues. Some key informants urged that addition of RUTFs would stretch an already weak supply chain. They noted that addition of RUTFs to the SSEML could imply that the product was a medicine and therefore liable for stringent quality assurance, which is still at a nascent stage in South Sudan.

Despite the arguments against inclusion of RUTFs, the current rate of undernutrition in South Sudan caused by the conflict and its inherent effects (i.e. food insecurity, economic crisis, huge populations in displacement camps) was highlighted as a significant factor in favour of adding RUTFs to the SSEML. Successful use of RUTFs has been recognized in the treatment of severe acute undernutrition and in large-scale programmes (16). Evidence from cases-studies of two countries in the region (Nigeria, Zimbabwe) that have included RUTFs in their national essential medicines lists demonstrated a successful process of inclusion and integration of the products into broader health services, particularly management of childhood illness (17). Since 90% of medicines in South Sudan are donor funded, the case for excluding RUTFs from a financing perspective was deemed unreasonable. Other participants and key informants argued that essential medicines lists are revised regularly (every 2–5 years), depending on a country's ability and context. The product would be removed from the essential medicines list if the situation changed, and rates of severe acute undernutrition in children aged under 5 years were properly addressed and, as a result, significantly reduced (18).

After wide consultation, the document was shared with all partners and key stakeholders within the country, region and WHO headquarters. The Ministry of Health organized a technical consultative workshop with key national stakeholders (Ministry of Health, partners, academia, researchers and civil society organizations), to validate the reviewed SSEML in July 2018. During the workshop, rigorous analysis was conducted for each item on the list. With the introduction of nutrition-related health products, such as RUTFs, to the SSEML, a clear method to measure the impact of inclusion was identified as a necessary step to serve as a case-study for South Sudan that could be tested or compared with other countries.

Rationale

The rationale built on to include nutrition-related health products in the SSEML 2018, in the context of South Sudan, is linked to three main elements: (i) the public health relevance of the use of specialized nutrition-related health products in the treatment of acute undernutrition in infants and children, in an exceptionally high-burden and deteriorating emergency context; (ii) the efficacy and safety of these products and their use, as recommended by the national *CMAM guidelines (11)*; and (iii) procurement considerations to minimize fragmentation and close gaps in terms of guidance for procurement.

Public health relevance

The public health relevance of including nutrition-related health products in the SSEML 2018 is seen from the perspective of the severity, magnitude and scale of the nutrition crisis in South Sudan, which has followed an unrelenting course and constitutes a dramatic and life-threatening public health challenge, affecting over 1 million children aged under 5 years, out of a population of fewer than 12 million people (19). The burden of acute undernutrition among children in South Sudan, which has deepened over the past 5 years of war (2013–2018), despite a concerted response, urges full-scale implementation of community-based management of acute malnutrition.

In light of this, the humanitarian nutrition sector, which includes nutrition cluster humanitarian partners, ranks the management of severe and moderate undernutrition as a top-priority activity, targeting 1.4 million people (78% of the total population in need of an emergency nutrition response) in 2018 (1). As of August 2018, the number of operational outpatient therapeutic programme¹ sites, each for the treatment of six children aged 6–59 months with severe acute malnutrition, was 858 and the number of targeted supplementary feeding programmes for the treatment of moderate acute malnutrition was 803. This marks an average increase of 19.7% in the number of targeted supplementary feeding programmes, and an average increase of 24.2% in the number of outpatient therapeutic programme sites, compared with 2017 (20). The nutrition response achievements from January to July 2018 reported that 60% of the annual targeted cases of severe acute undernutrition beneficiaries, and 47% of the annual targeted moderate undernutrition (also referred to as moderate acute malnutrition) beneficiaries had been reached, out of the 261 424 children with severe acute undernutrition and 827 324 children with moderate acute undernutrition targeted in 2018 by the whole humanitarian nutrition response (see Table A3.4.1).

Table A3.4.1. Summary of nutrition case-load and treatment coverage in South Sudan, 2018

Programme	People in need	Cluster target	New admission	Achieved versus people in need, %	Achieved versus target, %
Severe acute malnutrition	261 424	209 140	124 998	48%	60%
Moderate acute malnutrition	827 324	512 941	240 571	29%	47%
Pregnant and lactating women	672 562	356 458	191 929	29%	54%

Feeding is a critical part of the management of severe acute undernutrition. Children admitted to outpatient therapeutic programmes and targeted supplementary feeding programmes are treated with RUTFs and ready-to-use supplementary foods (RUSFs), respectively, for the management of acute malnutrition, as per the national guidelines for community-based management (11). Children with severe acute undernutrition and medical complications admitted to stabilization centres are estimated to comprise at least 15% of the total annual case-load of severe acute undernutrition. As of June 2018, the total number of children

¹ Sites for the outpatient therapeutic programme are not always embedded in a health facility; sometimes they can be just a site, used conventionally by the community, where children are screened and RUTF is provided.

reportedly admitted to stabilization centres was nearly 3000. Therapeutic milks (F-75, F-100) are the commodities used to treat children with severe acute undernutrition with medical complications in an inpatient setting (i.e. hospitalized). These figures are indicative of a large number of beneficiaries of nutrition commodities; based on the massive use of these products, they have therefore been included in the SSEML 2018.

Together with the Basic Package of Health and Nutrition Health Services and the national *Prevention and treatment guidelines for primary health care centres and hospitals* (21), the SSEML 2018 is expected to significantly improve the delivery of a quality essential health-care package for the South Sudanese population, moving towards universal health coverage through development and humanitarian programmes.

