Valid Nutrition charity: The successful use of crystallized amino acid technology in new plant-based ready-to-use therapeutic food

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Food Science in Action:

- ✓ Alternative protein sources
- ✓ Crystallized amino acid technology
- ✓ Product development
- ✓ Nutrition
- ✓ Food processing

Valid Nutrition's SMS-RUTF formula, a non-milk alternative to traditional RUTF formulations, is based on soy, maize, and sorghum with crystallized amino acid technology.

Valid Nutrition, an Irish-registered charity founded in 2007, has spent over a decade working to develop effective, locally- sourced, non-milk-based recipes for Ready-to-Use Therapeutic Foods (RUTF). This new recipe was developed using innovative techniques with crystallized amino acid technology to optimize the formulation. Valid Nutrition believes this new formula, when used as part of a Community-based Management of Acute Malnutrition (CMAM) program, can treat significantly more malnourished children than standard RUTF formulas alone.

Introduction

The majority of malnourished children live in Africa and Asia. Good nutrition sets children on a path to survive and thrive. Malnutrition, however, robs children of their full potential. Malnutrition manifests itself mainly in two forms: stunting and wasting. Children affected by stunting (when a child is too short for his/her age) may struggle to attain their full possible height and their brains may not develop to their full cognitive capacity, which in turn affects their educational performance. Wasting (when a child is too thin for his/her height) causes weakened immunity, the possibility of long-term developmental delays and an increased risk of death.[1]

According to the UNICEF/WHO/World Bank Group Joint Child Malnutrition Estimates (JME) in 2020, 149.2 million children worldwide under the age of 5 were stunted and 45.4 million children under the age of 5 worldwide suffered from wasting.[1]

The World Health assembly set global nutrition targets to reduce the number of stunted children under 5 by 40% in 2025 and by 50% in 2030; also, to reduce the number of children affected by wasting to less than 5% by 2025 and to less than 3% by 2030.[1]

Ready-to-Use Therapeutic Foods (RUTFs) are a valuable strategy for treating the most serious cases of malnutrition in children. These specialized foods are nutrient- and calorie-dense, oil-based pastes that are ready to eat from the

Box 1. Malnutrition Terminology

SAM : Severe Acute Malnutrition

CMAM: Community-based Management of Acute Malnutrition

Stunting: When a child is too short for his/her height

Wasting: When a child is too thin for his/her height

pack without the need for cooking and can be stored at room temperature. RUTFs are used to help millions of children threatened by severe acute malnutrition (SAM) worldwide. UNICEF is the global leader in RUTF procurement and distribution, responsible for almost 80% of the world's supply of RUTF.[2]

RUTFs play a central role in Community-based Management of Acute Malnutrition (CMAM), a model of care developed by medical doctor Steve Collins, with support from Concern Worldwide and Irish Aid charities. CMAM, which was endorsed by all the major UN agencies in 2007 and is now in use in over 70 countries worldwide, involves treating children without underlying medical conditions in their community rather than in hospitals. CMAM saves lives by radically improving coverage rates, as well as access to treatment, for SAM. By moving the delivery of RUTFs from hospitals to mothers at the community level, Dr. Collins had unlocked a new market for RUTF by creating a demand-led dynamic for the very first time.

Dr. Collins knew that the roll-out of CMAM would depend upon the importation of RUTF from developed countries. He was also aware that the only available UN-endorsed RUTF recipe requires expensive inputs, specifically milk powder and high-quality peanuts, which are not readily available in developing countries. With these two realities in mind, Dr. Collins recognized that for CMAM to add longer-term value to vulnerable lives and communities, alternative RUTF recipes needed to be developed exclusively from locally-sourced ingredients and manufactured within the countries where they are needed.

Response

Dr. Collins founded Valid Nutrition charity in 2007. Initially, Valid Nutrition's work focused on pioneering local manufacturing in developing countries, thereby establishing proof of concept. The charity succeeded in pioneering RUTF manufacturing in Malawi, and also engaged with and supported the establishment of local competitors in Kenya and in India. The formula was the standard RUTF formula, a peanut paste comprised of milk powder, sugar, vegetable oil, peanut butter, vitamins, and minerals. This was the first RUTF factory in Africa. Previously, all RUTF was imported. Producing RUTF locally in Africa gives power back to local communities by directly supporting local employment and the livelihoods of smallholder farmers. Valid Nutrition's product was purchased and distributed to children suffering from SAM by UNICEF in Malawi, the organization responsible for distributing the product to children who need it.

