

Technical Background Paper

Local production and provision of ready-to-use therapeutic food for the treatment of severe childhood malnutrition

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Abstract

RUTF has been shown to be a very effective therapeutic food in the rehabilitation of severely malnourished children, and facilitates home-based therapy of these children. RUTF can be safely and easily produced in small or large quantities in most settings worldwide. The local availability of the necessary ingredients limits its use in some settings, and further investigation to alternative ingredients is needed to overcome this limitation.

Home-based therapy for severe childhood malnutrition has been successful in a variety of settings over the last 5 years (1). The recent success of home-based therapy has been seen in conjunction with the availability of a novel food, a spread form of ready-to-use therapeutic food (RUTF) (2-5). RUTF is a generic term including different types of foods, such as spreads or compressed products suitable for feeding severely malnourished children. Among RUTFs, spread RUTFs are prepared with a simple technology which has already been successfully transferred to developing in countries with minimal industrial infrastructure. Hence, this paper will only refer to spread RUTFs, although other technologies could possibly be transferred in countries with more advanced industrial capacities.

The spread RUTF is made of powdered ingredients embedded in a lipid rich paste, resulting in an energy dense food that resists microbial contamination (6). This RUTF is a mixture of milk powder, vegetable oil, sugar, peanut butter and powdered vitamins and minerals. As the name implies, RUTF does not need to be prepared in any way prior to consumption, making it practical for use where cooking fuel and facilities are limiting constraints. RUTF has a very low water activity, thus it is impossible for significant bacterial growth to occur in these foods (7). This allows locally produced RUTF to be safely stored at ambient tropical conditions for 3-4 months. RUTF has a very high energy density, about 23 kJ/gm (5.5 kcal/g). A severely malnourished child can consume just a few spoonfuls of RUTF 5-7 times a day, and achieve sufficient nutrient intake for complete recovery. While RUTF must be consumed with water, no other foods are necessary for the rehabilitation of the malnourished child.

While the spread form of RUTF may not be the only therapeutic food that does not require cooking, it is the only one considered in this article, because it is the only one which has been locally produced in the developing world using modest technologies. The term RUTF in this article refers specifically to the spread form of RUTF.

Production Principles of RUTF

RUTF is a homogenous mixture of lipid rich and water-soluble foods. The lipids exist as a viscous liquid, and small particles of protein, carbohydrate, vitamins and minerals are mixed throughout this liquid. In order to achieve a homogenous mixture, a specific mixing procedure must be followed. The lipid elements of RUTF are first stirred and often heated; the powdered ingredients are then slowly added to the lipids during vigorous stirring. Once all the powdered ingredients are added, the entire mixture is stirred at higher speeds for several minutes. As long as the powdered ingredients do not have a particle size that is larger than 200 microns, the mixture does not readily separate. When mixtures are made with larger particles, RUTF must be stirred briefly by hand just prior to consumption, to temporarily suspend the large particles in the mixture. The use of oils that are liquids at ambient temperature facilitates the mixing process. Packaging of RUTF can be done from factory bowls or funnels, by hand (simply pouring

it) or using a mechanical device. Successful RUTF production has been achieved in Malawi, Niger and Congo using these principles.

Ingredients

The formulation of RUTF was derived from F-100 and uses the same ingredients with the addition of peanut butter (8). Peanut butter changes the physical properties of the food to a viscous liquid product instead of a powder. A typical recipe for RUTF is given in Table 1.

Table 1 A typical recipe for Ready to Use Therapeutic Food

	% weight
Full fat milk	30
Sugar	28
Vegetable oil	15
Peanut butter	25
Mineral Vitamin Mix	1.6

Milk powder – Local supplies of milk powder exist throughout the world, however the milk itself is often imported. Standard commercial techniques to produce milk powder yield a product that is suitable for RUTF production.

Vegetable oil – Several types of oil made by standard commercial methods may be used to RUTF, including soy oil, cottonseed oil, rapeseed oil and corn oil. Rapeseed oil and soybean oil have the advantage of providing a good balance of essential fatty acids.

Sugar – Commercial sources of granulated brown or white sugar can be used to make RUTF. The sugar must be ground into a fine powder, a product used in bakeries known as icing sugar or powdered sugar, to reduce the particle size to less than 200 microns.

Peanut butter – This is simply peanuts that have been roasted and ground, without added oil, salt or preservatives. In most areas of the world where peanuts are grown, a commercial food processing company makes peanut butter.

Powdered vitamins and minerals – This is a mixture of vitamins and minerals formulated to provide the same amount of micronutrients to the malnourished child as F-100, the standard therapeutic food. Currently it is available from a commercial supplier Nutriset (Malaunay, France). The content of the mixture is listed in Table 2.