Efficacy and safety of the products and their use recommended by the national community management of acute malnutrition guidelines

Evidence shows the efficacy and safety of home-based nutritional treatments for severe and moderate acute undernutrition and the therapeutic milks (F-75, F-100) used for the management of hospitalized children with severe acute undernutrition and with medical complications (22–24).

RUTFs are treatments for severe acute undernutrition that can be consumed at home, with follow up of cases usually done at a health facility. They are an adaptation of the therapeutic milk formulation F-100, which has revolutionized the treatment of severe undernutrition by providing foods that are safe to use at home and ensure rapid weight gain in severely undernourished children. The advantage of RUTFs is that they are formulated as ready-to-use pastes that do not need to be mixed with water, thereby avoiding the risk of bacterial proliferation. RUTFs require no cooking, mixing or dilution and are easy to consume. They are usually based on peanut butter mixed with dried skimmed milk, vitamins and minerals; can be consumed directly by the child; and provide sufficient nutrient intake for complete recovery (25). Most RUTFs can be stored for up to 3–4 months without refrigeration, even at tropical temperatures (26). The nutrients in RUTFs are easily absorbed and do not alter the acid–base metabolism in people with severe acute undernutrition. Food safety policy is in place to ensure that a complete quality-management system based on a hazard analysis and critical control points approach is implemented. Reference standards also apply and constitute requirements for any organization in the food chain (e.g. recommended international code of practice, general principles of food hygiene, food safety management systems).

Procurement considerations

The procurement and supply chain for RUTFs are predominantly managed by the UNICEF Supply Division, the largest buyer of RUTFs, with some occasional purchases made by Médecins sans Frontières projects (27). The South Sudanese Ministry of Health participates in the planning process for orders of RUTFs, but it faces capacity challenges in the organization and management of the supply chain. This situation has a significant bearing on national budgetary implications when planning for resources for the health system. Thus, inclusion of RUTFs in the SSEML 2018 could create the political will to prioritize treatment of severe acute undernutrition in the health-care facilities and communities in the country, and ultimately allocation of resources to treatment and more awareness at the facility and community levels.

The pharmaceutical supply chain is thought to be weak, owing to poor infrastructure and limited accurate data management systems. Including RUTFs as a commodity in the SSEML 2018 could ease integration into the national supply chain and foster health system-strengthening efforts that would have been directed towards a vertical programme. Integration could also allow sharing of best practices on collaborative approaches for strategic procurement and development of normative guidance. Capacity-building on the procurement and supply chain could complement efforts made by other building blocks of the health system.

Results

The participatory process was successful in adding the specialized nutrition-related health products listed in Table A3.4.2 to the SSEML 2018. This listing in the national essential medicines list aligns with the WHO Thirteenth General Programme of Work 2019–2023 (28) and national guidelines, which allow for strengthened integration and delivery.

Table A3.4.2. Specialized nutrition-related health products included in the *South Sudan Essential Medicine List 2018*

Product	Form	Constituents
F-75	Powder	75 kcal + 0.9 g protein/100 mL
F-100	Powder	100 kcal + 2.9 g protein/100 mL
Super Cereal Plus	Packets	787 kcal, 33 g protein, 20 g fat
Lipid-based nutrient supplements	Sachets	500 kcal, 13 g protein, 31 g fat
Ready-to-use therapeutic foods	Paste 500 kcal (92 g)	30% full-fat milk, 28% sugar, 15% vegetable oil, 15% peanut butter, 1.6% mineral–vitamin mix
Oral rehydration salts solution for severely undernourished children (ReSoMal)	Sachet	42 mg sachet/1 L

Each medicine or commodity in the SSEML 2018 has been assigned a level of use within the health-care system in South Sudan. It implies the medicine or commodity should be made available and can be prescribed and dispensed at this and higher levels in the health system. The designation of each medicine or commodity is in line with the diagnostic and clinical knowledge, competencies, skills and health infrastructure expected to be existing at that level.

Table A3.4.3 shows the levels of care stated in the SSEML 2018 and the corresponding highest-level professional cadre expected at each level of health facility and the community.

Table A3.4.3. Levels of care in the *South Sudan Essential Medicine List 2018* where specialized nutrition-related health products will be used

Level of care	Type of facility	Highest cadre of health worker
Referral	Teaching and specialized hospitals	Consultant/specialist
Hospital	State and county hospitals	Consultant or medical officer
Primary health-care centre	Primary health-care centres	Clinical officer
Primary health-care unit	Primary health-care units	Enrolled comprehensive nurse
<i>Boma</i> health team	Community/ <i>boma</i>	Community health worker

Alignment with the WHO Thirteenth General Programme of Work 2019–2023

In alignment with the WHO Thirteenth General Programme of Work 2019–2023, advancing universal health coverage is the utmost priority for WHO (28). Under this framework, the WHO response in South Sudan aims to increase access to essential health services for all and to reduce rates of acute undernutrition. Within the scope of reaching the marginalized or underserved populations through tackling determinants of health, WHO South Sudan will prioritize reducing wasting among infants and children aged 6–59 months. This entails improving access to good-quality nutrition treatment delivered through specialized nutrition-related health products

that are available as part of the recommended country-level management of severe and moderate acute undernutrition.

One of the strategies to address the burden of undernutrition was to ensure the inclusion of specialized nutrition-related health products in the SSEML 2018, to improve provision of cost-effective, safe and efficacious treatment for acute undernutrition in South Sudan.