Due in part to the high cost of making RUTF, only approximately 15% of children with SAM are receiving it.[3] Valid Nutrition has worked diligently to reduce the cost of the RUTF formula in order to reach more children struggling with SAM. The most expensive part of the formula was the cost of imported raw materials. Almost half the cost comes from imported milk powder, which accounts for approximately 25% of the standard formula.[4]

Valid Nutrition has spent 15 years developing a locally-sourced, non-milk based formula to address this issue. The new formula went through several iterations of a soy, maize, and sorghum recipe replacing the peanut butter and milk powder, referred to as "SMS-RUTF." Soy, maize, and sorghum can all be sourced locally.

Three clinical trials were carried out on variations of this new formula, beginning in 2010 with children between the ages of 6-59 months who were diagnosed with SAM. The test products were produced at Valid Nutrition's Malawi factory. Compared to the standard recipe (milk powder, sugar, vegetable oil, peanut butter, vitamins, and minerals), the SMS-RUTF formula was comprised of soy flour, maize, sorghum, sugar, vegetable oil, vitamins and minerals. Results of the first two trials did not match the standard peanut-based RUTF. However, the third trial, which utilized a

Box 2. Types of Ready-to-Use Therapeutic Food

RUTF: Ready-to-Use Therapeutic Food

PM-RUTF: Standard peanut and milk- based RUTF "Peanut-Milk"

SMS-RUTF: Plant-based alternative RUTF "Soy-Maize-Sorghum"

FSMS-RUTF: Plant-based RUTF with no milk "(Milk) Free-Soya, Maize and Sorghum"

MSMS-RUTF: RUTF with less milk than the standard "Milk, Soya, Maize, Sorghum"

formula fortified with crystallized amino acids, was a success.

Results

The first efficacy trial took place in Zambia and was funded by Irish Aid. This trial was not successful, but showed promise. The second trial, in the Democratic Republic of Congo, showed efficacy for children over 2 years of age, but not for children under 2.[4]

In 2014, Valid Nutrition partnered with Ajinomoto, an ingredient company based in Japan, which developed crystallized amino acid technology. According to Ajinomoto, the plant-based formulation developed by Valid Nutrition can be low or devoid of certain amino acids, which are important for growth. Supplementing with crystallized amino acids can enhance the overall amino acid profile that reflects a more balanced protein composition found in nature. Ajinomoto's crystallized amino acids are produced using an advanced fermentation manufacturing process and patented production technology. A sugar substrate from corn, such as glucose, is fermented using microorganisms. Specific amino acids are purified from the resulting fermented broth.

Adding crystallized amino acids to the RUTF formula provided a breakthrough and delivered parity with the standard peanut-based formula. Valid Nutrition provided the base recipe (soy, maize and sorghum) and Ajinomoto added the crystallized amino acids. This optimized formula was tested in Valid Nutrition's third efficacy trial in 2016 and the results were successful.[6]

In this third trial, two SMS formulas were tested simultaneously against the standard peanut-milk RUTF (PM-RUTF): one with no milk (FSMS-RUTF) and one with a smaller amount of milk (MSMS-RUTF). The trial was carried out in several health districts in Malawi. Study participants were selected from children in the CMAM outpatient program diagnosed with SAM based on their mid upper arm circumference (a standard method of diagnosing SAM) who had good appetite and no underlying medical

Children consuming Valid Nutrition's test SMS-RUTF product during a pilot study.

(Photo credit: Valid Nutrition)

Valid Nutrition's RUTF manufacturing facility in Malawi. This facility produced standard RUTF as well as SMS-RUTF test products that were used in Valid Nutrition's clinical trials.

(Photo credit: Valid Nutrition)

conditions. Both formulas showed results comparable to the standard PM-RUTF formula.

In addition to being more cost effective, this SMS-RUTF proved to be superior at treating anemia and replenishing body iron stores than the standard peanut-based formula (PM-RUTF). Also, it was manufactured locally with locally-sourced raw materials. At scale, non-milk SMS-RUTF formula is up to 30% cheaper to produce than the standard peanut-based formula.[6]

After this third efficacy trial, a subsequent operational pilot program was conducted by World Vision Malawi with the FSMF-RUTF (non-milk formula) at a government-run CMAM program in Malawi. While the efficacy trial was carried out in a controlled research environment, this pilot program provided a real-world program environment. Results were similar to the efficacy study and provided further evidence of the effectiveness of SMS-RUTF in the treatment of SAM.[7]

Lessons learned

Despite the success of Valid Nutrition's FSMF-RUTF formula, the World Health Organization (WHO) published a Guideline Review of RUTF in 2021 that stipulated at least 50% of the protein in RUTF must be derived from dairy sources.[3] This outcome contradicts an FAO published review of protein in RUTF in 2018,[8] which concluded that the fundamental issue is protein quality and not protein source. The updated WHO Guideline also contradicts the CODEX Standard whereby a protein digestibility-corrected amino acid score (PDCAAS) has been adopted by FAO/WHO as the preferred method for the measurement of the protein value in human nutrition.

