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Comparative Cost-Effectiveness of Four Supplementary Foods in Treating Moderate Acute Malnutrition in Children 6-59 Months in Sierra Leone

Section 1: Effectiveness Study

A Report from the Food Aid Quality Review

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ABBREVIATIONS AND ACRONYMS

BHA	Bureau for Humanitarian Assistance (USAID)
CHW	Community Health Worker
CI	Confidence Interval
CSB	Corn-Soy Blend
CSB+	Corn-Soy Blend Plus
CSWB	Corn-Soy-Whey Blend
DFN	Directorate for Food and Nutrition
DHMT	District Health Management Team
EED	Environmental Enteric Dysfunction
FAQR	Food Aid Quality Review
FBF	Fortified Blended Flour
FFM	Fat Free Mass
FFP	Office of Food for Peace (USAID)
FGD	Focus Group Discussion
FM	Fat Mass
FVO	Fortified Vegetable Oil
GDS	Gut Defense Score
HFIAS	Household Food Insecurity Access Scale
IDI	In-depth Interview
IHO	In-home Observation
IYCF	Infant and Young Child Feeding
IRB	Institutional Review Board
LNS	Lipid-based Nutrition Supplement
MAM	Moderate Acute Malnutrition
MDD	Minimum Diet Diversity
MEST	Ministry of Education, Science and Technology
MoHS	Ministry of Health and Sanitation
MT	Metric Ton
MUAC	Mid-Upper Arm Circumference
PCA	Principal Components Analysis
PHU	Peripheral Health Unit
PPB	Project Peanut Butter
RA	Research Assistants (enumerators)
RNI	Recommended Nutrient Intake
RUF	Ready-to-Use Food
RUSF	Ready-to-Use Supplementary Food
RUTF	Ready-to-Use Therapeutic Food
SAM	Severe Acute Malnutrition
SBCC	Social and Behavior Change Communication
SC+	Super Cereal Plus
SC+A	Super Cereal Plus with Amylase
SES	Socioeconomic Status
SFP	Supplementary Feeding Program
SNF	Specialized Nutritious Food
SRT	Saccadic Reaction Time
SRT	Saccadic Reaction Time
USAID	United States Agency for International Development
USD	United States Dollars ($)
USDA	United States Department of Agriculture
WASH	Water, Sanitation, and Hygiene
WashU	Washington University in St. Louis, Missouri
WFP	World Food Programme (United Nations)
WHO	World Health Organization
WHZ	Weight for Height Z-Score
WPC	Whey Protein Concentrate

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ABSTRACT

In 2011, the United States Agency for International Development (USAID) Food Aid Quality Review (FAQR), led by the Friedman School of Nutrition Science and Policy at Tufts University, released a report entitled *Improving the Nutritional Quality of U.S. Food Aid: Recommendations for Changes to Products and Programs.*[1] That report made recommendations to improve the nutritional quality of food assistance commodities. Those recommendations included increasing the amount of fortified vegetable oil (FVO) programmed with corn soy blend plus (CSB+) to achieve an oil to CSB+ ratio of 30g:100g; adding a dairy component in the CSB+ formulation; adding ready-to-use foods (RUFs) as an option in programming; and increasing the use of cost-effectiveness analysis in decision-making. Before integrating these recommendations into USAID Office of Food for Peace (FFP) – as of 2020, FFP was integrated into the newly formed Bureau of Humanitarian Assistance (BHA) – food assistance programming, FAQR Phases II and III were tasked with evaluating the comparative effectiveness and cost-effectiveness of these recommendations in real field settings. From April 2017 to November 2018, FAQR Phase III tested these recommendations for the treatment of moderate acute malnutrition (MAM) among children 6-59 months in Sierra Leone.

The *Four Foods MAM Treatment Study* determined the comparative effectiveness and cost-effectiveness of four specialized nutritious foods (SNFs) in achieving recovery (defined as a mid-upper arm circumference (MUAC) of 12.5 cm or more) from MAM within 12 weeks. The four foods were:

- CSB+ with fortified vegetable oil (CSB+ w/oil)
- Corn soy whey blend with fortified vegetable oil (CSWB w/oil)
- Ready-to-use supplementary food (RUSF)
- Super Cereal Plus with amylase (SC+A)

During the period of the study's implementation, CSWB w/oil and SC+A were novel formulations not previously programmed for MAM treatment in other contexts. Both CSB+ and CSWB were distributed in a novel package size of 1.2 kg of flour as opposed to the standard 25 kg bag often repackaged in-country or at points of distribution. Rations were isocaloric across SNFs (~550 kcal/day on average). Children were followed for one, three, and six months after recovery to track incidence of relapse to MAM. The study also explored certain behavioral factors that may have influenced recovery.

Section 1: Effectiveness and Cost-effectiveness Study details the methods and results of the *Four Foods MAM Treatment Study* comparing the effectiveness and cost-effectiveness of the four foods. The methods of data collection included caregiver report of common morbidities and anthropometric measurements; in-depth quantitative surveys of a subsample exploring cooking practices, perceptions of malnutrition, and certain household behaviors or practices; five-day consecutive in-home observations on a subsample; focus group discussions; facility-based observations; and key informant interviews. Together the data were compiled to explore questions about factors that influence effectiveness and cost-effectiveness of the MAM treatment foods in achieving recovery.

In total, 2,691 children were enrolled from April 2017 to September 2018. After exclusion criteria were applied, 2,653 children remained in the sample. The unadjusted recovery rates ranged from 62.1 percent to 64.5 percent. After adjusting for covariates, there were neither significant nor observable differences in recovery among the foods. Cost per recovered child ranged from $90 to $94 (in United States dollars, USD), and cost-effectiveness analysis showed no discernable differences among the four foods. Though opportunity costs to caregivers were lowest in the RUSF arm (~$5), the difference was not enough to change the conclusion that the four foods were similarly cost-effective when combined with the program perspective. Sustained recovery at four-weeks after discharge was different between RUSF and the comparator CSB+ (73% compared to 81%, $p<0.05$) but did not alter cost-effectiveness

conclusions in cost per child who sustained recovery from the combined perspective. Intrahousehold sharing rates were similar across arms (~25%) and unassociated with recovery. Rationales for sharing were reportedly community views of the foods as being healthy and necessary for childhood well-being. Preparing or feeding the foods according to recommendations was also not associated with recovery. However, observed consumption of the food by the target child was associated with recovery.

What We Learned from This Study: Main Conclusions and Recommendations:

1. **Because there were no differences in effectiveness or cost-effectiveness, selection of a treatment food should be context- or program-specific, based on cost and feasibility.**

1.1 Recovery rates across the four foods were similar. This finding is consistent with results from previous studies in which neither RUFs nor any of the fortified blended foods (FBFs) performed systematically better than the others in field trials.[4,5] This suggests that when choosing which commodity to distribute for MAM treatment, decision-makers should focus on improvements to program designs, foods that are fit for purpose, and budgetary and programmatic feasibility.

1.2 The four foods were also similarly cost-effective. There are few studies exploring the comparative cost-effectiveness of different SNFs for MAM treatment, and they have reported different results.[6,7] The findings in this study found no discernable difference in the cost-effectiveness of these four foods; however, further research in this area is needed to understand which local factors should be considered in selection of SNFs.

1.3 Caregivers' opportunity costs differed by food, but this did not alter the comparative cost-effectiveness. Reducing caregiver opportunity costs has been cited as a chief factor in improving recovery rates for severe acute malnutrition (SAM).[8] Caregiver opportunity costs have also been cited as a rationale for increasing use of RUFs instead of FBFs for MAM treatment.[9,10] The results of this study do not support these conclusions in the context of MAM treatment. A joint statement on MAM treatment from the World Health Organization (WHO), United Nations Children's Fund (UNICEF), World Food Programme (WFP), and the United Nations High Commission for Refugees (UNHCR) cited a need for improved understanding of opportunity costs to inform decisions about programs and commodities.[11] The findings from this study support the recommendation for further research to identify ways in which opportunity costs influence MAM treatment and recovery.