Alignment with national guidelines and description of use of specialized nutrition-related health products

The national *CMAM guidelines* (11) were developed in South Sudan in 2017–2018, to ensure quality nutrition services at both community and health-care-facility levels (1). These guidelines are comprehensive and are intended for the management of acute malnutrition along the continuum of care, across components of the community management approach, including community care, outpatient therapeutic care, supplementary feeding programmes and inpatient therapeutic programmes. The availability of therapeutic foods is a decisive condition to reduce acute undernutrition. The *CMAM guidelines* for South Sudan (11) recommend the use of RUTFs, RUSFs, fortified-blended foods and therapeutic milks (F-75, F100) as part of the management of malnutrition. Nutritional treatments are defined in the guidelines, according to the severity of acute malnutrition they are intended to address.

The nutritional treatment for children aged 6–59 months with moderate acute malnutrition is based on the provision of RUSFs – pre-packaged energy- and nutrient-dense products designed to treat moderate acute undernutrition without medical complications. The nutritional treatment in targeted supplementary feeding programmes aims to provide additional energy and nutrients to the existing home-based diet, to support catch-up growth in children aged 6–59 months with moderate acute undernutrition. This means adding at least 25% more energy and sufficient micronutrients. The guidelines also provide alternatives if RUSFs are not available, which consist of the provision of fortified blended foods (Super Cereal Plus) (29).

Strengthened integration of management of severe and moderate acute undernutrition in the health-care system through improved procurement of supplies

The inclusion of specialized nutrition-related health products in the SSEML 2018 is expected to strengthen the integration of management of severe and moderate acute undernutrition within the existing health-care system in South Sudan. This expected result builds on the prospect that products prioritized through the SSEML 2018 will be made available, prescribed, dispensed and used at the level of the community (*boma*) and health-care facilities. The *boma* and health-care facilities are where primary health-care services are delivered, in the context of a government-led and government-owned process, and take into account the government's obligation to prioritize and enable the procurement of essential medicines and products, as per the updated list. On the same basis, the supply-chain process to procure RUTFs, RUSFs, F-100, F-75 and ReSoMal is expected to be harmonized and optimized and, as it applies for each commodity in the SSEML 2018, the purchaser can negotiate for lower prices because of the higher quantities involved.

Discussion

The fragile health system of South Sudan experiences chronic shortages of essential medicines and supplies, which hamper its capacity to deliver effective and immediate treatment to address acute undernutrition and other conditions. The capacity of the Ministry of Health of South Sudan to manage health and nutrition services at the national or subnational level remains limited. This is particularly bad in conflict-affected and insecure areas, where currently few Ministry of Health-managed health facilities are operating; basic health services are delivered in inadequate modalities; and the referral pathway suffers major disruptions. However, the review and update of the SSEML 2007 has taken longer than anticipated because of interruptions caused by reasons beyond the review process itself. The inclusion of the specialized nutrition-related health products listed in the updated SSEML 2018 (see Table A3.4.2) is expected to lead to better health care, supply, storage and distribution and lower costs.

The levels of care shown in Table A3.4.3 can guide the supply-chain planning and procurement of medicines by the central medical stores, health-sector partners and health facilities, and eventually influence supply-chain management – that is, the composition of medicine kits for different health facilities.

To respond to the crisis and to the poor nutrition situation, with global acute undernutrition persistently above the emergency threshold in the vast majority of assessed counties (1), community-based management of acute malnutrition is implemented in South Sudan, essentially based on the presence of humanitarian partners carrying out health and nutrition programmes. The United Nations' World Food Programme (WFP), UNICEF and WHO, which operate through implementing partners and under the coordination of the nutrition cluster, are committed to tackling context-specific nutritional concerns, characterized by acute undernutrition. Capitalizing on field presence and ability to work with governments and other stakeholders, United Nations agencies work in partnership to enhance the management of acute undernutrition, with the WFP and UNICEF notably supporting the outpatient treatment and prevention of moderate and severe acute undernutrition, respectively, and WHO putting increased efforts into supporting the management of children with severe acute undernutrition with medical complications, who are admitted to stabilization centres.

Financial constraints remain an overall issue, impacting the procurement and provision of supplies for treatment and prevention of undernutrition. In this context, the inclusion of RUTFs, RUSFs and therapeutic milks F-100 and F-75 in the SSEML 2018 is aimed at improving the availability of and access to specialized nutrition-related health products for beneficiaries. This can support national-level prioritization, procurement and streamlining of their distribution and use through the existing health-care system. The SSEML 2018 is an application of the WHO essential medicines concept that aims to promote the efficient use of resources by establishing and using a limited list of carefully selected medicines. Selection of these medicines is made with due regard to the disease burden and prevalence in South Sudan, and evidence of efficacy, safety and comparative cost-effectiveness, and is done in an extensive consultative process with multiple stakeholders at national and subnational levels.

An example of prioritizing medicines included in the SSEML during emergencies is given by the WHO Emergency Nutrition Response in South Sudan (30). An improved inpatient care component of community-based management of malnutrition in South Sudan called for measures to address the critical shortage of medicines through timely procurement of essential medicines, ensuring coverage countrywide, including in conflict-affected areas and protection-of-civilians sites. In this challenging context, WHO South Sudan identified the provision of a medical kit for stabilization centres as a successful strategy to support the management of severe acute undernutrition with medical complications (31). The innovative procurement strategy shaped by WHO in South Sudan entailed the design and technical development of an innovative kit that has been distributed in South Sudan and has been available in the online WHO catalogue since April 2016. Standardization of the set of medicines needed in stabilization centres was carefully aligned to the SSEML 2007 and national medicines usage, taking into consideration the quality, safety and efficacy of the medicines supplied.