Table 2: Mineral and vitamin content in 100 g of powdered mix

<p>Vitamins: Vit A (57 mg), vit D (1 mg), vit E (1.25 g), vit K (1.30 mg), vit B1 (37.5 mg), vit B2 (116 mg), vit B6 (37.5 mg), Vit B12 (110 mg), vit C (3.3 g), biotin (4.1 mg), folic acid (13 mg), niacin (332 mg), pantothenic acid (194 mg).</p>	<p>Minerals: Potassium (36 g), magnesium (587 mg), iron (704 mg), zinc (717 mg), copper (92 mg), iodine (5 mg), selenium (1.54 mg).</p>
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The World Food Programme and UNICEF have donated ingredients for the production of RUTF in Malawi. The World Food Programme has donated milk, sugar and oil, and UNICEF has donated powdered vitamins and minerals. The RUTF is then used by projects supported and approved by these organizations.

Scale of Production

A mechanical mixer is required for all RUTF production. While hand mixing of the ingredients is possible for very small quantities, the quality of the product that is made by hand mixing is so inconsistent it cannot be reliably used.

The procedure and equipment used to mix RUTF is contingent upon the quantities of RUTF needed. If a few hundred kg of RUTF is needed each week, small scale production is possible. Small scale production requires a small room dedicated to food production that is free of rodents and other pests. A 40 L planetary bakery mixer, such as the MacAdams SM 401, can be used to prepare the RUTF. Such mixers will mix a 25 kg batch of RUTF. Ingredients are added by volume to the batch. The containers used to measure the ingredients need to be carefully chosen and calibrated by accurately weighing of the ingredients. Oil and peanut butter should be added directly into the mixing bowl and combined using a mixing speed of 105 rpm until homogenous. The Z-shaped kneader blade, rather than a wire whisk device, should be used to minimize the amount of air impregnated into the mixture. Sugar, milk powder, and mineral and vitamin mixture are first hand mixed as dry powders in a dedicated plastic drum, and then emptied into the electric mixing bowl. The RUTF is then mixed at 105 rpm for 6 minutes, 210 rpm for 6 minutes, and 323 for 6 minutes. These mixing times are necessary to ensure homogeneity of the RUTF and to prevent separation during storage. RUTF can be poured or hand-packed into 250 g plastic bottles, a typical daily dose for a malnourished child.

If 500-1500 kg of RUTF is needed each week, production is best achieved by partnering with commercial food processing company that has machinery which can efficiently mix, grind and package RUTF. This equipment is commonly found in industrial bakeries or pastry factories. Several planetary mixers can be used or a larger capacity customized barrel mixer. Whole peanuts can be mixed in with the other ingredients, and this mixture is then run through the same grinder used to make peanut butter. A

mechanical or pneumatic semi-automatic device that will fill a container with a prescribed amount can package the RUTF.

If more than 3000 kg of RUTF are needed every week, an industrial production facility dedicated to RUTF is needed. This can be part of a larger food processing company, which has technical expertise in food production or an NGO formed specifically for the purpose of making RUTF. The machinery required for large scale production is custom designed to mix batches of 200-500 kg and automatically package the product. Rather than typical 'batch' production, the product can move continuously from the mixer, to a grinder and then to a packaging device, by using a series of mixing chambers. An operator is needed to add the ingredients to the initial mixing chamber and remove the final filled containers from the packaging device.

The scale of production will determine the methods of quality control and the cost. Quality control is independent on the overall quantity of RUTF produced, and will be more easily implemented at a lower cost with centralized, large scale production. Economy of scale will come up for other aspects of RUTF production, and, if feasible, large scale production should be considered as a long term objective in countries with a high level of severe malnutrition and where a sustained demand is likely.

There are two resources that potential local producers can use to get technical assistance in establishing a production facility, Nutriset (Malaunay, France) and Valid International (Oxford, UK).



Standard Planetary Bakery Mixer



Automatic Packaging Device for RUTF



Single mixing/ packaging unit for large scale of RUTF

Quality Control

Choice of ingredients: Whichever the scale of production is used, quality control is achieved by safe storage of the ingredients, adequate training and supervision of the production personal, and product testing for composition and contaminants. Throughout the world, authorities set standards for food production companies; those organizations involved in RUTF production should adhere to these standards (9). Key issues in quality control are listed as follows.