1.4 Changes in body composition did not differ by the type of study food. As with the effectiveness results, this too is consistent with other studies which showed that over the course of supplementation children gained weight, but there were no food-specific differences in FM or FFM accretion.[12,13] Though further research into field-friendly methods of measuring body composition are warranted, there is little evidence that there are food-specific effects of SNFs on body composition.

1.5 Recovery among children with EED did not differ by study food. Presently, we are unaware of any studies exploring improvements in EED that are attributable to differences in SNF composition. Independent of food, the presence of EED — across measures — did reduce the rate of recovery from MAM. This supports the recommendation for increased investment in implementation research and evaluation of programs designed to reduce the impact of underlying biological conditions in order to improve rates of recovery.

1.6 Expanding definitions of "recovery" may change cost-effectiveness conclusions. Instead of cost per child who recovered, substituting cost per child who *sustained recovery* yielded different point estimates that rendered RUSF less cost-effective than the FBFs. We are unaware of any published studies that have examined sustained recovery through a cost-effectiveness lens. Since children who relapse into MAM after recovery require another course of treatment, sustained recovery is critical to cost-effective programming. More attention is needed to understand and appropriately measure sustained recovery.

In summary, there were no differences in recovery rates. The same was true of cost-effectiveness measures from the program perspective; the four foods were equally cost-effective measured in cost per recovered child. Caregivers' opportunity costs differed by food, but not so drastically as to alter the relative cost-effectiveness of the four foods when combined with the program perspective. Consistent with the effectiveness and cost-effectiveness findings, there were no differences in change in body composition by food. There were also no food-specific differences in recovery rates across the foods among children with EED, though the presence of EED did reduce recovery rates. These findings underscore that FFP can choose from a range of commodities with evidence supporting their use and given a range of price points. There is no single preferred product for all situations.

Introduction: In 2011, the United States Agency for International Development (USAID) Food Aid Quality Review (FAQR), led by the Friedman School of Nutrition Science and Policy at Tufts University, released a report entitled *Improving the Nutritional Quality of U.S. Food Aid: Recommendations for Changes to Products and Programs.*[1] That report made recommendations to improve the nutritional quality of the specialized nutritious foods (SNFs) provided in food assistance programs aimed at improving nutritional status. Those recommendations included increasing the amount of fortified vegetable oil (FVO) programmed with corn soy blend plus (CSB+) to achieve an oil to CSB+ ratio of 30 g to 100 g; adding a dairy component in the CSB+ formulation; adding ready-to-use foods (RUFs) as an option in programming; and increasing the use of cost-effectiveness analysis in decision-making. From April 2017 to November 2018, FAQR Phase III tested these recommendations for the treatment of moderate acute malnutrition (MAM) among children 6-59 months in Sierra Leone.

Methods: This was a cluster-randomized trial operating through a supplementary feeding program (SFP) providing SNFs for treatment of MAM. The study foods were: Super Cereal Plus w/ amylase (SC+A), CSB+ w/oil, Corn-Soy-Whey Blend w/oil (CSWB w/oil), and Ready to Use Supplementary Food (RUSF). Children with MAM, defined as mid-upper arm circumference (MUAC) ≥11.5 cm and <12.5 cm without bipedal edema, were enrolled at participating health clinics and received rations biweekly until they reached an outcome with a maximum of 7 rations received (approximately 12 weeks of treatment). An activity-based ingredients approach was used to measure costs per child enrolled and cost per child recovered in 2018 USD. Recovered children were followed for one, three, and six months after recovery to track incidence of relapse to MAM. A subset of participants was observed in the home for five consecutive days and/or interviewed with an in-depth survey or participated in focus group discussions.

Results: 2,683 children were enrolled out of a planned sample size of ~5,000. Overall, 63% graduated from SFP, 19% developed severe acute malnutrition (SAM), 7% defaulted (missed three consecutive visits), 1% died, and 10% remained MAM within 12 weeks. Twenty-five percent were transferred into the study from SAM treatment once they reached MAM status. By study arm, graduation rates were: 62% in CSWB w/oil, 65% in SC+A, 64% in CSB+ w/oil, 62% in RUSF. In adjusted and unadjusted models, no statistically significant differences in graduation rates among the arms were detected. A difference was observed in adjusted and unadjusted models of relapse: more children receiving RUSF relapsed within one month than those receiving CSB+ w/oil, the reference arm. Product and international freight were greatest drivers of cost differences across arms. Cost per enrolled child ranged from $86 in RUSF to $94 in SC+A. Cost per recovered child was $137 ($130 - 145) in RUSF, $142 ($134 - 151) in CSB+ w/oil, $146 ($138 - 155) in SC+A, and $149 ($140 - 160) in CSWB w/oil. Sharing was equally prevalent in all arms. Neither sharing nor adherence to recipe directions affected the likelihood of graduation but observed consumption of the supplementary food was associated with a higher likelihood of graduation.

Conclusions: Foods should be fit for purpose to maximize the cost-effectiveness of the supplementary feeding program. Since all four foods showed similar effectiveness and cost effectiveness, other programmatic factors should drive food selection. Household behavior does play an important role in effectiveness, with more focus needed to ensure consumption of the food by the beneficiary. Though no single food was found to be more effective in achieving graduation, RUSF was less effective in achieving sustained recovery. Further research is needed to understand factors that influence relapse; these may be different from behaviors influencing recovery.

1. Introduction and Background

Title II of the United States Food for Peace Act is the primary funding mechanism through which the U.S. Congress authorizes and funds international food assistance programs. [30] The Food for Peace Title II program(s) has been the dominant U.S. food assistance program since the 1980s.[30] The goal of Title II programs is to reduce the food insecurity of vulnerable populations in low income countries. Title II in-kind donations are food commodities sourced in the United States and shipped to the recipient country for distribution to target populations. The United States Agency for International Development's Office of Food for Peace (USAID/FFP), in collaboration with the United States Department of Agriculture (USDA), is responsible for overseeing Title II in-kind food assistance programs. To understand the scale of this assistance provision, in fiscal year 2018 alone, USAID/FFP distributed food assistance to more than 70 million vulnerable people globally at an estimated cost of more than USD 3 billion.[31]

As part of continuous efforts to improve the *quality* and *efficiency* of USAID/FFP Title II food assistance programs, USAID/FFP initiated the Food Aid Quality Review (FAQR) Phase 1, implemented by the Friedman School of Nutrition Science and Policy at Tufts University (Tufts) beginning in 2009. FAQR's task was to review the "state of the evidence" related to Title II food assistance as well as the nutrition-related needs of traditionally vulnerable populations who are recipients of this assistance. The findings of the review — completed in 2011 — were detailed in *Improving the Nutritional Quality of U.S. Food Aid: Recommendations for Changes to Products and Programs*.[1] Specific recommended changes to the existing USAID/FFP food commodity list included updating the micronutrient premix and the macronutrient profiles of existing fortified blended flours (FBFs); considering the addition of a dairy component to the FBF typically programmed by USAID/FFP, – Corn Soy Blend version 13 (CSB13); including ready-to-use foods (RUFs) in the food basket available for programming; and improving the cost-effectiveness evidence base for deciding when to program which commodities, given diverse programmatic needs (i.e., allowing for "fit for purpose" programming). Since 2011, the FAQR team has tested the applicability of these recommendations in field settings in Malawi and Burkina Faso.[32,33] The study detailed in this report represents the first time the effectiveness of these recommendations was tested in field settings specifically for the treatment of moderate acute malnutrition (MAM) in children 6-59 months of age in Sierra Leone.