The inclusion of specialized nutrition-related health products in the SSEML 2018 ideally leads to improved supply, storage and distribution and lower costs, and eventually to use and uptake by beneficiaries. Government ownership and accountability of the overall process is critical to guide the supply-chain planning and procurement of nutritional products by the central medical stores, health-sector partners and health facilities, and to ensure regular quality control.

The identification and inclusion of nutritional products in the SSEML 2018 implies recognition of these products as high-priority commodities of public health relevance at the national level, by the Government of South Sudan, and it can therefore oblige (and enable) the Ministry of Health to make them available and affordable more systematically, also advocating for increasing resources being invested and allocated to the treatment of acute undernutrition.

The greater awareness of the importance of the treatment, its prioritization and the possibly higher financial resources allocated to procuring specialized nutrition-related health products will potentially stimulate local or regional production; will address the chronic shortage of supplies recurrently experienced across the country; and will serve as a stop-gap measure for prioritizing the procurement of nutritional products rather than non-prioritized products. This would entail a national-level and Ministry of Health-led monitoring of data on stock availability and consumption, and projections of supply requirements and quantifications. Moreover, besides government-led processes, medicines and products included in the SSEML are also generally prioritized during emergencies, by humanitarian partners and donors. The following are some of the challenges that might affect implementation of the SSEML 2018 and the distribution and use of specialized nutrition-related health products:

- the South Sudanese Government's capacity and expenditure for health, including essential medicines and specialized nutrition-related health products;
- substantial evidence documenting the effectiveness of specialized nutritional products in the treatment of acute undernutrition;
- addressing the risk that adding RUTFs, RUSFs and F-100 and F-75 to the SSEML could be seen as a way to promote a product-based approach to acute undernutrition, undermining or distracting from other preventive or mitigating interventions, such as promotion of breastfeeding;
- misuse of specialized nutrition-related health products, which are sometimes used improperly by family members, thus depriving children of treatment and creating fictitious demand.

Conclusion

This case-study has demonstrated that, through multi-stakeholder engagements and dialogue at the national and subnational levels, it is possible for the Ministry of Health and partners to include nutrition-related health products in the SSEML. The main rationale and justification for the inclusion were the high burden of undernutrition in South Sudan; the country context and health systems; the public health relevance; and the availability of supporting policy frameworks and guidelines. Although there were divided opinions, through extensive policy dialogue and technical discussions with experts, the country stakeholders were able to reach consensus and agreed to include the nutrition-related health products.

It is envisaged that addition of the nutrition-related health products to the SSEML 2018 will facilitate and improve access to these products and contribute to improved management of undernutrition and treatment outcomes. This can be replicated in similar contexts with protracted conflicts and fragile health systems and a high burden of undernutrition. The addition of specialized nutrition-related health products will contribute towards attainment of universal health coverage and the triple billion goals (1 billion more people benefiting from universal health coverage; 1 billion more people better protected from health emergencies; 1 billion more people enjoying better health and well-being) under the endorsed WHO Thirteenth Global Programme of Work (28) in selected countries. Future studies could explore the impact of this in the medium to long term, and the contribution to improving procurement and supply-chain management.

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The road to sustainable availability of ready-to use therapeutic foods for the management of acute undernutrition in the Plurinational State of Bolivia

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Abstract

The Plurinational State of Bolivia has improved its social and health indicators and reached the nutrition-related Millennium Development Goals. The main objective of this paper is to describe the process of adding ready-to-use therapeutic foods (RUTFs) to the list of essential medicines for the management of moderate and severe acute malnutrition in the Plurinational State of Bolivia. A timeline analysis tool, in-depth interviews with key informants, and revision of selected documents were performed. Also, the Health Insurance Benefits database of the logistics of RUTFs was reviewed and an electronic survey conducted to illustrate current use. The initial process of adding RUTFs to the list of essential medicines was reconstructed with information provided by key informants, verified with available documentation. This paper highlights factors such as the existing legal framework, public health insurance, and implementation of the Programa Multisectorial Desnutrición Cero (Zero Malnutrition Programme) that seem to have facilitated the process and ensured the sustainability of use of RUTFs. RUTFs remained in the 2018 *National Essential Medicines List* and are currently available and used in primary health-care facilities. In summary, the process of incorporating RUTFs in the Bolivian essential medicines list, from inception to expansion, was a positive experience, was done in a timely manner and is regarded to have contributed to the reduction in infant mortality rate in the country.

Keywords: *Bolivia; essential medicines list; ready-to-use therapeutic foods; RUTFs; severe acute malnutrition*

Introduction

The first commercially available ready-to-use therapeutic food (RUTF) product was developed by the French Institute of Research for Development and a French manufacturer, and patented in 1997 (1). In 2007, the World Health Organization (WHO), the United Nations Children's Fund and the World Food Programme released a statement on community-based management of severe acute malnutrition, with different activities for countries to undertake, including making RUTFs available to families of children with severe acute malnutrition through a network of community health workers or community-level health facilities, preferably by encouraging the local food industry to produce RUTFs in settings where families do not have access to appropriate local foods (2).

The Plurinational State of Bolivia is a multicultural country with remarkable geographical diversity. In recent years, the country has reduced extreme poverty from 41.2% in 1996 to 17.3% in 2014, accomplished the nutrition-related Millennium Development Goals (3), and reduced the infant mortality rate from 50% in 2008 (4) to 25% in 2016 (5).

The Plurinational State of Bolivia launched its National Policy of Medicines in 1996, supported by a specific law (6), with an updated regulation published in 1998 (7) and norms released in 2000 (see Table A3.5.1). To comply with the law's mandate, the Bolivian Ministry of Health started to assemble an essential medicines list approved by a ministerial resolution (2003) (8); since 2003, the list has been updated every 2 years (9, 10).