WHO came to this conclusion by pooling data from all three of Valid Nutrition's trials, effectively distorting the successful third trial results with the results from the first two trials. This Guideline prevents Valid Nutrition's new formula from being used by UN agencies to treat severely malnourished children.

Next steps / call to action

Due to pandemic-related delays in undertaking a planned expansion project for Malawi and which subsequently and negatively affected grant funding, Valid Nutrition made the difficult decision to close the Malawi RUTF manufacturing facility in 2021. Despite this, the charity is proud of having pioneered and demonstrated that local manufacturing of RUTF is critical and should be undertaken in countries directly affected by undernutrition. In all, Valid Nutrition Malawi manufactured and distributed over 50 million packets of RUTF which provided treatment to over 355,000 severely malnourished children. The factory also served as the charity's main innovation center and was involved in their ground-breaking R&D projects, as well as providing product that was used in the various trials and pilot programs.

Currently, Valid Nutrition has two goals:

1. Remove the WHO barrier to allow non-milk and other plant-based RUTF recipes to be used globally in the treatment of SAM.
2. Apply Valid Nutrition's plant-based food technology to other product formats in collaboration with strategic partners in order to move forward on addressing the prevention of other forms of malnutrition.

In summary, Valid Nutrition has achieved major accomplishments and will continue to work to end starvation and other forms of malnutrition.

References

[1]United Nations Children's Fund (UNICEF), World Health Organization, International Bank for Reconstruction and Development/The World Bank. Levels and trends in child malnutrition: key findings of the 2021 edition of the joint child malnutrition estimates.2021. https://www.who.int/news/item/06-05-2021-the-unicef-who-wb-joint-child-malnutrition-estimates-group-released-new-data-for-2021. Accessed May 1, 2022.

[2]Hart, M., Ferguson, S.: What is Ready-to-Use Therapeutic Food? https://www.unicefusa.org/stories/what-ready-use-therapeurtic-food/32481. Accessed May 1, 2022.

[3]Valid Nutrition Annual Review 2021

https://www.validnutrition.org/wp-content/uploads/2022/02/220208_Annual-Report-2021_F.pdf. Accessed May 1, 2022

[4]Bahwere, P., Balaluka, B., Wells, J., Mbiribindi, C., Sadler, K., Akomo, P., Dramaix-Wilmet, M., Collins, S.: Cereals and pulse-based ready-to-use therapeutic food as an alternative to standard milk-and peanut-based formulation for treating severe acute malnutrition: a non-inferiority, individually randomized controlled efficacy clinical trial. Am J Clin Nutr 2016: 103; 1145 -1161. https://doi.org/10.3945/ajcn.115.119537

[5]How Amino Acids Are Made.

https://www.ajinomoto.com/aboutus/amino-acids/how-amino-acids-are-made. Accessed October 10, 2022.

[6]Bahwere, P., Akomo, R., Mwale, M., Murakami, H., Banda, C., Kathumba, S., Banda, C., Jere, S., Sadler, K., Collins, S.: Soya, maize, and sorghum-based ready-to-use therapeutic food with amino acid is as efficacious as the standard milk and peanut paste-based formulation for the treatment of severe acute malnutrition in children: a noninferiority individually randomized controlled efficacy clinical trial in Malawi. Am J Clin Nutr 2017: 106: 1100-1112. https://doi.org/10.3945/ajcn.117.156653

[7]Banda, T., Chawanda, K., Tsuchida, W., Kathumba, S.: Report of a Pilot Program Using a Milk-Free Ready-to-Use Therapeutic Food Made From Soya, Maize, and Sorghum to Treat Sever Acute Malnutrition. Food and Nutrition Bulletin 2021: 42(1) 91-103. https://doi,org/10.1177/0379572120968703/journal.sagepub.com/home/fnb

[8]Food and Agriculture Organization of the United Nations: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods. Report of the FAO Expert Working Group, Rome, November 6-9, 2017. https://www.fao.org/3/CA2487EN/ca2487en.pdf. Accessed August 22, 2022.