2. Study Rationale

Specialized nutritious food products (SNFs) have been proven to be effective in treating MAM, although there remains no globally accepted standard of care.[4] SNFs are categorized into one of two groups: FBFs or RUFs. The FBFs are flours composed of a mix of precooked and milled cereals and legumes that have been fortified with a micronutrient premix, sometimes with an animal-sourced protein; vegetable oil fortified with vitamins A and D may be added to the flour at the time of manufacture or provided separately to be added to the porridge prepared in the home. RUFs are lipid-based nutritional supplements commonly composed of peanuts, soybeans, and milk powder formulated as pastes and fortified with a micronutrient premix, often with an animal-sourced protein and additional fortified vegetable oil.[4] Different studies have compared these diverse formulations, yielding inconsistent results regarding which SNF groups or formulations may be most effective for MAM treatment.[34]

From April 2017 to November 2018, a research team from FAQR Phase III implemented a study in southern Sierra Leone examining the comparative cost-effectiveness of four specific SNFs for use in the treatment of MAM (hereafter "Four Foods Study"). Based on the recommendations of the 2011 FAQR report, the four foods tested in the Four Foods Study (see **Section 2.2** for more details) were:

- USAID/FFP FBF formulation: Corn Soy Blend Plus (also referred to as "Super Cereal") distributed with fortified vegetable oil (**CSB+ w/oil**)

- FAQR's recommended reformulation of CSB+ to include a dairy component, w/oil: Corn Soy Whey Blend with fortified vegetable oil (**CSWB w/oil**)
- A novel formulation of World Food Programme's commonly programmed FBF: Super Cereal Plus with amylase (**SC+A**), and
- The standard RUF formulation for MAM treatment: ready-to-use-supplementary food (**RUSF**)

In addition to determining the comparative cost-effectiveness of the four foods, the study sought to identify behaviors that may be associated with effectiveness, such as preparation and consumption or sharing and selling of SNFs either within or between households, whether any of these behaviors differed by food, and whether they differentially influenced recovery from MAM.

2.1 Specific Objectives

The Four Foods Study had three main objectives:

Objective 1: Effectiveness
Determine whether there are differences in recovery rates among children with MAM treated with one of four supplementary foods.

Objective 2: Cost Effectiveness
Assess program costs among the four study arms, including costs of procurement, supply chain, clinic operations with food distribution, community-based activities, and caregivers' time and out-of-pocket expenses. Use these costs to determine and compare the cost-effectiveness of each SNF, measured in (1) cost per case of MAM recovered and (2) cost per recovered case of MAM that sustained recovery for 4 weeks after graduation from SFP.

Objective 3: Factors Influencing Effectiveness
Identify intervention components, behaviors, demographics, and other factors associated with effectiveness. Specifically, the study explored factors related to biweekly ration collection, preparation, consumption, sharing, and selling behaviors; knowledge and communication of social and behavior change communication (SBCC) messages regarding biweekly ration use among health workers and beneficiary mothers, and determine if any of these were different across foods.

2.2 The Four Foods in Detail

As summarized in the introduction, the Four Foods Study in Sierra Leone tested four foods: CSB+ w/oil, CSWB w/oil, SC+A, and RUSF. The differences among these four foods are described below and with greater detail in **Appendix 1**.

A. CSB+ w/oil

CSB+ is the upgraded formulation of CSB13.[35] The new formulation of CSB13 was predicated on two factors: that the micronutrient premix and macronutrient content be equal to 115 percent of recommended nutrient intake (RNI), and that any formulation changes result in a product that is at least as cost-effective as CSB13. The improved micronutrient premix included increases in zinc and vitamins B_1, B_2, B_3, B_5, B_{12}, D_3, and E; the addition of potassium and vitamin K; and the combination of two forms of iron (NaFeEDTA and ferrous fumarate) to improve absorption. Additionally, the new premix decreased the amounts of magnesium, calcium, iodine, sodium, and vitamin A. To improve the macronutrient profile and increase caloric density, the recommended quantity of FVO included in the biweekly ration and added to the prepared porridge was increased to a ratio of 30 g FVO for every 100g of FBF.[35]

B. CSWB w/oil

To address the recommendation to add an animal-sourced protein without excessively increasing costs of the product, the FAQR team recommended that whey protein concentrate with 80 percent protein content (WPC80) be added to CSB+ w/oil instead of the alternative, dried skim milk. In nutritional value, WPC80 is protein-dense and, in small quantities, its addition to CSB+ would not displace other nutrients already in the mix, while still adding important amino acids and growth promoting factors necessary for recovery. Though the cost per metric ton (MT) of WPC80 was higher than dry skim milk at the time of the report's publication in 2011, [1] its historical price in the United States has been less variable than that of dried skim milk, giving WPC80 an element of stability for program planning.[35] The new product, CSWB, which is programmed with oil in the same ratios as CSB+, remains novel and in need of further field testing to understand the potential effects of added WPC80 on overall effectiveness and cost-effectiveness in field settings.

C. SC+A

An alternative name for CSB+ flour is Super Cereal, and the separately branded Super Cereal has been a commonly programmed FBF for WFP food assistance programs. The alternate formulation of Super Cereal is Super Cereal Plus (SC+). SC+ is CSB+ with the FVO added into the flour at the time of manufacturing rather than provided as a separate ingredient to be mixed at the home. Since 2011, WFP has experimented with updated formulations in laboratory settings, with one iteration resulting in the addition of the amylase enzyme. Amylase reduces viscosity by breaking down carbohydrates in the cooking process to ease digestion and absorption without decreasing the energy density of FBF porridges.[36] Previous studies have shown that energy intake by young children increases when amylase is a part of the SC+ mix and that acceptability is not degraded with a thinner texture.[37] Also, a novel commodity such as CSWB w/oil or SC+A requires field testing to gauge comparative effectiveness and cost-effectiveness before being included in the WFP's standard commodity list.

D. RUSF

RUSF is a modified formulation of ready-to-use therapeutic food (RUTF) that contains proportionately less milk powder that is also cheaper to produce. It is supplied in individually packaged metalized polyethylene sachets with a 24-month shelf life and is generally made with heat-treated oil seeds, pulses, cereals, sugar, milk powder, vegetable oils, vitamins, and minerals; it requires no preparation.[10]