Table A3.5.1. Legal framework for the regulation of medicines in the Plurinational State of Bolivia^a

Policy	Legal document number	Date
National Medicines Policy	Ministry of Health Resolution 0034	20 January 2003
Medicines Law	Law 1737	17 December 1996
Regulation of Medicines Law	Supreme Decree 25235	30 November 1998
Pharmacological Norms	Ministry of Health Resolution 0216	5 May 2000
Ethical Rules for the Promotion of Medicines	Ministry of Health Resolution 0136	1 March 1994
Regulations of the National Pharmacological Commission	Ministry of Health Resolution 0138	14 April 1998
Guidelines of Sanitary Registry	Ministry of Health Resolution 0909	7 December 2005
National Supply System	Supreme Decree 26873	21 December 2002
Regulations to the National Supply System	Ministry of Health Resolution 0735	27 December 2002
National Medicine Control And Monitoring System	Ministry of Health Resolution 0250	14 May 2003
National List of Essential Medicines	Ministry of Health Resolution 0763	21 October 2005
Contract Model for the Acquisition of Pharmaceutical Products	Ministry of Health Resolution	1 April 2004

^a Ministry of Health and Sports National Strategy of Generic Medicines Series of Technic Normative Documents Bolivia 2012.

The Bolivian essential medicines list includes not only medicines for treatment of common infections and other health conditions but also nutrients and preventive medicines such as oral rehydration salts and other quality nutrition-related health products (11). The most recent essential medicines list includes vitamin A, zinc, fortified oil and a supplementary enriched food for children aged 6–24 months.

The Integrated Management of Childhood Illnesses (IMCI) (12) programme was adopted in the Plurinational State of Bolivia in 1996, as a strategy to reduce mortality and improve the health and development of children (13). Given that malnutrition was a main problem in this age group, the nutritional component of IMCI was strengthened and the modified package applied as IMCI plus Nutrition, starting in 2006 (14). This IMCI adaptation was developed as part of the Programa Multisectorial Desnutrición Cero (Zero Malnutrition Programme) (15), which targets chronic and acute malnutrition in children under 5 years of age and aims to reduce the prevalence of these problems and the deaths associated with severe acute malnutrition. The programme included evidence-based interventions recommended by nutrition experts worldwide (16–18).

RUTFs were officially included in this new version of the reviewed IMCI (19). Considering the situation of undernutrition and the fact that many children with acute undernutrition were managed in primary health-care centres and at home, it was decided to use RUTFs to treat severe and moderate acute undernutrition (20, 21).

A Maternal and Child National Insurance system started in the country in 1996, with the purpose of reducing maternal and under-five mortality. This expanded in 2002 to the Universal Maternal Child Insurance (SUMI), with coverage of all pathology in children aged under 5 years, pregnant women, and women with children under 6 months of age. In January 2006, SUMI was expanded to cover the population between 5 years and 59 years of age, linking with the Insurance for Older Adults, which covers people aged 60 years and older (22, 23). Since 2014, the public insurance system has included free and quality-assured medicines, vaccines and other health products (24).

This paper describes the process of inclusion of RUTFs in the national essential medicines list in the Plurinational State of Bolivia, the role of the partners involved, the resources, and the main lessons learnt in the process. Additionally, it describes the collaboration between government and non-state actors at the national level, and the trade-offs of RUTF use in health facilities.

Materials and methods

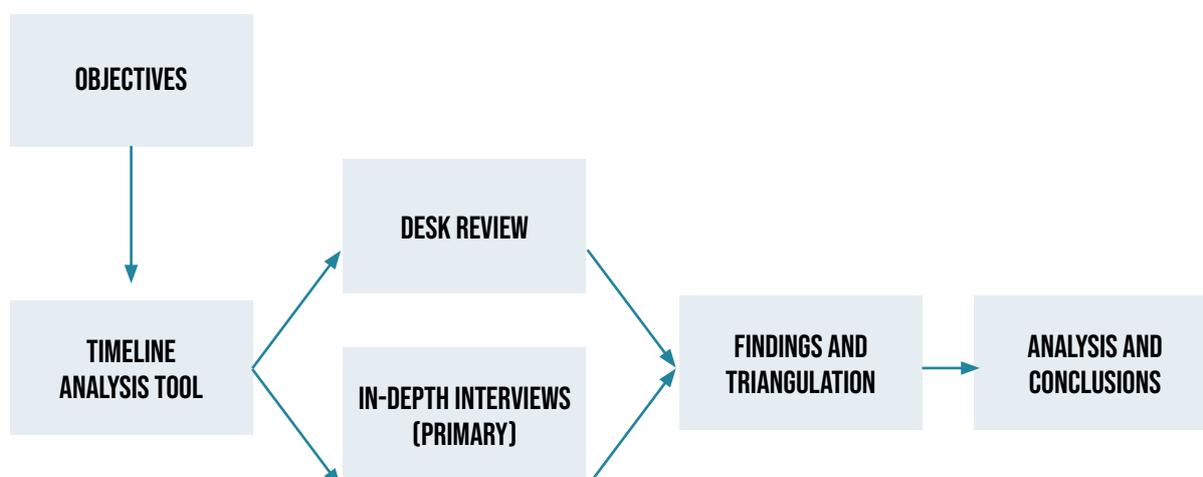
This is a case-study paper, developed considering the following general objective: to describe the process of adding RUTFs to the list of essential medicines for the management of moderate and severe acute malnutrition in Bolivia. It had the following specific objectives:

- to review the process of inclusion of RUTFs in IMCI;
- to describe the cooperation between the public and private sectors and nongovernmental organizations to include RUTFs in the national list of essential medicines and ensure their availability;
- to identify the main lessons learnt from the process of adding RUTFs to the national list of essential medicines.

