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

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WHO/NMH/NHD/19.1

Suggested citation. Technical consultation: nutrition-related products and the *World Health Organization Model List of Essential Medicines* – practical considerations and feasibility, Geneva, Switzerland, 20–21 September 2018. Meeting report. (WHO/NMH/NHD/19.1). Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

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This publication contains the report of the WHO technical consultation: nutrition-related products and the *World Health Organization Model List of Essential Medicines* – practical considerations and feasibility, 20 – 21 September 2018 and does not necessarily represent the decisions or policies of WHO.

Contents

Abbreviations

ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency), Brazil
COFEPRIS	Federal Commission for Protection against Sanitary Risk, Mexico
EML	*WHO Model List of Essential Medicines*
EMLc	*WHO Model List of Essential Medicines for Children*
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

Acknowledgements

This meeting report was prepared by the World Health Organization (WHO) Department of Nutrition for Health and Development. Mr Filiberto Beltran-Velazquez and Dr Maria Nieves Garcia-Casal led the organization of the meeting and the preparation of the document, under the supervision of Dr Juan Pablo Peña-Rosas. Dr Damian Francis was commissioned by WHO as a meeting rapporteur. WHO acknowledges the technical contributions of the following individuals (in alphabetical order): Dr Francesco Branca, Ms Bernadette Capello, Dr Nicola Magrini, Dr Lorenzo Moja, Mr Kim Petersen, Dr Pura Rayco-Solon, Dr Lisa Rogers, Dr Nigel Rollins and Ms Zita Weise Prinzo. Thanks are also due to the following WHO regional advisers who supported the organization of the meeting (in alphabetical order): Dr Ayoub Al-Jawaldeh (Eastern Mediterranean Region), Dr Angela De Silva (South-East Asia Region), Dr Ruben Grajeda (Region of the Americas), Dr Adelheid Onyango (African Region) and Dr Juliawati Untoro (Western Pacific Region).

Ms Loubna Al Atlassi from the Department of Partnerships and non-State Actors provided support in relation to the *Framework of engagement with non-state actors* and Ms Alma Alic from the Department of Compliance and Risk Management and Ethics provided support in the management of the conflicts of interest procedures. Ms Rosa A Seminario from the Department of Nutrition for Health and Development provided logistic support for the meeting.

Financial support

WHO gratefully acknowledges the contribution of Nutrition International (Canada) and the Bill & Melinda Gates Foundation (United States of America), for providing financial support to cover the costs of the WHO Secretariat for convening the technical consultation and publication of this report.

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 undernutrition,[1] 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, disease-management, 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 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] Africa (4.0 million) and Asia (12.1 million) were the most affected continents, accounting for about 98% of the global burden. 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 and feasibility of including

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

[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).

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, country perspectives and discussions that occurred during the technical meeting 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 6 commissioned papers are published as part of this report.

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 micronutrients such as anti-anaemia medicines, medicines used for diarrhoea, and vitamins and minerals.

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 the national lists. Bolivia (Plurinational State of), Nigeria, Sudan and South Sudan already include these 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 milks[2] and supplementary foods[3] 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 their 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

[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, 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).

categorization and regulation in the country might impact on access to these products.

The other commissioned papers 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, facilitate 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 management of acute undernutrition drew attention to factors such as the existing legal framework, public health insurance, and the implementation of the Zero Malnutrition Program, 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,[1] 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,[2] as well as the WHO triple billion goals,[3] 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 5 of the manuscripts that served as the basis for the consultation.

[1] 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).
[2] World Health Organization. Global Nutrition Targets 2025. Policy brief series (https://www.who.int/nutrition/publications/globaltargets2025_policybrief_overview/en/, accessed 25 February 2019).
[3] 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-briefing.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, disease-management, 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*). Africa (4.0 million) and Asia (12.1 million) were the most affected continents, accounting for about 98% of the global burden. 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 than 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.

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

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, new 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,[1] stunting[2] 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)*.

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, while high-dose vitamin A is recommended for vitamin A deficiency 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

[1] 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)*.

[2] 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)*.