2.3 Comparison of the Four Foods

Table 1: General Differences Among the Four Study Foods

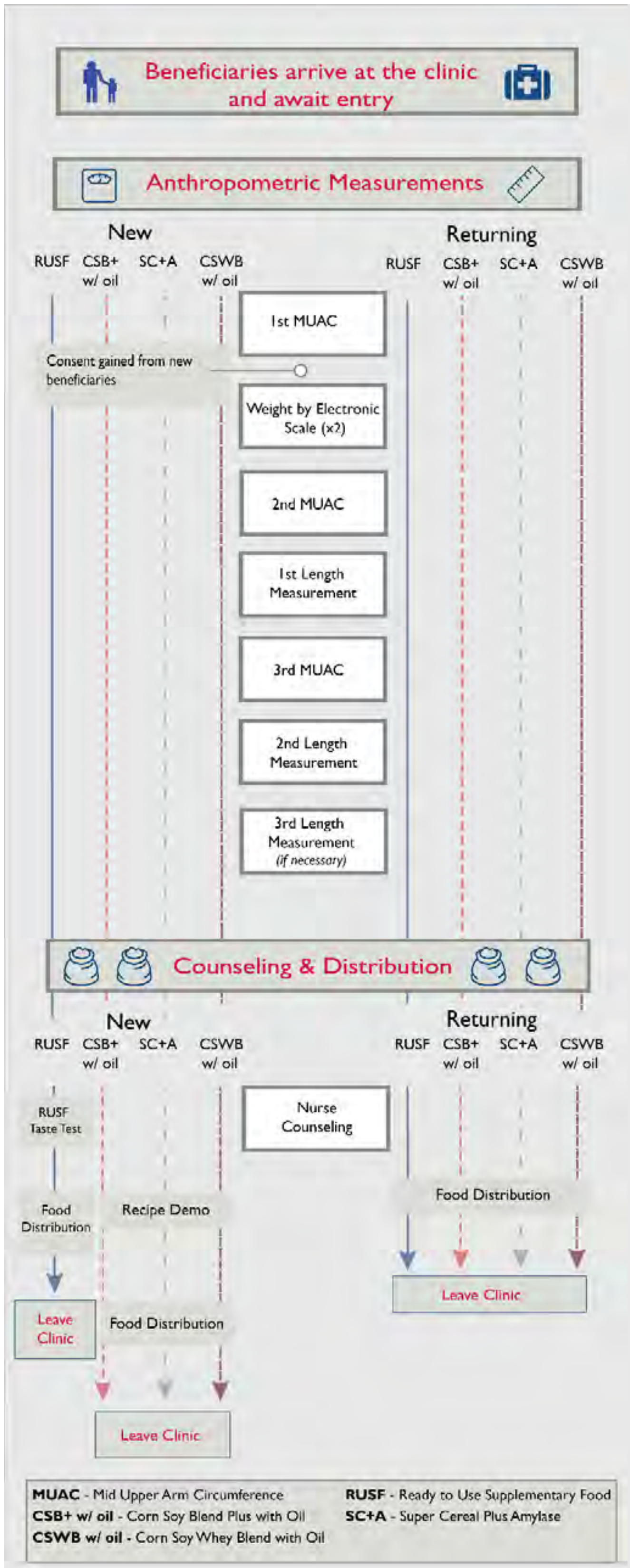
	CSB+ w/Oil	CSWB w/Oil	SC+A	RUSF
Fortified Blended Flour (FBF)	✓	✓	✓	
Programmed Separately with FVO	✓	✓		
Ready-to-Use				✓
Dairy Component (Milk or Whey)		✓	✓	✓
Experimental Formulation		✓	✓	
Experimental Packaging (1.25 kg bag)	✓	✓		

Differences among the four SNFs and their daily rations are summarized in **Table 1,** with additional detail and nutrient breakdowns in **Appendix 1**. The FBFs were distributed in hermetically sealed bags with plastic foil and a metalized layer. The packaging for the CSB+ and CSWB flours was a novel size (~1.2 kg), large enough to contain a biweekly ration (14 servings), similar in design to the 1.9 kg bags used by WFP when distributing the standard SC+ for MAM treatment. SC+A was packaged in the 1.9 kg standard size and model bags. Within the CSB+ w/oil and CSWB w/oil arms, FVO was distributed after repackaging from 4-liter metal cannisters into standard 0.5-liter plastic bottles. These foods also required preparation in the home by combining the flour with water (and oil in the case of CSB+ and CSWB) and cooking for five to ten minutes to make a porridge-like cereal. The fourth food, RUSF, required neither mixing nor cooking. The beneficiary received 14 sachets per clinic visit. If prepared and consumed by the beneficiary child as directed, all four treatment foods provided the same amount of energy (i.e., rations were isocaloric), approximately 550 kcal/day.

These packaging types contrast with what is typical for FBFs, which are distributed in either standard biweekly rations (e.g., 1.9 kg bags as with SC+) or in 25 kg bags that are repackaged at some point during the distribution chain. These differences in packaging may affect cost-effectiveness. The CSB+ and CSWB packaging used in this study (1.2 kg bags) is more expensive than the commonly programmed 25 kg bags. However, the smaller bags may reduce losses, possibly potential for contamination, and time costs from repacking that occurs along the supply chain, and may also improve the efficiency of distribution. The potential impacts of these differences on opportunity costs and packaging costs and overall cost-effectiveness are explored in more detail in the cost-effectiveness section (**Section 9**) of this report.

All the foods were distributed using a uniform clinic and distribution protocol. (See **Figure 1** for detail on SFP flow.) The only difference in clinic flow across the arms was for new beneficiaries: those receiving any of the FBFs were required to stay to the end of the clinic in order to see and participate in a cooking demonstration, whereas those in the RUSF arm received a taste test during counseling (see **Section 5.1** and **Section 5.2** for more details). On occasion, clinic staff asked caregivers to participate in the demonstration a second time if the caregiver was unable to demonstrate an understanding of the recipes during the counseling session.

Figure 1: Clinic Flow for Both New and Returning Beneficiaries



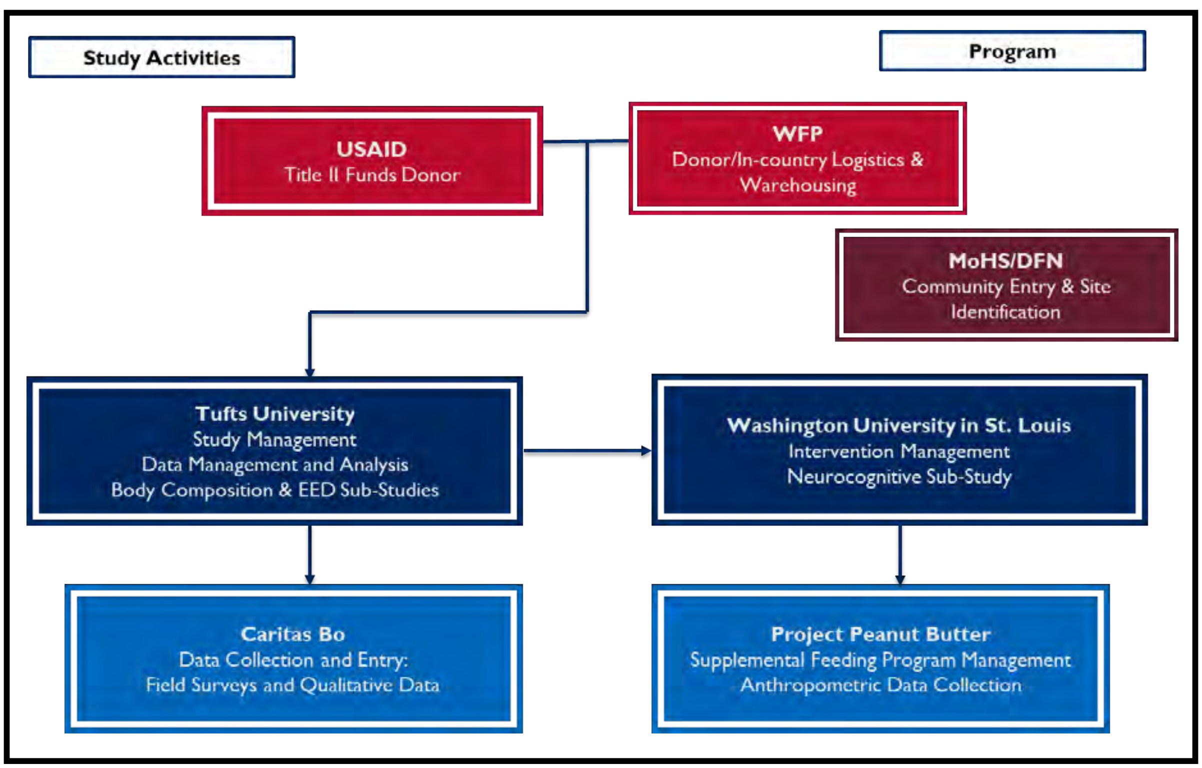
3. Partners and Institutional Roles

The Four Foods Study was made possible through a collaboration between USAID/FFP, Tufts, the School of Medicine at Washington University in St. Louis, Missouri (WashU), WFP, Sierra Leone's Directorate of Food and Nutrition in the Ministry of Health and Sanitation (DFN-MoHS), Project Peanut Butter (PPB), and Caritas Bo (**Figure 2**).