Methodology

This exploratory study case used the methodological steps shown in Fig. A3.5.1. Based on the study objectives, a timeline analysis tool was developed. This tool incorporates the step-by-step sequence of events that occurred since the inclusion of RUTFs in the essential medicines list up to the current availability status of the product in Bolivia. The timeline analysis tool also allowed identification of key informants and selection of the documentation needed for the desk review.

Fig. A3.5.1. Sequence of methodological steps used



The desk review considered all available documents kept in the archive of the Ministry of Health, such as reports of meetings where the use of RUTFs was discussed, normative series (25), protocols (26), pertinent laws and regulations (27, 28) and demographic and health surveys (29).

In-depth interviews were conducted, based on semi-structured questionnaires (see [Appendix A3.5.1](#)) with selected key informants, including staff from the Ministry of Health, local health staff and selected partners.

All the findings were analysed, establishing converging lines of evidence to increase the robustness of findings and to establish the real facts, based on triangulation of multiple sources of evidence.

As the case-study used a qualitative methodology, the data were analysed and presented in that way. The secondary qualitative data were obtained from the database of the Public Insurance Unit of the Ministry of Health, which reports the delivery of supplies in each institutional municipal pharmacy (27, 30), and presented using frequencies.

Additionally, to provide information about the current use of RUTFs, an electronic questionnaire was applied to staff of primary health-care clinics in municipalities with the highest rates of attention to moderate and severe acute malnutrition (see [Appendix A3.5.2](#)).

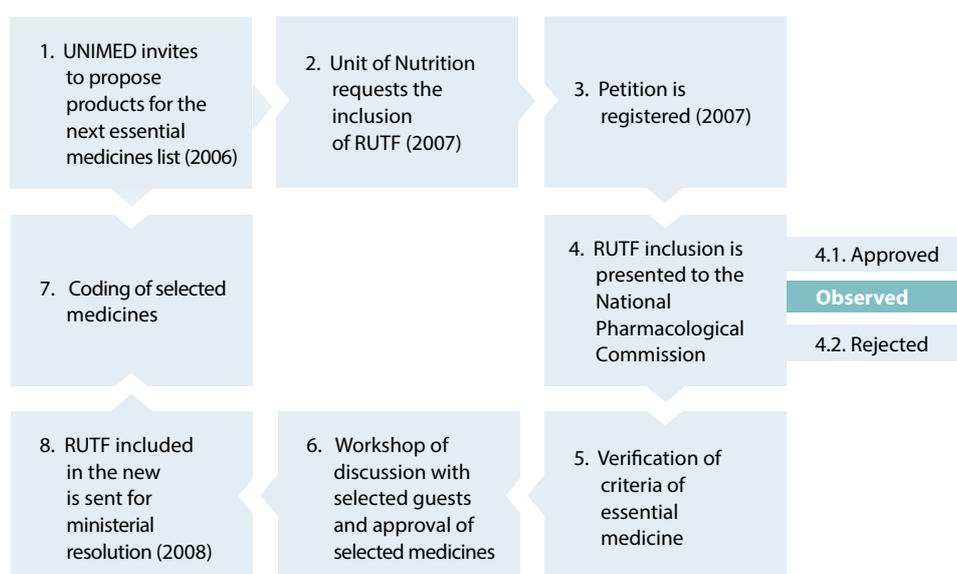
Finally, the conclusions were established, based on discussions and validation with key people involved in the process.

Results

The study had the approval of the Nutrition Unit of the Ministry of Health, and access to available documentation was granted. All key selected informants agreed to be interviewed (see [Appendix 3.5.2](#)).

Each informant contributed to describing the context in which RUTFs were included in the essential medicines list for more than 10 years. The process of adding RUTFs to the essential medicines list is described in Fig. A3.5.2; the steps shown are generic and apply to all products with the potential to be included in the list.

Fig. A3.5.2. Process for incorporation of ready-to-use therapeutic foods (RUTFs) in the essential medicines list



