



# FOOD AID QUALITY REVIEW

## Comparison of four different supplementary foods in the treatment of moderate acute malnutrition (MAM) in children

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### BACKGROUND

The proposed research seeks to determine the relative effectiveness and cost effectiveness of alternative supplementary foods in the treatment of moderate acute malnutrition (MAM) in normal program settings. The results of this study will guide decisions about what commodities to use in supplementary feeding programs in particular contexts and populations, and what factors need to be addressed to ensure maximum effectiveness in the treatment of moderate malnutrition.

Tufts University, Washington University in St. Louis, School of Medicine, Sierra Leone Ministry of Health and Sanitation (MoSH), Project Peanut Butter, Caritas Bo, World Food Programme (WFP), and the United States Agency for International Development (USAID) are collaborating to conduct an assessment of the effectiveness, cost, and cost-effectiveness of food aid commodities in treating moderate acute malnutrition (MAM) in young children. The study comparison is based on a targeted food delivery to children 6-59 months who are screened for MAM. Study participants will receive one of four approximately isoenergetic test foods:

1. Super Cereal Plus (SC+) with amylase
2. Corn-soy Blend Plus (CSB+) and oil
3. Corn-soy Whey Blend (CSWB) and oil (CSWB is a new product which is a modified version of CSB)
4. Ready-to-use Supplementary Food (RUSF, lipid-based)

### TYPE OF STUDY

This will be a prospective, randomised, controlled study of the effectiveness of various approaches to managing moderate acute malnutrition in young children. This study is not a clinical trial.

### STUDY DESIGN

Peripheral Health Units (PHU) will be selected within the Pujehun District in Sierra Leone. These 28 PHUs and the villages they serve will be used as the study sites to test the effectiveness of four supplementary foods in the treatment of MAM. The PHUs will be grouped into 4 to represent each food or arm of the study. The study is targeting 5320 children in total: 1250 children per arm. Children will be enrolled and graduated based on mid-upper arm circumference (MUAC); weight and height will be recorded as well and also used in final analysis. Locations (communities, clinics) will be assigned to one of the four arms (that is, foods to be tested). The foods distributed as part of the study will require a safe storage location.

## **TREATMENT OF MAM**

The Project Peanut Butter and Caritas Bo teams will have staff at each PHU during the food distribution to collect data and distribute food. Supplementary food rations will be delivered for up to 12 weeks from enrollment (enrollment takes place when a child is diagnosed with MAM in accordance with a mid-upper-arm-circumference [MUAC]  $>11.5$  cm and  $\leq 12.5$  cm). Children will be asked to return to the PHU every two weeks for follow-up, where caretakers report on the child's clinical symptoms and use of the food at home, growth measurements are re-assessed, until they reach one of the primary outcomes listed below. A ration of supplementary food sufficient for two weeks (14 days) will be distributed at each visit. Children will be monitored for relapse after discharge.

The primary outcome measures are recovery from MAM (achieving MUAC  $\geq 12.5$  cm by 12 weeks) once or failure (death, development of severe acute malnutrition, transfer to hospital for inpatient care, failure to recover from MAM by 12 weeks, default). Secondary outcome measures include rates of weight, height, and MUAC gain, time to graduation, and any possible adverse effects from the supplementary foods. Cost effectiveness will assess differences among the four study arms in cost per case of MAM recovered.

The research team, led by Caritas Bo and Tufts University, will randomly select a subsample of caregivers of enrolled children for in-depth interviews and in-home observations, which will take place in the participants' home. In addition, the research team will conduct focus group discussions with a smaller subsample of caregivers, to take place in a central and convenient location. The purpose of the in-home observations is to observe aspects of the family's preparation and consumption of the ration that they would be unlikely to be able to report during focus groups or individual interviews, because respondents may not be conscious of their actions. All interviews, observations, and focus group discussions will be administered by trained research assistants. The team will also conduct interviews with community health volunteers working in the PHUs and the catchment villages they serve.

## **SUB-STUDIES**

The research team, led by Tufts University and Washington University St. Louis, will also implement three sub-studies: 1) A study comparing body composition (fat mass and fat free mass) achieved by one of the 4 foods in children recovered from MAM. 2) A study measuring neurocognitive recovery of children with MAM. 3) A study assessing the effectiveness of each of the 4 foods in healing non-specific gut inflammation, environmental enteric dysfunction (EED) seen in conjunction with MAM.

All methods are safe for children and have been validated previously in many research sites.

## **EXPECTED VALUE OF EFFECTIVENESS STUDY RESULTS**

This study will benefit the food assistance community by providing new research on the cost and cost-effectiveness of supplements to treat MAM, where effectiveness is measured in terms of growth outcomes.

Besides the long term and broader benefits, this work will benefit a large number of young children in the Sierra Leone population. This study will directly benefit Sierra Leone by improving the nutrition of its children and providing education on children's nutrition. The enrolled child will have enough study food provided at home for the recovery from moderate acute malnutrition when consumed along with the regular diet and will be monitored regularly during recovery. This may result in fewer complications (diarrhea, respiratory illnesses) as the child recovers. Medical treatments that are needed will be provided during these follow-up visits.