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 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 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. Background papers on stakeholder's perceptions of RUTFs and other nutrition-related health products and case-studies of adding RUTFs to essential medicines lists were designated for the second day of the

meeting agenda. Four plenary discussion sessions were planned for each day of 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 5 of the 6 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, who were asked for their feedback before its publication. Finally, the report underwent the WHO executive 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 mean that the 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 officer 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 next:

- 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

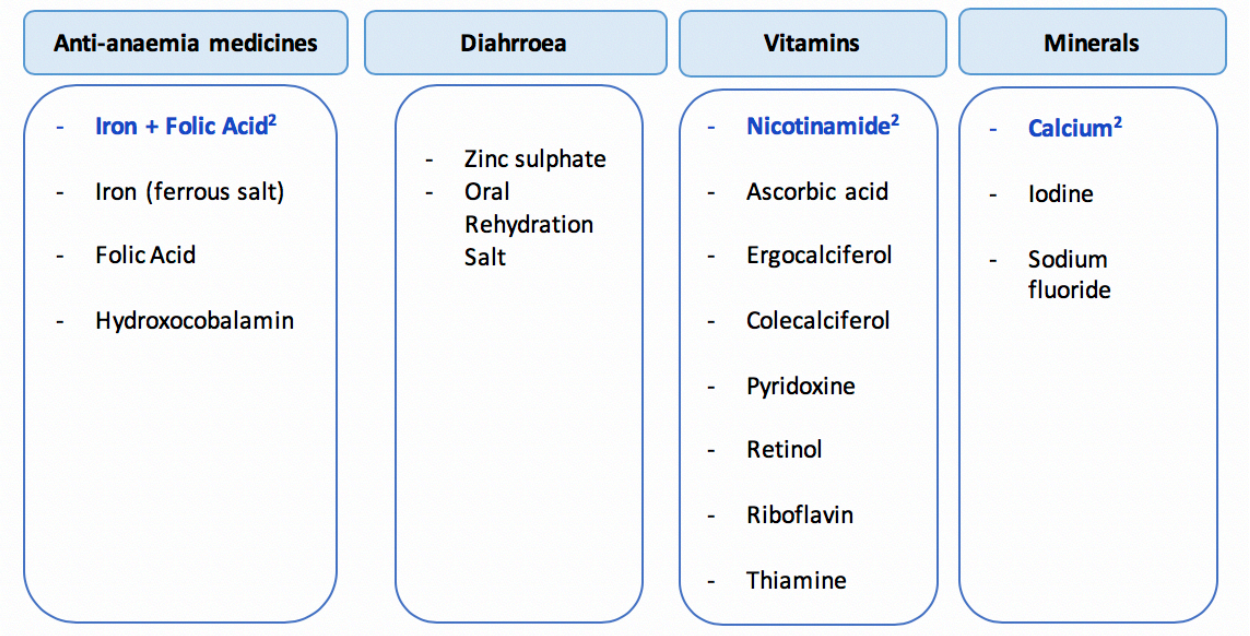
WHO's 13th General Programme of Work (GPW13) highlights three strategic priorities *(7)*:

- advancing universal health-care 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.

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* (EML) and 6th *Model List of Essential Medicines for Children* (EMLc)