DFN-MoHS identified Pujehun District, in southern Sierra Leone, as the study site and provided technical support during the design phase of the study (see **Section 4** for more details). Within Pujehun District, the local District Health Management Team (DHMT) gave approval for the SFP to operate at specific peripheral health units (PHUs – see **Section 6** for more detail) and provided support in gaining community entry for the PPB team during start-up. Over the course of the study, the DHMT also conducted monitoring visits to strengthen collaboration between PPB and PHU clinic staff. WashU, through a partnership with PPB, managed the implementation of the SFP in Pujehun District and was responsible for screening children for MAM and collecting all clinical data from beneficiaries, including anthropometric measures and morbidity information in the previous two-week period. Tufts held primary responsibility for monitoring the technical quality of the field data collection and managing the overall study's progress. Caritas Bo gathered all field survey data, entered all data, facilitated all focus group discussions, and transcribed all focus group discussion recordings and translated them from Mende to English. WFP provided logistical support on management of the four foods, warehousing support, and in-country transport between warehouses, and managed the importation of the FBFs and the procurement of the RUSF.

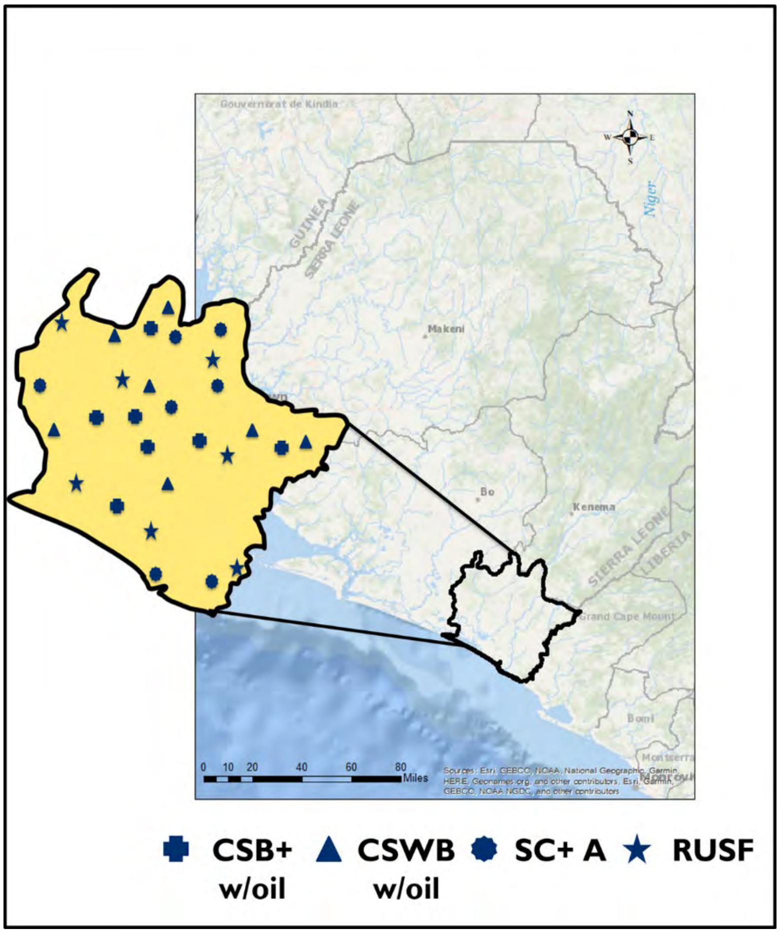
3.1 SFP Team and Mobile Clinic Model

Figure 2: Institutional Partners, Roles and Responsibilities of the Four Foods Study



The SFP was implemented by three different PPB teams, each composed of a trained nurse fluent in Mende, a clinic manager, and a driver. Under the mobile-clinic model, each day the three PPB teams loaded the appropriate quantity and type of food and necessary supplies into a Toyota Land Cruiser, which transported the team to the SFP sites and back to the PPB office in Pujehun. In this model, although government facilities (PHUs) served as the unit of randomization, the SFP was a parallel program (i.e., not integrated into MoHS service provision). **Figure 1** provides a detailed view of the SFP's data collection and daily flow from arrival to exit, and **Figure 3** provides a map of each SFP's location across Pujehun District.

Figure 3: Representative Map of Pujehun District and Study Sites



3.2 Field Data Collection Team

All enumerators (12 males and 8 females) spoke fluent Mende and had completed an undergraduate degree in social sciences. In order to gain entry to homes and be allowed to observe female caregivers' preparation behaviors, the study team determined that only females could safely observe fellow females for long periods of time. Therefore, to respect cultural sensitivities, only females collected data for the in-home observations.

To identify 20 qualified enumerators, the study team recruited 52 candidates. Over the course of six weeks, the candidates were trained in the study's methods and given rigorous ethical training and in-depth training on all the data collection instruments. The students also translated and adapted the informed consent forms. The final exam was three parts: a practical in which students conducted an enrollment interview on a role-playing caregiver, an oral Mende recitation of an informed consent form chosen at random, and a written exam covering topics from ethical scenarios to survey questions. The top scorers were hired, and the next five were placed on a roster should a backup enumerator be needed. Refresher trainings were held approximately every six months.

4. Context

Sierra Leone is a relatively small country (72,000 square km) situated on the western coast of sub-Saharan Africa, between the Republic of Guinea to the north and east and Liberia to the south.[38] Despite robust growth measured in annual change in gross domestic product(GDP) over the previous 20 years, economic growth has stagnated since the onset of the Ebola Virus Disease (EVD) crisis in 2014, and Sierra Leone remains one of the poorest countries in the world.[38,39] The country is administratively divided into four regions (Northwest, South, East, and West), subdivided into 16 districts, and subdivided further into approximately 192 chiefdoms. The climate is tropical, with the main rainy season lasting from May to November, and the dry season comprising the rest of the year. [39] The long rainy season provides conditions well suited to the production of rice, the main dietary staple. In addition to rice, the Sierra Leonean diet consists of green leafy vegetables such as cassava leaf, groundnuts/peanuts ground into paste, and palm oil, which serves as the main ingredient in sauces. [38]

In 2014, FAQR Phase II implemented a study in the Kenema District of Sierra Leone to compare the cost-effectiveness of four foods used in the treatment of MAM in children under five. Due to the Ebola Virus Disease (EVD) outbreak, the study was terminated after a short recruitment period, resulting in an insufficient sample to detect differences in effectiveness or cost-effectiveness. Understanding the comparative effectiveness and cost-effectiveness of the four foods remained a priority research endeavor under FAQR Phase III. When Sierra Leone was declared EVD-free in 2015, the FAQR team asked DFN-MoHS if Sierra Leone could be considered as a location for a new Four Foods MAM Treatment Study. DFN-MoHS was supportive of the study and identified Pujehun District as the study site.

At the time of scoping for the new study, Sierra Leone reported poor health outcomes among children under five measured in high rates of infant mortality (56 deaths/1,000 live births) and under-five mortality (94 deaths/1,000 live births). Nationally, roughly 5% of children under-five suffered from MAM and 2% from SAM, and 40% were stunted.[40] In Pujehun District specifically, rates of acute malnutrition were deemed to be above international thresholds for supporting SFP based on available data (facility data). However, over the course of the study, the team found rates of MAM were lower than previously reported (see **Section 6** for more information on sample size).

