Ready-to-use Therapeutic Food (RUTF) and Ready-to-use Supplementary Food (RUSF)

New approaches in formulation and sourcing

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Key messages

> Our vision is to eradicate childhood malnutrition and our mission is to advance the treatment of acute malnutrition, using effective, locally produced ready-to-use therapeutic foods (RUTFs).

> While RUTF is an energy-dense, peanut butter paste with proven efficacy giving the high-quality nutrition necessary for a child to recover from acute malnutrition, we are continuously working to improve the formulation.

> Our aspiration is to see children – more than just surviving or recovering – truly thriving with the enduring benefits from their RUTF treatment.

Introduction

Globally, 51.7 million children under five are wasted, defined as a weight-for-height below the third percentile. Wasting is a symptom of acute malnutrition – a significant public health challenge that, although declining in prevalence and related mortality, still persists, leaving millions of children at increased risk of illness and death. The greatest incidence of acute malnutrition occurs in children between 6 and 59 months of age, a crucial period of dynamic and rapid physical and neurological development. As a result, it can cause long-term consequences that pose a threat to a child’s ability to reach full cognitive potential.

Ready-to-use therapeutic foods (RUTFs) were derived from the existing liquid F-100 diet recommended by the World Health Organization (WHO) for the treatment of children with severe acute malnutrition (SAM) prior to 2007; at the time, F-100 had already been used successfully to treat a million of these children. The formulation of the first RUTF in the early 2000s was obtained by replacing about half of the milk in the F-100 formula with peanut paste. This resulted in a food that looked like a paste and could be used without the addition of water, which eliminated the risk of bacterial contamination after opening the container/sachet. Standard RUTF has since proven to be highly effective in promoting rapid weight gain in children recovering from SAM.

“Providing greater access to this lifesaving treatment is a moral and global health imperative”

Challenges

In the late 1990s, when convenient and effective treatments were needed to treat children with SAM, the nutrition community rose to the challenge. The development of RUTF revolutionized the management of children with acute malnutrition, offering a superior alternative to inpatient treatment, but with a vision to increase the numbers of children under treatment and eradicate malnutrition. To accomplish this, it is essential to improve RUTF and increase its distribution.
1. Economic logic, misconceptions, and millions of children without a lifesaving treatment

A study conducted in Northern Nigeria on the cost-effectiveness of community-based management of acute malnutrition (CMAM) reported a cost of US$1,117 per death averted and a US$30 cost per DALY (disability-adjusted life year) averted.\(^{12}\) Given the GDP per capita of US$610.60 to US$2,078.80 in low- and lower-middle-income countries, this intervention is considered exceptionally cost-effective by WHO standards.\(^{13}\) Unfortunately, economic logic for the investment in the treatment of acute malnutrition is overshadowed by the misconception that acute malnutrition is characteristically a byproduct of emergency crisis situations such as famine or war. These beliefs have guided inconsistent implementation of acute malnutrition management, leaving 80% of children suffering from SAM without access to treatment.\(^ {11,14}\) Given the irrefutable link between wasting and mortality, providing greater access to this lifesaving treatment is a moral and global health imperative.

2. More than just surviving, thriving with enduring benefits from RUTF treatment

The essential fatty acids or polyunsaturated fatty acids (PUFA), such as omega-6 and omega-3, require dietary consumption, as they cannot be synthesized endogenously.\(^ {15}\) Children suffering from SAM have depleted all of their fat stores and are placed on a very monotonous diet, primarily RUTF.\(^ {15,16}\) The fats come from vegetable oils and peanuts. Peanut fat is almost entirely omega-6 PUFA, and the vegetable oils commonly used in RUTF are monounsaturated fats. Diets high in omega-6 support recovery and weight gain but are antagonistic to endogenous production of the key omega-3 fatty acids DHA and EPA, both required for neurocognitive restoration.\(^ {17}\)