[1] 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

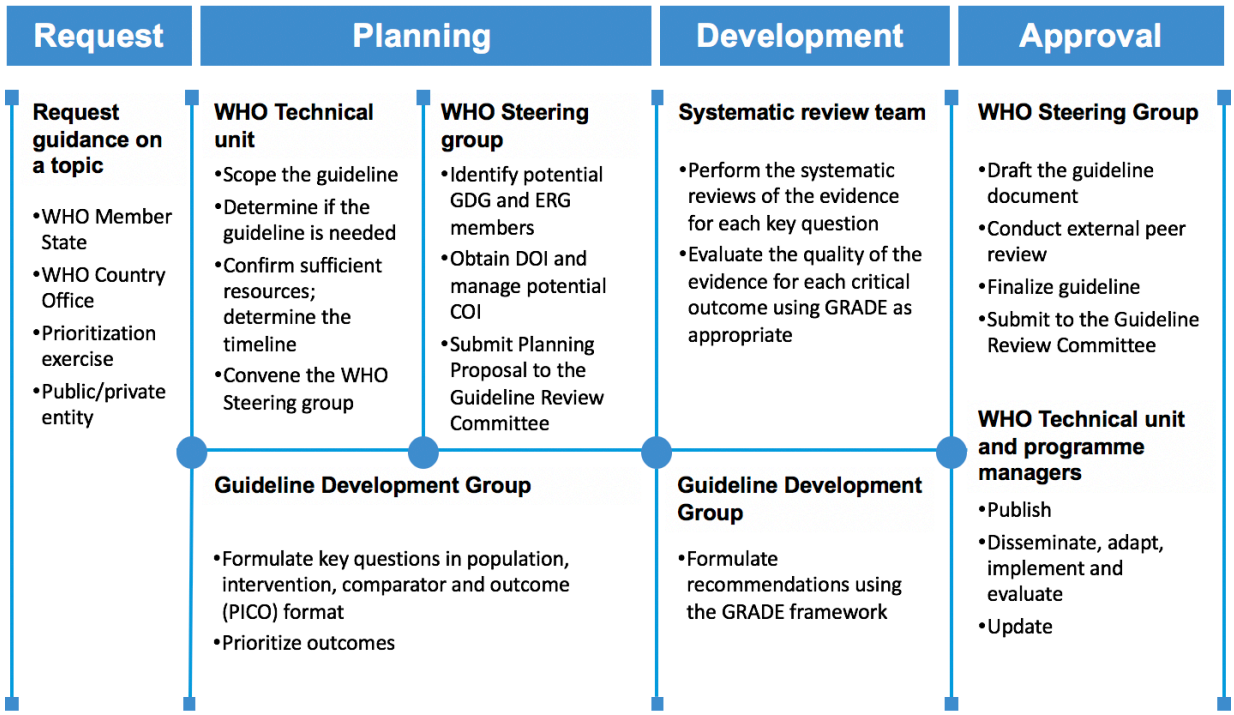
WHO recommendations for health intervention in clinical care, public health and health policy are published as guidelines. A WHO guideline is any document, whatever its title, that contains WHO recommendations about health interventions, whether they are clinical, public health or policy interventions. 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 all 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, disease-management, 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	
Guideline: daily iron supplementation in adult women and adolescent girls (2016) *(24)*	Adult women and adolescent girls	Ferrous salt: Tablet equivalent to 60 mg iron Oral liquid equivalent to 25 mg iron (as sulfate)/mL	10. M the b 10.1 medi
Guideline: daily iron supplementation in infants and children (2016) *(25)*	Children		
Guideline: vitamin A supplementation for infants and children 6–59 months of age (2011) *(14)*	Children	Retinol: Capsule 50 000 IU, 100 000 IU, 200 000 IU (as palmitate)	27. V mine
Guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries (2011) *(26)*	Infants aged 2 weeks–6 months	Ferrous salt: Oral liquid equivalent to 25 mg iron (as sulfate)/mL Colecalciferol: Oral liquid 400 IU/mL Ergocalciferol: Oral liquid: 250 µg/mL	10. M the b 10.1 medi 27. V mine
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 (2016) *(13)* *Preventing and controlling micronutrient deficiencies*	Infants and young children	Multi-micronutrient powders	—

in emergencies. Multiple vitamin and mineral supplements for pregnant and lactating women, and for children aged 6–59 months (2007) *(27)*			
Vitamin and mineral requirements in human nutrition (2004) *(28)*	Infants and young children	Ascorbic acid Hydroxocobalamin Pyridoxine Riboflavin Thiamine	27. V mine
Guideline: fortification of rice with vitamins and minerals in public health (2018) *(29)* *WHO guideline: fortification of maize flour and corn meal with vitamins and minerals* (2016) *(30)* *Fortification of food-grade salt with iodine for the prevention and control of iodine deficiency disorders* (2014) *(31)*	Populations	Fortificants Iron Folic acid Vitamin A (rice) Iodate or iodide (salt)	—