5. Formative Research

In July 2016, the FAQR team collaborated with Sierra Leone's DFN-MoHS and Ministry of Education, Science, and Technology (MEST), with support from the Sierra Leone offices of WFP and PPB, to conduct formative research prior to the start of the Four Foods Study. This activity explored locally standard or "proper" cooking methods in order to inform development of locally appropriate FBF cooking instructions for caregivers. This activity also helped the study team understand taste acceptability for CSB+ w/oil, CSWB w/oil, and SC+A. The details of that research are reported elsewhere.[41] In total, 96 female caregivers participated in standardized sensory and taste tests of one of

the three foods (32/food). Trained facilitators and home economics teachers engaged in controlled cooking observations of potential caregivers to gauge their ability to adhere to instructions. Focus group discussions provided additional insight into common porridge cooking practices.
The research team identified a standard and widely available plastic "baby feeding cup" for caregivers to use when measuring the flour. The baby feeding cup had an indented ring at a standard location on the cup. A single serving of SC+A was 136 g of flour, which equated to one full "baby feeding cup." A single serving of either CSB+ w/oil or CSWB w/oil required 86 g of flour, the equivalent to "flour filled just to the line" of the baby feeding cup. (See **Section 6** for more information on ration sizes.)

FVO was to be added to the CSB+ and CSWB flours at 26 g FVO for every 86 g of FBF. Three standard tablespoons of FVO proved accurate to arrive at this quantity. However, this measurement was identified before the plastic reusable oil bottles were procured. Once the oil bottles arrived, the team learned that "four bottle caps" of FVO was a more accurate measurement than three tablespoons. The local clinic team was thus trained to counsel caregivers to use "flour filled just to the line" and "four bottle caps of oil" for the CSB+ w/oil and CSWB w/oil study arms.

Porridge consistency was important to consumer acceptability and recipe adherence. As noted above, the addition of amylase to SC+ reduced the porridge's viscosity. Additionally, the longer the porridge cooked, the thinner it became (in contrast to the other FBFs)., although the thinning effect ceased after five minutes of cooking time Among Sierra Leone caregivers, thicker porridge is more culturally normal. Caregivers therefore required additional counseling to understand the counterintuitive nature of SC+A. If caregivers wanted a thicker porridge, study team members counseled them to reduce the quantity of water and not to increase the cooking time or the quantity of flour.

5.1 SBCC Program

From July to August 2017, the research team engaged in activities to develop counseling cards and training for PPB staff, community health workers (CHWs), and community-based lead mothers (LMs). The counseling cards were meant to improve understanding of how the foods should be prepared, consumed, and used within the context of healthy complementary practices. The operational theory behind the program was that by training health workforce leaders (i.e., CHWs, LMs, and PPB staff), those individuals would serve as advocates who would then reinforce positive behaviors among beneficiary caregivers while in the community, at home, or at the SFP.

The purpose of the SBCC formative research process was to understand community-level barriers and facilitators to recommended complementary food preparation practices in Pujehun District. The process also allowed the team to determine appropriate message delivery strategies to encourage change in feeding practices, when necessary. Ultimately, the research team included community and social mobilization methods such as weekly radio broadcasts, community talks, and community screening activities, as well as counseling cards tailored to the Pujehun context for use by community health workers, nurses, and lead mothers. These delivery strategies targeted factors such as knowledge, self-efficacy, and motivation, which were identified as either barriers or facilitators to effective use of the foods for MAM treatment.

The results of eight focus group discussions identified household members (e.g., mothers-in-law or husbands) who could be advocates for recommended preparation behaviors. The results also identified individuals (e.g., siblings under-5) who created challenges to sustaining recommended preparation and consumption patterns. From these discussions, counseling cards and radio messages were developed around four themes: ration size, ingredient quantities, dietary diversity in supplementary feeding, and strategies to reduce sharing. Once messages and instruction materials were created, training modules were developed for local trainers, who then trained CHWs, PPB Clinic staff, and LMs. Further details of the formative research and focus group results can be found at foodaidquality.org.

6. Study Design

This study was a cluster-randomized, clinical effectiveness trial. The PHU sites where PPB screened, enrolled, and treated malnourished children were the clusters that served as units of randomization, each to one of the four SNFs. The CSB+ w/oil arm served as the comparison group because it was the SNF for MAM commonly programmed by FFP programs. **Figure 3** shows the locations of the selected PHUs in the study area and the arm to which each was assigned.

At each SFP visit, participants were given a two-week ration of the food randomized to that PHU and were told to return two weeks later to be evaluated. At each two-week visit, PPB staff took beneficiaries' anthropometric measurements, which were recorded on a paper clinic card, and provided another two-week food ration as illustrated in **Figure 1**. This continued until an outcome was reached for up to 12 weeks of rations distributed (whichever occurred first). Outcomes were defined as:

- Graduated (achieving MUAC ≥12.5 cm)
- Developed SAM (MUAC <11.5 cm or presence of bipedal edema)
- Death
- Default (missed three consecutive clinic visits)
- Failure (did not achieve MUAC ≥12.5 cm after receiving 12 weeks of rations)

The study also included mixed-methods data collected on subsamples of beneficiaries: structured interviews, qualitative focus group discussions, and direct observations both in beneficiaries' homes and at the PHU. (See **Section 6.4** for more detail)

Consent was obtained from beneficiaries' caregivers prior to their participation in the study; additional consent was obtained from the subsamples of caregivers selected for structured interviews, focus group discussions, or in-home observations. This study received ethical approval from the Tufts University Health Sciences Institutional Review Board, the WashU School of Medicine Institutional Review Board, and the Sierra Leone Ethics and Scientific Review Committee. The trial is registered at ClinicalTrials.gov: NCT03146897.

6.1 Sample Size and Sampling

For a cluster-randomized design comparing two proportions (i.e., one treatment arm to the comparison arm, CSB+ w/oil), planned sample sizes of 1,330 per arm (total of 5,320) sampled from seven sites per arm was calculated to achieve 80% power to detect a difference between the group proportions of 0.07 (7 percentage points). The test statistic used for this calculation was the two-sided Z-test (H0: P1 - P2 = 0; H1: P1 - P2 = D1 ≠ 0). The intracluster correlation used was 0.006 (based on prior data from Sierra Leone), and the significance level of the test was 0.05. This calculation assumed a baseline recovery rate of 70%. **Figure 4** shows the sample selection scenarios, assuming a graduation rate in the comparison group of 70%.

For this study, the sample size calculation was based on the primary outcome of "percent of children graduated from SFP." PASS 14 software was used for the calculations.[a]
However, for feasibility reasons, the total study sample size was capped at approximately 5,000 (i.e., 1,250 per arm). Increasing the number of PHUs (i.e., clusters) per arm allowed for a smaller detectable effect size with a lower total sample size (smaller n per site). Based on these scenarios, seven sites per

[a] PASS 14 Power Analysis and Sample Size Software (2015). NCSS, LLC. Kaysville, UT, ncss.com/software/pass.

arm (28 sites total) were chosen (see **Section 6.2**) as the most feasible option. An eighth site was later added to the CSWB w/oil arm due to low enrollment (described further below).

Section 4 (above) details why actual enrollment figures and graduation rates were lower than expected. During the study, the CSWB w/oil arm had lower overall enrollment numbers than the other three arms. To achieve better statistical power and balance among the arms, an eighth PHU site was added to the CSWB w/oil arm in January 2018. With sample sizes of between 579 and 768 per arm and graduation rates of between 62 and 65% per arm, the detectable effect size shifted from ~7 percentage points (as originally planned) to ~9 percentage points.