Treatment with RUTF has allowed for home-based care of malnourished children, reducing costs and increasing effectiveness, and there is a critical demand to make RUTF more accessible. However, for those that survive SAM, lifelong effects such as neurodevelopment insults can persist, presenting an additional challenge. Recent evidence suggests that RUTF formulations could be optimized to help these children not just survive, but also thrive.\(^ {15}\)

3. Opportunities to optimize RUTF as a supplement for vulnerable populations

Moderate acute malnutrition (MAM) treatment protocols include a health and nutrition component, and many different foods have been used with success to treat MAM.\(^ {18}\) The most common
supplemental foods for MAM treatment are fortified blended flours (FBF). These flours require preparation in the home; they must be mixed with water and heated for 5–10 minutes to make a porridge-like cereal. Though more involved in terms of preparation and packaging, the new formulations have shown to have equivalent outcomes to soy ready-to-use-foods (RUF); however, ready-to-use supplementary food (RUSF) has showed the most effective recovery rates.

Malnutrition in low- and middle-income countries is largely the result of food insecurity, lack of food diversity and disease, resulting in inadequate nutrient intake and losses. Pregnancy exacerbates these risk factors by requiring additional nutrients that further deplete a woman’s nutritional status. Maternal undernutrition is estimated to contribute to 20% of maternal deaths and increases risk for adverse pregnancy outcomes, childhood mortality, and stunting. This implies that pregnancy is a critical time-window during which adequate nutrition leads to healthy fetal growth and development, producing lifelong benefits. Several supplemental foods targeting malnourished pregnant women have been introduced; however, minimal evidence demonstrating the effectiveness of the supplementation has been generated. Additionally, the development of a product that is accepted and also meets all the nutrient requirements for the mother’s recovery has remained challenging. Lack of an endorsed standard for treating pregnant women with malnutrition and the vagueness and limited implementations of existing recommendations for treating these women highlight the need for improved, evidence-based solutions.

**“There is a need for improved, evidence-based solutions”**

**Solutions**

1. **Linear programming technology, local ingredients, innovation, and acceptability**

Reducing the overall cost of treatment could help promote scale-up of treatment. One way this can be achieved is through reducing the cost of RUTF ingredients. The standard formulation for RUTF has been used for over a decade, and although several alternative formulations have been developed and tested by leading researchers, most of these products have not been successful in achieving comparable effectiveness to the current milk- and peanut-based formula. This emphasizes the need for a solution that could produce alternative RUTF formulations that do not compromise the high-quality nutrient specifications of the well-known and effective standard formulation.

In 2013, a multiphase alternative RUTF formulation project began with support from the Children’s Investment Fund Foundation (CIFF). This work began with a comprehensive literature and nutrient database analysis and subsequent development of a food formulation linear programming (LP) tool. The LP tool is a conventional computer database program that lists all potential ingredients, nutritional composition, prices, and country-specific availability for the countries we have worked in. The tool has default nutrient constraints that help ensure the formulations align with the UNICEF RUTF nutrient specifications, but these can be adjusted to help meet specifications for other populations. The tool also allows for ingredient constraints, which supports organoleptic optimization.

The process of formulation development is more complex than setting constraints in an Excel-based program; however, this eliminates and streamlines some of the trial and error characteristic in the process. One of the most significant functions is that the program’s objective uses Solver to meet the set objectives (ingredient and nutrient constraints) using the most cost-optimal ingredients. There is a small cost increase from the default formulation (with no ingredient constraints) when the formula is optimized for production feasibility and taste acceptability, but overall cost savings are still easily obtained with the LP tool.

A total of eight alternative RUTFs with cost savings have been produced and tested for acceptability among malnourished children. Alternative cost-optimal RUTFs with locally available ingredients have been developed for Ghana, Ethiopia, Pakistan, and India. These formulas were all found to be at least as acceptable compared to standard RUTF. Local RUTF producers in Ghana, Ethiopia, and India also successfully produced alternative formulations in-country. The alternative RUTF in Ghana is being investi-
gated in a non-inferiority clinical trial. A low-cost alternative RUTF was also formulated for the international market, optimized for ingredient costs in the United States. The RUTFs have demonstrated acceptability among children in Sierra Leone and Malawi. This reduction in ingredient costs is one strategy for making RUTF more accessible and enabling treatment to reach those who need it.