Guidelines related to preconception

Guideline	**Target group**	**Product**	**EML**
Guideline: intermittent iron and folic acid supplementation in menstruating women (2011) *(12)* *Guideline: daily iron supplementation in adult*	Menstruating women	Iron + folic acid tablets	10. M the bl 10.1 A medic

women and adolescent girls (2016) *(24)* *Weekly iron–folic acid supplementation (WIFS) in women of reproductive age; its role in promoting optimal maternal and child health* (2009) *(32)*			

Guidelines related to antenatal care

Guideline	**Target group**	**Product**	**EM**
Recommendations on antenatal care for a positive pregnancy experience (2016) *(33)* *Integrated Management of Pregnancy and Childbirth. Standards for maternal and neonatal care* (2007) *(34)*	Pregnant women	Ferrous salt: Tablet: equivalent to 60 mg iron Folic acid: Tablet: 400 µg (periconceptual use), 1 mg, 5 mg Iron + folic acid tablets: Tablet: 60 mg iron + 400 µg folic acid	10. the 10. me
WHO recommendation: calcium supplementation during pregnancy for prevention of pre-eclampsia and its complications (15)	Pregnant women	Calcium: Tablet: 500 mg (elemental)	27 mi
Reaching optimal iodine nutrition in pregnant and lactating women and young children (2007) *(35)*		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 a
Guideline: updates on the management of severe acute malnutrition in infants and children (2013) *(1)*	Children with severe acute malnutrition	Ready-to-use therapeutic foods	—
		Therapeutic formula diets:	—
		F-75	
		F-100	
Technical note: supplementary food for the management of moderate acute malnutrition in infants and children 6–59 months of age (2012) *(36)*	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 a
Ending preventable child deaths from pneumonia and diarrhoea by 2025: the integrated Global Action Plan for Pneumonia and Diarrhoea (GAPDD) (37)	Children	Zinc sulfate:	17. G medic
		Solid oral dosage form: 20 mg (in acute diarrhoea)	17.5 diarrh
			17.5. diarrh
		Oral rehydration salts:	26. S water
		Powder for dilution in 200 mL, 500 mL, 1 L	acid–
			26.1
Guideline: preventive chemotherapy to control soil-transmitted helminth infections in at-risk population groups (38)	Children, non-pregnant adolescent girls and women of reproductive age, pregnant women	Albendazole/mebendazole	6. An medic
		Albendazole:	6.1 A
		Tablet (chewable): 400 mg	6.1.1 anthe
		Mebendazole:	

		Tablet (chewable): 500 mg	
Guideline: nutritional care and support for patients with tuberculosis (2013) *(39)*	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 except 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 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 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 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 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 the segregation of 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 B_1–B_6–B_{12}, multivitamins and minerals, vitamin B_1, vitamin B_{12}, 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 premixes 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 supplement 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 foods (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