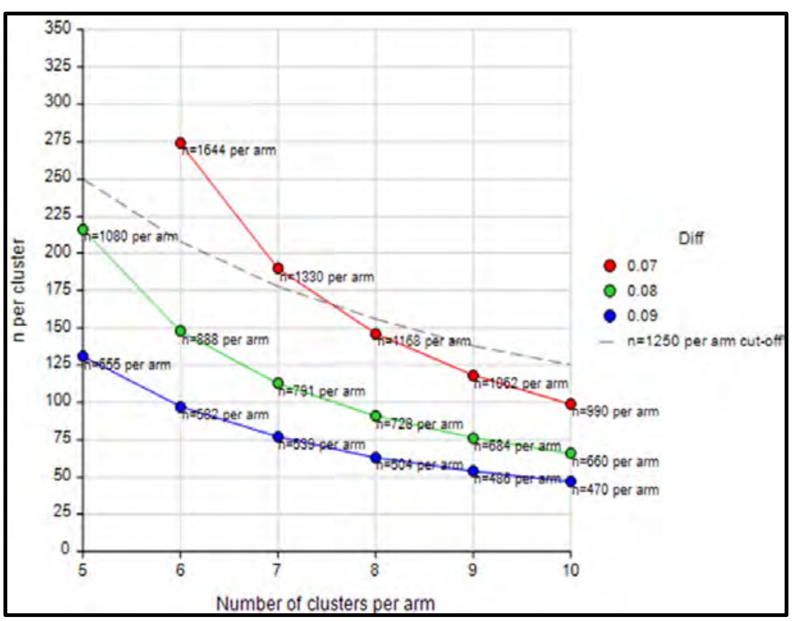
In addition to the primary analysis, three subsamples (not related to the biological sub-studies) of caregivers were selected to explore behavioral factors influencing effectiveness of the four foods. These sample sizes were chosen for logistical reasons: 420 in-depth interviews per study arm (maximum), of which 112 would include in-home observations (maximum). These subsamples were randomly chosen without replacement and were drawn from the list of beneficiaries who had received a study food within the last seven days and had not yet been interviewed.

A final subsample of caregivers was selected for participation in focus group discussions. To be selected for a focus group discussion, caregivers needed to have attended SFP within the last 90 days and have never been interviewed previously. Generally, the goal was to reach six caregivers for each focus group, but this was not always possible and so four was considered an allowable minimum.

6.2 PHU Selection and Randomization

There were 77 PHUs located throughout the peri-urban and rural chiefdoms of Pujehun District at the start of the study. A stratified block randomization technique was used to obtain four groups of seven PHUs; each group represented the variability of the district as equally as possible (**see Figure 3**). First, 60 PHUs with the highest 5-month accumulated MAM caseload were selected as the sampling frame based on data provided by the DHMT from the previous 12-month period. This list of 60 PHUs was then categorized according to the stratification criteria noted below, which were based on input from

Figure 4: Cluster and Total Sample Size Scenarios



community and government stakeholders. In the case that a selected PHU could not be included in the study (e.g., due to proximity to another study PHU or other logistical reasons), another PHU was selected from those remaining on the list.

PHU stratification criteria:

- MAM caseload
- Located within a town
- Chiefdom (all 12 chiefdoms of Pujehun District must be represented and fairly evenly distributed among the four arms)
- Type of PHU, i.e., Maternal and Child Health Post, Community Health Centers, and Community Health Posts (all three types of PHUs) must be represented and fairly evenly distributed among the four study arms
- Predominant mining PHU catchment areas (because livelihood can affect consumption patterns)
- Located on a major water body (indicates fisherman occupation)
- Presence of a current outpatient therapeutic treatment program (OTP) evenly distributed between the arms
- Accessibility (each arm containing some PHUs located either in Mano Sakrim chiefdom or on the upper/west side of the Moa river)

Details about the sampling process are provided in **Appendix 2.** The four groups were designated A, B, C, and D by Tufts. Then a researcher at WashU who was blinded to the PHU selection scheme randomly assigned the four groups into treatment arms by choosing a random order of four numbers (1,2,3,4) which were then decoded by Tufts.

6.3 Subjects' Eligibility and Enrollment

Eligible subjects were children 6-59 months old with MAM, defined by mid-upper arm circumference (MUAC) ≥ 11.5 cm and < 12.5 cm, without bipedal oedema, and having not received food rations from another organization for treatment of MAM. All eligible children who arrived at the PHU for evaluation and whose caregivers gave informed consent were included without regard to presence of chronic illness or permanent residence in the local community. Enrollment occurred on a rolling basis from April 2017 until September 2018. While participants were enrolled passively (i.e., based on whether they came to clinic), outreach was conducted in the surrounding communities by PPB staff and CHWs who periodically screened for MAM cases and made referrals to the PHUs. Children with MAM who were screened at a PHU that was not a study site were referred to the nearest study PHU for enrolment in the program. Screenings at non-study PHUs was conducted ad hoc (i.e., only when children arrived at the PHU and were actively screened; PHUs did not engage in community-based screening for MAM). In this way, although the program was resident in only 29 PHUs, the entire district was captured. If a child was found to be enrolled twice or at two separate PHUs, the child was removed from the study but still actively treated for MAM as part of the SFP.

6.4 Data Collection Instruments

This mixed method study collected quantitative and qualitative data. Specific data collection instruments are summarized in **Table 2.** KoBoToolbox[b] was used for electronic data collection and overall data management.

[b] https://www.kobotoolbox.org/

The SFP-specific data, which included anthropometric and morbidity information as well as the demographic enrollment questionnaire, were collected by PPB staff on paper clinic cards and entered in KoBoToolbox webforms by trained Caritas Bo data clerks. Every clinic card was entered twice (once by each of the two data clerks) within 48 hours of the caregiver arriving at clinic. Every month, the total database of newly enrolled beneficiaries was downloaded from the KoBoToolbox cloud and compared against the logged informed consent forms. Any discrepancies were resolved during the first week of every month. (See **Figure 1** for more detail.)

The field surveys and observational data collection were conducted by the team at Caritas Bo and were collected using Samsung Galaxy A6 tablets with the KoBoCollect data collection app. Each tablet was equipped with a SIM card in which mobile data were loaded, and all surveys were uploaded to the web-based cloud from the field. Field notes from the in-home observations were typed by a group of professional typists. Focus groups were recorded using either handheld recorders or tablets. Recordings were then translated and transcribed by hand by two different research assistants (RAs) working separately. The final transcripts were then compared against each other for discrepancies by a supervisor. Any discrepancies were resolved by reviewing the recording and two supervisors agreeing on the correct translation. The agreed upon translation was then typed by the typists.

Table 2: Data Collection Tools for Each Thematic Area of the Four Foods Study

Effectiveness	Cost-effectiveness	Influencing Factors
Bi-weekly anthropometry	Clinic Day observations	Key Informant Interviews
Bi-weekly morbidity and treatment notes	Warehouse observations	Individual interviews with recipients, lead mothers, and HNPs
Socio-economic surveys at enrollment	Individual interviews with CHWs and lead mothers	In-home observations with recipients
Community questionnaires	In-home observations with recipients Financial records	Focus group discussions with recipients and distribution committees

7. Qualitative Methods

Transcripts were analyzed using a thematic analysis that was developed during the study's design and focused on behaviors broadly related to use of the study foods. The analysis was guided by questions in the interview guide as well as relevant literature.[42] QSR International's NVivo version 12 was used for data management and analysis.[c] Development of the codebook by two analysts began with line-by-line coding of three randomly selected focus group discussion (FGD) transcripts from the list of 25 completed FGDs. The codebook included parent codes, child codes, and definitions that materialized through consensus between the two coders. Any discrepancies were discussed and resolved by mutual agreement. This iterative process was used to develop the finalized codebook.