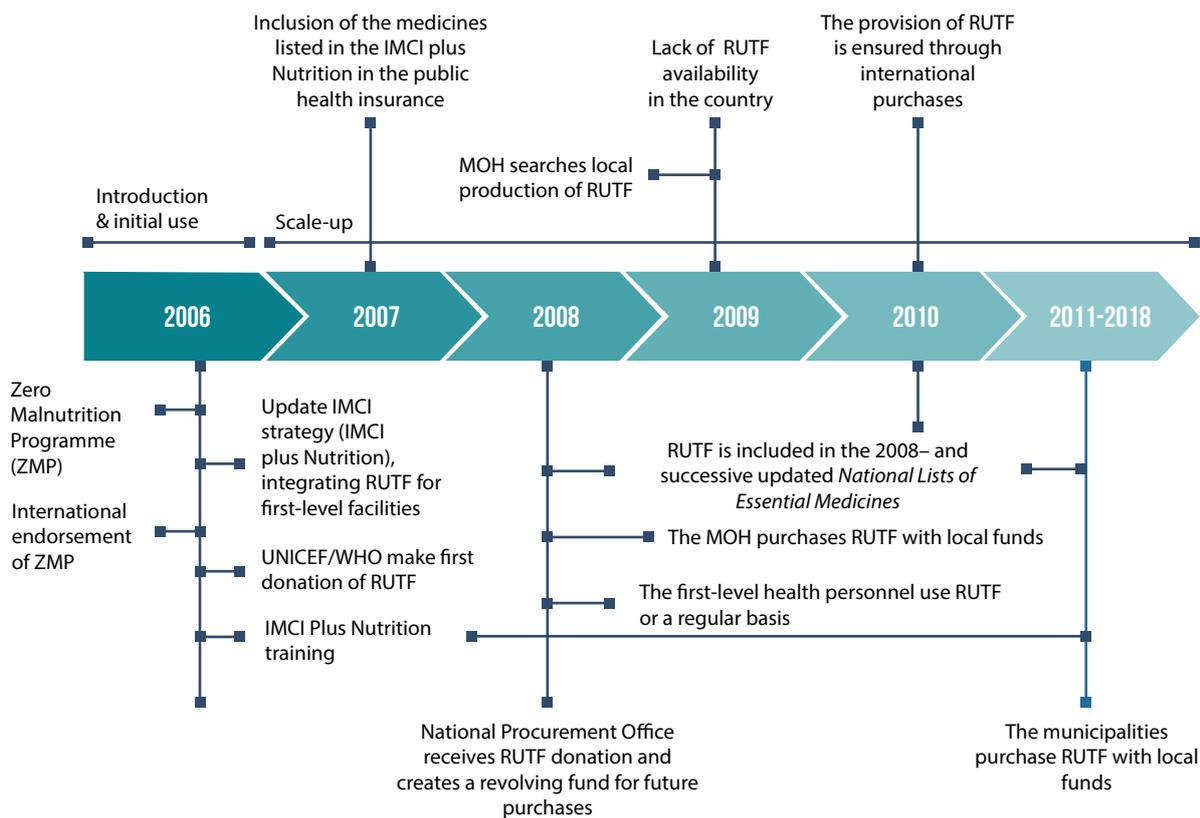
UNIMED: Unidad de medicamentos y tecnología en salud, Plurinational State of Bolivia.

The interviewees agreed that the inclusion of RUTFs in the essential medicines list was subject to a working system in place that called for new proposals every 2 years (step 1). The request for the inclusion (step 2) was done in the context of the implementation of the Programa Multisectorial Desnutrición Cero (15). The National Pharmacological Commission accepted the product with observations related to insufficient evidence. The observations were addressed and resolved with the presentation of an updated bibliography at the time.

Informants concurred that the cooperation between the public and private sectors, United Nations organizations and nongovernmental organizations was done within the framework of the Programa Multisectorial Desnutrición Cero (15).

Fig. A3.5.3, constructed with information from the interviews and revision of documents, gives an idea of the context and timing of the events that took place during the process of including RUTFs in the essential medicines list.

Fig. A3.5.3. Timeline followed in the Plurinational State of Bolivia for adding ready-to-use therapeutic foods (RUTFs) to the local essential medicines list

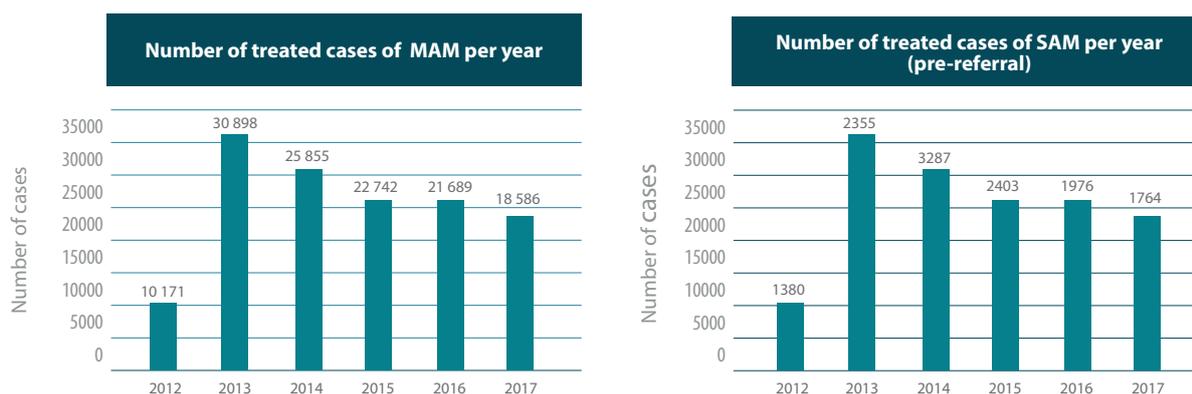


IMCI: Integrated Management of Childhood Illnesses (12); MOH: Ministry of Health; UNICEF: United Nations Children's Fund; WHO: World Health Organization.

Before the inclusion of RUTFs in the essential medicines list, the components of the Programa Multisectorial Desnutrición Cero (15) were all in place and had been endorsed by international institutions, so RUTFs were available for use. These actions contributed to ensuring sustainability in the period 2012–2018, when all municipalities were purchasing the products with local funds.

The current use of RUTFs after a decade of their inclusion in the essential medicines list was provided by assessment of the information system of the institutional municipal pharmacy (30). Fig. A3.5.4 shows the trend of treatments dispensed for moderate acute malnutrition and prereferral treatment for severe acute malnutrition since 2012 in primary health-care facilities.

Fig. A3.5.4. Cases of acute malnutrition, treated at first-level facilities, by year



MAM: moderate acute malnutrition; SAM: severe acute malnutrition.

The electronic survey conducted among primary health-care staff from 94 municipalities from all departments in the Plurinational State of Bolivia (see [Appendix A3.5.2](#)) indicated that all staff interviewed had used RUTFs in the past year; however, only 80.85% mentioned that RUTFs were available at the time of the interview. The experience with RUTFs was good in terms of child acceptability and recuperation of malnutrition (67.02% of staff surveyed); the remaining 32.98% found some limitations in younger children, such as low tolerance and patience of the family. Most RUTFs used in primary care facilities (74%) were purchased by the municipality.