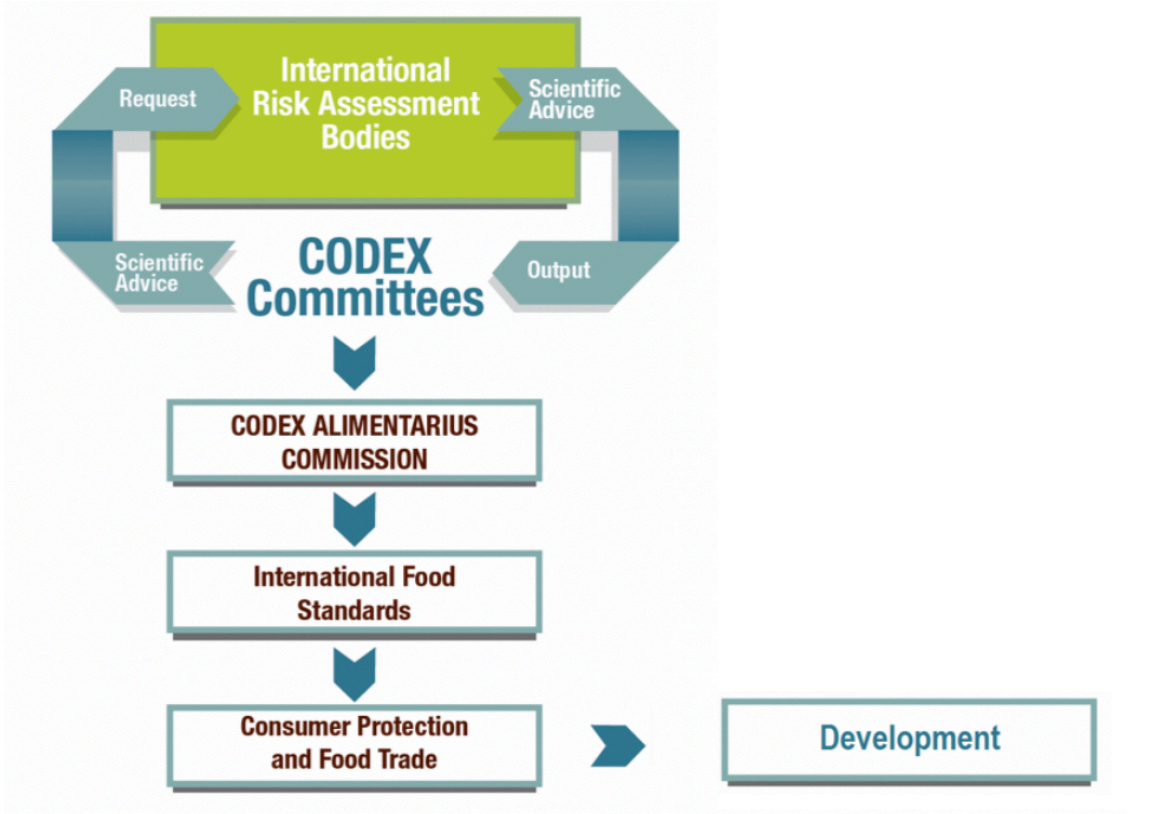
stakeholders prefer the Food Safety and Standards Authority of India rather than the Drugs Controller General of India regulatory framework for RUTFs. Overall, the inclusion of nutrition-related health products for public health programmes, and probably for the national essential medicines list, would 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

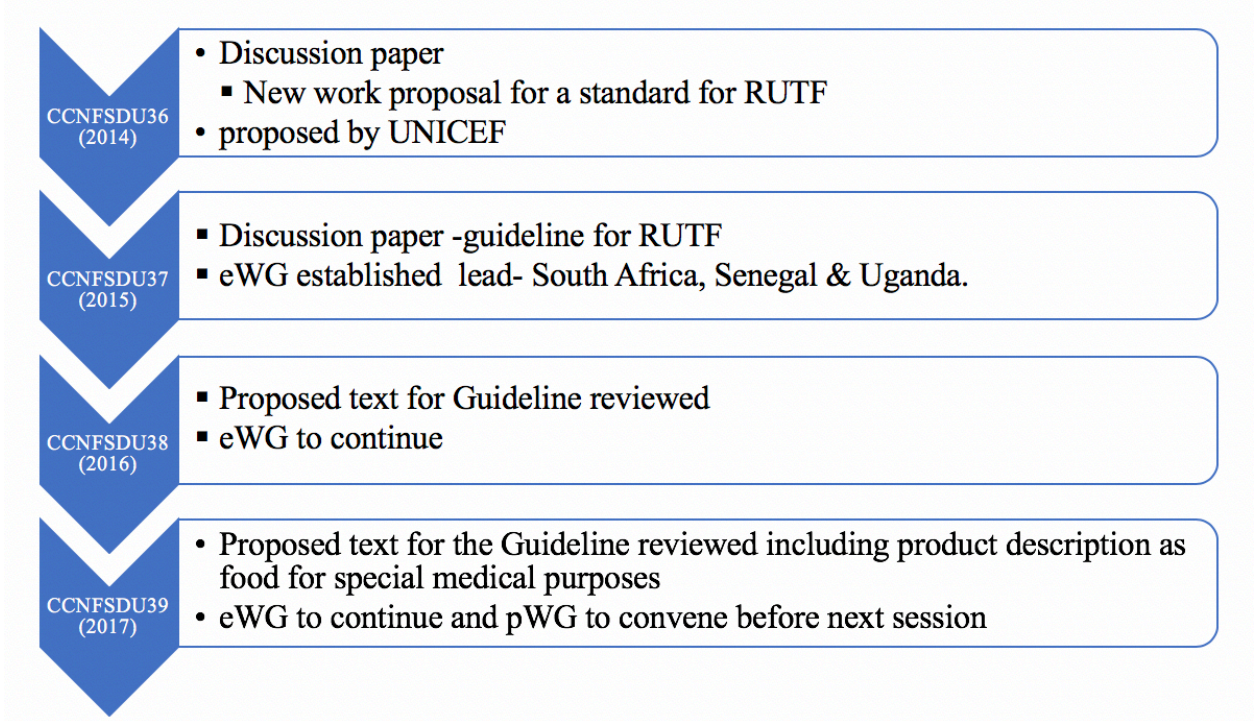
The Codex Alimentarius includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution to consumers *(41)*.