2. Improved PUFA RUTF
We have developed a new RUTF recipe, improved PUFA RUTF, with a new variety of peanut (high-oleic peanuts) and a small amount of a less common vegetable oil, linseed oil. A pilot study with 140 severely malnourished children compared standard RUTF to improved PUFA RUTF. Blood concentrations of omega-3 PUFAs were low during therapeutic feeding in children receiving standard RUTF but increased in the children consuming improved PUFA RUTF. This is compelling evidence that RUTF could be improved by changing the dietary fatty acids in their composition. It may well be, for example, that if a child loses 10 IQ points when he/she has severe malnutrition and typically gains back 5 of these points, the improved PUFA RUTF might mean a gain of 4 more IQ points.

3. RUSF optimization for moderate acute malnutrition and malnourished pregnant women
The advent of home-based therapy with RUTF and its proven efficacy for treatment of SAM has led to the consideration of possibilities of optimizing RUTF for other vulnerable populations such as children with MAM and malnourished pregnant women. A recent study comparing the effectiveness of peanut-based RUSF with soy protein and novel dairy RUSF with whey permeate and whey protein concentrate showed that the proportion of children that recovered from MAM was significantly higher in the group that received whey RUSF than in the soy RUSF group. One assumption about this evidence is that dairy proteins, such as cow’s milk, have high-quality protein with generous quantities of essential amino acids, which has been associated with improved growth. However, several factors may explain the apparent superiority of milk protein, and the effect of protein quality needs to be more comprehensively quantified.

To gain a better understanding of protein quality, we have developed two isonitrogenous peanut/dairy RUSFs, one of which has been optimized for protein quality, whereas the other, the control RUTF, has standard protein quality. The protein quality of these RUSFs was assessed using the digestible indispensable amino acid score (DIAAS), which uses true ileal digestibility of each amino acid in the protein components of the RUSF relative to the human reference amino acid requirement. The human reference amino acid requirement has been adjusted based on the physiological state of the consumer, children with MAM. These two RUSFs will be investigated in a clinical effectiveness trial for the treatment of MAM.

A need to prioritize effective interventions for malnourished pregnant women has propelled the development of a novel supplementary food. The LP tool was adapted to list potential ingredient data specific to Sierra Leone, and the nutrient parameters
were determined through a panel of maternal nutrition experts. The supplement is optimized to provide ideal protein quality and PUFA composition with the use of dairy proteins and high oleic oil. Organoleptically, the product was optimized in-country through acceptability testing among the target population. The informal acceptability showed millet, a locally available cereal, to be the overwhelming favorite. The RUSF, referred to as Mama Dutasi, has been produced on a large scale at Project Peanut Butter, a local RUTF (Dutasi) production factory in Freetown. Mama Dutasi is currently being investigated as the nutrient component of a bundled nutrition and anti-infective interventions clinical trial to reduce intraterine growth restriction and low birth in Sierra Leonean malnourished pregnant women.

Impact: Saving futures and saving lives
Acute malnutrition puts 52 million children at high risk of not reaching their physical and cognitive potential, and the regions shouldering the highest burdens of this life-threatening condition, southern Asia and Africa, represent some of the most underresourced and underdeveloped countries in the world.1 The call to end hunger in Sustainable Development Goal 2 will require more than just advancing the treatment of acute malnutrition using effective, locally produced RUTF.14 RUTF saves lives as a proven and high-quality nutrition treatment needed for a child to recover, but ensuring that all children can reach their full development potential requires us to go further.

“The global nutrition community must encourage the use of innovative approaches for improving RUTF formulations”

The global nutrition community must step up to lingering challenges by encouraging the use of innovative approaches for improving RUTF formulations so that they become more accessible, reach more vulnerable populations, and provide lifelong benefits. In doing this, we will save not just lives, but also futures.

References