Aflatoxin contamination: This toxin is produced by an aspergillus species of fungus, which contaminates the peanuts after they have been harvested, but before they have been ground into peanut butter. The fungus is ubiquitous, fungal growth can be curtailed by storing the peanuts in a cool, dry environment, and can also be controlled using chemical fungicides. Methods to prevent aflatoxin contamination have been described in detail elsewhere (10). Peanuts should be purchased from a supplier that can ensure that steps to prevent contamination have been implemented during harvest and storage. Aflatoxin contamination is more likely to be seen in peanuts with black discoloration, and among nuts that have a shriveled, irregular appearance. Consumption of aflatoxin can result in hepatic oxidative stress, and predispose the individual to hepatic cancers. RUTF should conform to international standards for maximum aflatoxin content, 10-20 ppb (9). Very high doses of aflatoxin can produce acute intoxications (11). Moderate doses may depress child growth (12).

Bacterial contamination: The inherent microbiological safety of RUTF allows it to be packaged under clean and dry, but not sterile, conditions. Care must be taken to prevent the introduction of water into RUTF during production. Increasing the water content of RUTF allows bacteria and mold to grow within the food, promoting product degradation and exposing the malnourished child to potential pathogens. Water is most likely to be introduced from residue left on the mixing bowls and containers after they have been washed. Therefore, it is better to limit the number of times the implements of production are cleaned with soap and water, and to simply dry wipe them clean instead. Typically implements need to be cleaned with soap and water only once a week. If the containers in which the RUTF is to be dispensed are first washed, care should be taken to see that they are completely dry.

Enteric bacterial contamination is most likely to occur from fecal contamination of stored ingredients or during the mixing process. Care should be taken to store ingredients in areas which are free of rodents. Workers should wash and thoroughly dry their hands before manipulating the RUTF, wear clean plastic gloves, hair coverings and protective coats during RUTF production. Milk and RUTF should be periodically checked for salmonella contamination by standard microbiological methods in reliable laboratories.

Prevention of oxidation: Oxidation of the fatty acids contained in the RUTF and of some vitamins, mainly vitamin A and C, is the main factor limiting the storage life of RUTF. During the production, some preventive measures should be taken to avoid initiating the oxidation process (13). While it is helpful to heat the oils during the mixing process to achieve a homogenous mixture, heating to temperatures over 45°C accelerates the oxidation of the lipids, which reduces the period of time that the product is stable after production (shelf life). To prevent oxidation, it is also better to use airtight containers and containers filled as much as possible so that the quantity of oxygen within the container is minimized. The shelf life of locally produced RUTF without airtight packaging is 3-4 months. When RUTF is packaged in airtight foil envelopes under a nitrogen atmosphere (devoid of oxygen), the shelf life can be extended to 24 months.

Composition of RUTF: Errors may be made during the mixing process, which result in RUTF that has a substantially different nutrient content. These are best avoided by careful training of workers mixing the food, use of convenient measures of ingredients for batches of RUTF and periodic compositional testing of RUTF. Measuring a single mineral, such as potassium, by atomic absorption (14) is an inexpensive, reliable way to monitor the vitamin/ mineral content, since the minerals are added as a premix product. If an atomic absorption spectrophotometer is not available, a colorimetric assay for Vitamin C can be substituted (15). Measuring fat and protein content assure that the other ingredients are being added in appropriate amounts.

Quality control is achieved by adopting operating procedures that are internationally accepted as standards for food production, the Codex Alimentarius (16) and the Hazard Analysis and Critical Control Point Program (HACCP, 17). These procedures prescribe raw material procurement, storage of ingredients, mixing of ingredients and storage of finished product. In addition to international standards, every nation of the world has a Bureau of Standards which regulates the production of food. These Bureaus also prescribe operating standards, conduct inspections of factories and issue licenses to produce food. Product testing is used to verify the quality of the production process, and should be done with every large batch of finished product, certainly every week. In Malawi, finished product is tested weekly for contaminating microbes (salmonella, staphylococcus, total flora of aerobic mesophilic bacteria, coliforms, E. Coli, yeast, mold), aflatoxin and product composition (fat, protein and potassium). Testing is best done locally so that it can be used to identify lapses in production quality in a timely manner. Batches of RUTF should not be sent to consumers without verification of product quality. Almost every nation of the world has a laboratory associated with their Bureau of Standards that can conduct the independent testing.

Costs and Sustainability

The primary cost associated with RUTF production are the costs of the ingredients, since the production process is relatively simple. Certainly the costs and availability of ingredients must be assessed at a local level. Reliable comparative cost data concerning RUTF production is lacking. The author has produced RUTF in Malawi from 2002 to 2005, and specific figures for Malawi are cited as an example. Currently in Malawi the cost per kg of RUTF of the ingredients are as follows milk \$0.63, sugar \$0.17, peanut butter \$0.18, oil \$0.18, vitamins/ minerals \$0.26, for a total of about \$1.40/kg. These costs include the transport of the ingredients to the factory. Packaging is also significant cost, in Malawi about \$0.50/kg (plastic bottles and cardboard boxes). Additional costs include labor, facility rental, and utilities. In Malawi the total cost of producing RUTF is about \$2.60/kg. The cost savings that can be realized by local production are from reduced transport of ingredients and finished products, and lower tariffs.