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 food 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 cannot 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 Special Committee on 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 undernutrition is clearly

defined by the WHO *International classification of diseases*, eleventh revision, as *(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 milks 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 diet to F-100 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 malnutrition, 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 malnutrition 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, 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 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.

Background paper: 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.

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

Presented by Katherine P Adams

Access to nutrition-related health 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 health 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

health 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 (*53*). The authors conclude that the decision to add RUTFs and other nutrition-related health products to the EML should be contingent upon demonstrating, with reasonable confidence, that the cumulative effect of adding RUTFs and other nutrition-related health 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. The full text

For more information, see Annex 3.2 .

Background paper: 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 (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, registered 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 *(55)*.

Background paper: 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 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 products, formed a large part of the context for reviewing and updating the *South Sudan Essential Medicines 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 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 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 products are included in the essential medicines list;
- misuse of specialized nutrition-related products by family members.

Full details of the study *(56)* are presented in the manuscript Annex 3.4.

Background paper: 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 Zero Malnutrition Program, 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 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 had the following comments:

- 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 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 malnutrition.

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 RUTFs, RUSFs and Super Cereal Plus are set by the buying agencies, as there are no Codex standards for these foods *(51, 58)*.

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 to consumers these foods 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 the 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 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

According to the WHO *International classification of diseases (49)*, severe acute malnutrition is considered as a disease accounting for significant morbidity and mortality. 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 developing 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 RUTF.

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.

WHO supports strengthening country and regional regulatory capacity and supply of quality-assured and safe health products, as indicated in the GPW13 *(7)* results framework outputs and outcomes for achieving the triple billion

targets and maximizing the impact on people's lives at the country level. These specifically include expanding coverage of effective interventions to improve nutrition across the life-course, such as treating children affected by acute undernutrition, and improving vitamin and mineral intake during adolescence and conception; improving access to essential medicines, vaccines, diagnostics and devices for primary health care; encouraging manufacturers to submit more applications for prequalification to increase applications for the EML; building capacity and supporting the development of policies and guidelines on improving governance and stewardship of health technologies; and development, review and updating of national lists of essential medical products (outcomes 1.3 and 3.1 and also outcome 2.1 on preparedness and prevention of emergencies *(7)*). As for most of WHO's work, this effort will cross-cut with other projects to impact the three-level framework that reflects the theory of change of the organization.

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

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 *World Health Organization Model List of Essential Medicines* and criteria for selection
10:30–11:00	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*
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	Background paper: 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 (Annex 3.1)
10:15–10:45	Discussion
10:45–11:10	Break
11:10–11:30	Background paper: Stakeholder perceptions of adding ready-to-use therapeutic foods and other nutrition-related products to the *World Health Organization Model List of Essential Medicines* (Annex 3.2)
11:30–11:50	Background paper: Process and impact of integration of ready-to-use therapeutic foods in national essential medicines lists (Annex A3.3)
11:50–12:20	Discussion
12:20–13:20	Lunch
13:20–13:40	Background paper: Public health relevance of including specialized nutrition-related products in the *South Sudan Essential Medicine List 2018* (Annex 3.4)
13:40–14:00	Background paper: 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

Annex 3. Background papers