The value of a ready-to-use therapeutic food guideline for severe acute malnutrition

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Ready-to-use therapeutic foods (RUTFs) are used in the treatment of children with severe acute malnutrition (SAM) without medical complications. This article focuses on the value of an RUTF guideline. Knowing what is required for children with SAM helps manufacturers produce safe, efficacious, and good quality products, which will ultimately benefit end users. It will also help with the evaluation of products and provide guidance for researchers or innovators.

Keywords – ready-to-use therapeutic foods, RUTF, SAM, severe acute malnutrition

Introduction
Since 2000, the number of children globally suffering from undernutrition has been reduced by one-third.1 Childhood undernutrition contributes to about 45% of deaths among children younger than 5 years, mainly in low- and middle-income countries. Globally, in 2020, it was estimated that 149 million children
younger than 5 years were stunted (too short for their age) and 45 million were wasted (too thin for their height). 2 Undernutrition is a major global health problem, which contributes to mortality, morbidity, and long-term health consequences. 3, 4

Acute malnutrition is due to an inadequate energy or protein intake because of food insecurity caused by social, economic, and environmental factors. 5 SAM is when children aged between 6 and 59 months, have a mid-upper-arm circumference of less than 115 mm. 6 A weight-for-height z-score of more than 3 standard deviations, also indicates SAM. 7, 4

Patients with SAM are classified into two groups – those with and those without medical complications. Hospitalization is required only for patients with SAM and medical complications, so that they can be stabilized. Those without medical complications can be managed in an outpatient or home-based care setting. 4, 8 In these settings, RUTF may be used. 8

RUTF are foods for special medical purposes. 9 It is a lipid-based therapeutic food with a high energy content and contains adequate amounts of protein, vitamins, and minerals. 8, 9 The major ingredients typically include ground peanuts, oil, sugar, milk powder, vitamins, and minerals. They are soft or crushable foods that can be easily consumed by children from age 6 months or older, without requiring any prior preparation. 6, 9 Children can consume RUTF with minimal supervision at home, often directly from the package, at any time of the day or night. 6, 10

International guideline for RUTF
RUTF, as part of the dietary management of uncomplicated SAM, has saved millions of lives of children. 8 Yet there has been no official, international standard for RUTF that countries could follow to ensure a safe and efficacious product. Until now, some purchasing agencies have written their specifications based on the 2007 joint statement on community-based management of SAM 6 and technical guidance 11 and the United Nations Children’s Fund provided technical support to governmental and nongovernmental organizations on the use of RUTF. 10 During the 37th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in 2015, the committee agreed to establish an electronic working group – chaired by South Africa and cochaired by Senegal and Uganda – to develop a guideline for RUTF for children with SAM. 12 The guideline was finalized at the end of 2021 during the 43rd CCNFSDU meeting and is expected soon to be endorsed by the CODEX Alimentarius Commission. It provides a reassuring framework and will assist in the development and endorsement of new producers and products. It may be used as an appropriate reference for imported or locally produced products to facilitate local regulations and encourage allocation of national budgets to these products. 11 The guideline includes the following sections: 13
Preamble
Purpose of the guideline – To provide guidance on technical and nutritional aspects of the production of RUTF for children aged between 6 and 59 months with SAM.
Scope – RUTF for children aged 6 to 59 months with severe acute malnutrition.
Descriptions – Provide definitions for RUTF and SAM as there was no previous universal agreement on what should be termed an RUTF. \(^9,14\)
Suitable raw material and ingredients – For example, milk and other dairy products, legumes and seeds, fats and oils, cereals, roots and tubers and their derived products, vitamins, and minerals. It also includes a section on the type of carbohydrates that must be used as well as the permitted additives.
Nutritional composition and quality factors – Includes macronutrients and essential micronutrients.
Contaminants
Processing technologies
Good manufacturing and good hygiene practices
Methods of analysis and sampling – Include macronutrients and essential micro-nutrients.
Packaging – Guidelines to ensure products are packaged so as to safeguard hygienic and other qualities, including its nutritional properties for the duration of its defined shelf-life. \(^13\)
Labelling guidelines – Include what the product should be called, the ingredients listing, and mandatory statements. RUTFs must include the following statement: “Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to 2 years or beyond.” \(^9\)

The guideline development process encouraged a better understanding of stakeholders’ needs and constraints. It was based on careful consideration and vigorous debate around what is possible to manufacture, what is known by fieldworkers on the ground, and what current and available scientific evidence says. It sparked debate on whether current products are sufficiently efficacious. For example, the calcium and fatty acid profiles were questioned. The maximum level for calcium has increased from what is mentioned in the 2007 joint statement on SAM. \(^6,9\) The required levels for omega-3 fatty acids increased, whereas the level for omega-6 fatty acids decreased. \(^9\) Omega-3 fatty acids, and specifically docosahexaenoic acid (DHA), are known to support optimal brain development. \(^15\)

Stephenson and colleagues\(^{16}\) conducted a triple-blind, randomized, controlled clinical feeding trial to examine the impact of low linoleic acid foods with added DHA on cognition in children in Malawi with uncomplicated SAM. Study participants received one of the following RUTF formulations:

- Standard RUTF;
- RUTF made with reduced amounts of linoleic acid, achieved by using high oleic peanuts and palm oil; or
• RUTF made with reduced amounts of linoleic acid, but with added DHA.

Children who received the product with added DHA scored higher on the global Malawi Developmental Assessment Tool, compared with those who received the standard RUTF. They also achieved higher gross motor and social domain z-scores. However, it should be noted that, while the addition of DHA to RUTF shows benefit, it also increases the cost of the product and may affect its palatability.

Potani and colleagues also looked at alternative formulations, using ingredients that were more culturally acceptable and contained low or no dairy and were potentially cheaper. A systematic review found these formulations were not as effective as standard RUTF for treating children with SAM, based on weight gain, recovery, and weight-for-age z scores, but the researchers suggest that further research is required to explore the potential of future alternative formulations.

Thus, although the guideline provides an indication of what ingredients need to be used and what nutrient target levels should be met, it does not stifle innovative thinking. It leaves room for the development and sale of several alternatives to the RUTFs currently available, provided that these products have been shown, through scientific evidence, to be safe and effective.

Benefits of the RUTF guideline

The new guideline will benefit end-users of RUTF, because the products that they currently receive will be assessed against an international, evidence-based reference. Other benefits of the guideline include that it:

• Can be used to facilitate trade disputes and provide guidance on importation requirements;
• Provides a framework for sustainable procurement of quality products;
• Provides manufactures with an official global reference for the minimum requirements for RUTF. This will help ensure products are safe, efficacious, and of a good quality;
• Provides an advocacy opportunity for children’s rights to good nutrition;
• Provides an opportunity for clarifying certain issues, such as contaminants, so that the formulation can be improved; and
• Can be used as a tool to assist in the development of a regulatory framework at national level.

RUTF is safe when used properly. However, it should also not be used for the prevention of child malnutrition. It should also not be seen as a substitute for best nutritional practices, breastfeeding, or normal household food, but as part of the medical management of SAM that should only be used in conjunction with necessary primary health care and in accordance with standards for such care. The guideline should also not be seen as a substitute for sustainable policies and programmes to combat all forms of malnutrition.
Every child has the right to nutrition. And there is a great need for diets, services, and practices that protect, promote, and support good nutrition.¹

**Acronyms and abbreviations**

CCNFSDU, Committee on Nutrition and Foods for Special Dietary Uses; DHA, docosahexaenoic acid; RUTF, ready-to-use therapeutic foods; SAM, severe acute malnutrition.

**About the author**

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