The cost of RUTF, even locally produced, and even if some cost saving can be expected in future with a modified recipe, is beyond the reach of poorest families where malnutrition is most prevalent. RUTF based programs will be sustainable only if RUTF is purchased by social welfare programs supported by government or non government agencies. UN organizations, such as WFP and UNICEF, have donated ingredients in Malawi to lower the cost of producing RUTF, and this may be an option in other circumstances of crisis to make RUTF accessible to welfare programs.

The cost of the therapeutic food is just a portion of the total cost of rehabilitating a malnourished child. The expenses of maintaining inpatient units, staffs to distribute the food and monitor the child's progress and supplies needed to administer the feeding are considerable. It must be kept in mind that RUTF facilitates home-based therapy, which is less expensive than center-based therapy. While the cost of RUTF may not be substantially less than foods used in center-based therapy (F-100), the overall cost of the therapeutic feeding endeavor may well be.

The notion that RUTF can be locally produced in circumstances of nutritional crisis is quite practical. The production process does not require large specialized machinery, nor do production workers require extensive training or skills that require a secondary school education. The advantages of local production in crisis situations are that production can be responsive to the dynamics of the crisis, and the amount of food produced can be controlled to meet the demands of the situation.

One notion that is attractive about local production is that locally grown peanuts, oil and sugar can be purchased in the country they are being used, and this in some way will support the local economy. While this is technically true, the economic impact of such local purchases is likely to be negligible since

the total amounts of peanuts, oil and sugar used to make RUTF are not substantial when the scale of national agricultural outputs are considered.

This report considers only RUTF that is used for the treatment of childhood malnutrition. It is plausible, but not proven, that other formulations of ready-to-use foods may prove very useful for feeding malnourished HIV infected adults, as a supplemental food for vulnerable populations and as a complementary food for children at risk for the development of malnutrition. Local production of ready-to-use foods for these other purposes could easily be done within the same factory using the same machinery. These potential other uses of ready-to-use foods should be considered when establishing local production facilities, as several nutritional support programs may be supplied from one local production unit.

Formulations of RUTF without milk and/ or the vitamin/mineral premix

The nutrient composition of RUTF is similar to F-100, the standard milk-based formula demonstrated to be effective in the treatment of severe childhood malnutrition. RUTF contains significant amounts of milk powder, which has traditionally been used successfully in refeeding malnourished children. Similar nutrient compositions to the current RUTF could be achieved without milk, and these formulations might be less costly to produce. To date these recipes have been made in laboratories and kitchens on a very small scale. A soy based spread, highly fortified with iron and minerals, was tested to prevent anemia and stunting in a few hundreds Saharawi children aged 3-6 years and found well accepted and effective (18). It has been demonstrated that these alternative recipes can be effectively mixed, that they are palatable and that the nutrient composition can be made similar to F-100 (19). Effectiveness trials of alternate formulations of RUTF in the treatment of severe childhood malnutrition are needed before they can be considered as substitutes for the milk-based RUTF. An area of concern is the high level of non digestible carbohydrates and anti-nutrients in alternative formulations in which milk powder is replaced by legumes to provide proteins in the recipe. Also their low content of absorbable phosphorus is a concern. It is quite possible that an adapted mineral supplement could compensate for the poorer availability of added minerals in food mixtures containing legumes, but comparative trials are needed to test this option.

The only vitamin/ mineral premix that there has been any substantial experience with has 18 micronutrients and is formulated by a single producer in Europe (Nutraset). Given the amounts, range and diversity of micronutrients needed for RUTF, there is a not combination of locally available, micronutrient rich foods suitable for producing RUTF that can supplant this commercial product. Of note, water containing foods cannot be used for preparing RUTF recipes, which precludes the use of mineral rich foods such as meat, organ meat, leaves, fruit and vegetables, unless dried beforehand. Thus local RUTF production is always likely to require the importation of a specialized micronutrient premix. Other

commercial sources of a suitable micronutrient mix for RUTF are likely to emerge as the demand for this product increases.

Knowledge Gaps and Issues for future research

1. Development of alternative mineral and vitamin supplements adapted to RUTF prepared without milk.
2. Effectiveness of recipes with a similar nutrient composition as F-100, but containing no milk, for therapeutic feeding of severely malnourished children need to be evaluated.
3. Use and effectiveness of formulations of ready-to-use foods for supplemental feeding and other nutritional support programs need to be assessed.
4. Systematic cost comparisons/ analyses of the different options of therapeutic feeding needs to be performed.
5. Systematic cost comparisons of the different scales of production to meet local and regional needs for RUTF production.

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