Discussion

The process of inclusion of RUTFs in the Bolivian *National List of Essential Medicines*, according to the results presented, was constructive, was done in a timely manner, and benefited from high national and international support for the reduction of malnutrition prevalence and mortality in children under 5 years of age.

Three relevant factors were pointed out: (i) the legal framework for the regulation of medicines; (ii) the implementation of the Programa Multisectorial Desnutrición Cero; and (iii) the existence of national public health insurance for children aged under 5 years and pregnant women.

The national regulation system of medicines indicated the way forward for the inclusion (see Fig. A3.5.2) (31). Every 2 years, the *National List of Essential Medicines* is revised and a call for new proposals is opened. Products that are demonstrated to respond to national epidemiological problems and have documentation to endorse their validity have priority. In the case of RUTFs, the duration of inclusion was less than 1 year. The implementation of the Programa Multisectorial Desnutrición Cero, which upgraded the protocols of management of moderate and severe acute malnutrition and introduced RUTFs, among other new products, contributed to complying with all the steps required. However, long-term sustainability would have been difficult to achieve if RUTFs were not included in public insurance (23).

Background documentation presented to the National Pharmacological Commission (Fig. A3.5.2, step 4) included a nutrition-improved IMCI strategy according to international recommendations (19, 26, 32, 33);

in-service management of severe acute malnutrition and implementation of community-based interventions for the management of severe acute malnutrition without complications (34); and a summary of positive outcomes of the use of RUTFs in the field (35–37). The revised IMCI protocol extended the use of RUTFs to primary health-care facilities, to treat moderate acute malnutrition without complications, based on the fact that the prevalence of moderate acute malnutrition exceeded 4.4 times that of severe acute malnutrition (1.3% versus 0.3%) (25, 27), and at that time no protocols for the management of moderate acute malnutrition were in place.

The technical support given by United Nations organizations providing references and first-hand experience of use of RUTFs was critical to guaranteeing the approval. Moreover, the interinstitutional collaboration went beyond the registration process; it was crucial to ensure availability in the short term, by providing a donation of the first shipment of RUTFs and later promoting engagement of the private sector to import and distribute RUTFs in the country.

At present, RUTFs are part of the public health system. In 2017, their cost represented approximately 0.21% of the Bolivian Ministry of Health budget. They have been used almost uninterruptedly for the past 8 years and are valued by health staff for the treatment of moderate and severe acute malnutrition.

Given the benefit that the use of RUTFs presents for the management of children with malnutrition at the community level (38, 39), the way the process was conducted in the Plurinational State of Bolivia could be useful in other situations. The following points should be considered when the addition of RUTFs to a national essential medicines list is proposed: (i) a national or local policy for the reduction of malnutrition; (ii) coordination between decision-makers and technical staff; and (iii) a financing scheme to ensure sustainability over time.

In summary, the process of incorporating RUTFs into the Bolivian essential medicines list, from inception to expansion, was done in a timely manner and, among other actions of the Programa Multisectorial Desnutrición Cero, is regarded to have contributed to a reduction in the infant mortality rate in the country.

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Appendix A3.5.1

Open questions for interview: English translation

Ask consent for the interview and permission for recording

According to their role:

To identify main milestones in the initial process of incorporation of ready-to-use therapeutic foods (RUTFs) in the essential medicines list

1. Could you please describe your position and role, regarding the process of incorporating RUTFs in the essential medicines list?
2. Could you please tell us the name of persons and institutions involved in the process?
3. Could you please tell us what was the role of United Nations organizations, nongovernmental organizations, academic institutions and medical associations?
4. Could you please tell us the main outcomes and how they were achieved?

To describe the initial implementation of RUTF use in health facilities

1. Could you please describe the framework of existing regulations that facilitated the process of incorporating of RUTFs in the essential medicines list?
2. In your view, which were the elements, institutions and programmes that facilitated the availability of RUTF in the country and later in the field?
3. Could you please describe how this new nutrition product was introduced in the protocols? In what way were the staff of the health centres trained in its use? Did some organizations refuse to use the product? Did any health staff complain after using the product?

To identify the main lessons learnt

1. Based on the experience of incorporating RUTFs in the essential medicines list, if you needed to incorporate a new product in the list what would be the main things you would search for to facilitate the process and what actions would you take or avoid?
2. Could you provide some examples of barriers and difficulties that interfered with the process of incorporating RUTFs in the essential medicines list? What successful actions were taken?

Appendix A3.5.2

Electronic questionnaire: English translation

Utilization of ready-to-use therapeutic foods (RUTFs)

Full name

Profession Date:

Position

Name of health centre

Municipality Department

1. Do you know about RUTF? Yes No
2. If, yes:
3. At the moment, are RUTFs available in the facility where you work? Yes No
4. How do you obtain RUTFs in your facility?
 - Bought by municipality Donation
 - Given by department Another health service
5. In the last six months have you used RUTFs? Yes No
 If Yes, what did you use them for? (Please mark as applicable)
 - Treatment of children with severe acute malnutrition
 - Treatment of children with chronic malnutrition
 - Treatment of children with moderate acute malnutrition
 - Other
6. How is your experience of using RUTFs for acute malnutrition (severe or moderate)?:
 - Good Average Bad Don't know
7. Were you trained in the use of RUTFs? Yes No

Date of training:

Would you like to make any other comments about RUTFs?



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