[c] NVivo qualitative data analysis Software. QSR International Pty Ltd., Version 12, 2019.

After resolving discrepant codes, one analyst led coding for the remaining focus group discussions. The finalized codebook was revised iteratively as new concepts arose throughout this process. When a new code was identified, all prior FGDs were recoded using the amended codebook. This coding process continued until similar concepts and topics were apparent in all FGDs, known as theoretical saturation.[43] Axial coding was used to connect themes relating to factors influencing the way the study foods were oded text was displayed in a matrix and stratified by study arm to connect themes among the study foods. To ensure coding consistency, intercoder reliability checks were conducted once by two researchers on the team. A Kappa score average of 99.6% was obtained by randomly selecting one FGD and having the two researchers code the same transcript using the final codebook.

8. Effectiveness

8.1 Methods

a. <u>Effectiveness</u>

The primary analysis aimed to determine whether differences in recovery rates existed among children treated with one of four SNFs. A conceptual framework was developed that included individual child level and household level characteristics. Using this framework, descriptive statistics were calculated and stratified by study arm. Variables identified as potential confounders or predictors using a stepwise approach were selected for inclusion in the regression models as covariates. Mixed-effects logistic regression models were fit using PHU as the random effect. The outcome was defined as achieving MUAC ≥ 12.5 cm within 12 weeks versus not (see **Section 6** for more information). Post-estimation marginal predictions for the study arm variable were obtained and used for the cost-effectiveness evaluation. In addition to the main outcome, a survival analysis was conducted to assess the time to graduation among the subsample of those who graduated from the MAM treatment SFP (n=1,676). Cox Proportional Hazards Models were built to obtain hazard ratios to represent the rate of graduation per unit time (days) for each study arm compared to CSB+ w/oil. A more detailed description of the modeling procedures is in **Appendix 2**.

Secondary outcomes included weight gain velocity (g/kg/day) and total MUAC gain (in cm) throughout the treatment period. These were tested for differences between arms using mixed-effects models adjusted for child's age, sex, baseline weight-for-length Z-score (weight gain model) or MUAC (MUAC gain model), and number of rations distributed.

b. <u>Sustained recovery at one-month follow-up</u>

A secondary analysis, exploratory in nature as a secondary research question, determined whether differences in sustained recovery exist among graduated children treated with one or another of the four SNFs. The same process used to structure the main effectiveness analysis was used to analyze the incidence of sustained recovery at one-month post-graduation. The one-month post-recovery time period was chosen because it was the time point with the most complete data and closest to outcome so as to capture food-specific differences. As shown in **Table 3**, at the three- and six-month follow-up appointments, the proportion of missed visits was deemed too high for reliable analysis. Descriptive statistics were calculated and stratified by study arm. Variables selected for inclusion in the final model as covariates were those considered potential confounders or predictors.

The binary outcome variable was defined as not having sustained recovery if one of two conditions were met: the MUAC at the one-month follow-up appointment was <12.5 cm or the nurse recorded "relapse" on the clinic card, indicating that a child had relapsed between graduation and the one-month follow-up appointment. Crude and adjusted mixed-effect logistic regression models were fit using PHU as the random effect. Observations with missing covariate data were dropped from the models. To evaluate whether missed visits had an impact on the parameter estimates, three models were compared: 1) excluding those with missed visits at one month post-graduation, 2) categorizing the outcomes of those with missed visits at one month post-graduation as all relapsed, and 3) categorizing the outcomes of those with missed visits at one month post-graduation as all sustained recovery. The marginal predictions estimated from these models for each study arm were calculated and used for additional cost-effectiveness evaluation.

Data were analyzed using Stata 15 (StataCorp, College Station, TX).

Table 3: Data Collection Tools for Each Thematic Area of the Four Foods Study

	CSWB w/oil n (%)	**SC+A n (%)**	**CSB+ w/oil n (%)**	**RUSF n (%)**	**Total n (%)**
Sustained Recovery	267 (74%)	294 (71%)	317 (75%)	313 (66%)	1191 (71%)
Relapsed by 1-month	62 (19%)	79 (19%)	82 (19%)	116 (24%)	339 (20%)
Missed the 1-month Visit	31 (9%)	42 (10%)	25 (6%)	48 (10%)	146 (9%)
Missed the 3-month Visit	135 (38%)	155 (37%)	125 (29%)	206 (43%)	621 (37%)
Missed the 6-month Visit	231 (64%)	256 (62%)	233 (55%)	323 (68%)	1043 (62%)

8.2 Results

a. Effectiveness

A total of 2,691 children were consented and enrolled; 38 were excluded; and 2,653 were included in analysis. A flowchart in **Figure 5** shows enrollment and outcome figures by study arm. Reasons for exclusion included:

- Enrollment error, i.e., MUAC ≥ 12.5cm or < 11.5 cm at start (n=10)
- Known to be younger than 5.5 months or older than 59.5 months at enrollment (n=14)
- Child had Cerebral palsy (n=1)
- Error with assigned outcome or child progressed to SAM status because of a twin diagnosed with SAM (n=7)
- No recorded outcome or no outcome reached before the study ended (n=4)
- Incomplete information to complete enrollment in study (n=2)

Table 4 shows descriptive characteristics of the sample at enrollment by study arm. Overall, the study arms were balanced. Some differences were noted and controlled for in analysis, including:

- Sex
- Whether the child was transferred into the study from SAM (i.e., received prior treatment for SAM and transferred to SFP when MUAC increased to 11.5 or greater)
- Whether the child had a twin
- Caregiver's age

- Number of males age 0-5 years in the household
- Baseline weight-for-height Z-scores
- Baseline morbidities

Additional covariates that were related to the outcome in univariate models included:

- Child's age
- Caregiver's level of education
- Season of enrollment
- Presence of females age 65 or older
- Number of females age 0-5 years
- Socioeconomic index (radio, mattress with bed, motorcycle/scooter, agricultural land)
- Household toilet type
- Unprotected well as the main drinking water source
- Zinc roof type

There were few missing data overall and within each study arm, with <2% missing for each variable. Overall, 63.2% of treated children graduated from the SFP. By study arm, the graduation rates ranged from 62.1% (RUSF arm) to 64.5% (SC+A arm) see **Figure 5**. In all models, there was no significant difference in outcomes by study arm. The adjusted marginal predictions for graduation from MAM treatment within 12 weeks are displayed in **Figure 6**. Due to collinearity with the other anthropometric-related covariates, the average length and the average weight of the 3 measurements taken per child per visit as well as the weight-for-age Z-score at baseline were dropped from the adjusted model.

Table 4: Child and Household Characteristics at enrollment[1]

Child & Household Characteristics at Enrollment	CSWB (n=579)		SC+ (n=643)		CSB+ (n=663)		RUSF (n=768)		Total (n=2653)	
	n or mean±SD	*% or med(min,max)*	*n or mean±SD*	*% or med(min,max)*	*n or mean±SD*	*% or med(min,max)*	*n or mean±SD*	*% or med(min,max)*	*n or mean±SD*	*% or med(min,max)*
Female sex	329	57%	399	62%	365	55%	430	56%	1,523	58%
Age, in months	13.2±7.9	10.7 (5.8,59.5)	13.2±8.1	10.5 (5.8,58.1)	13.1±7.7	10.5 (5.7,55.6)	13.5±8	11.1 (5.6,59.3)	13.3±7.9	10.7 (5.6,59.5)
Breastfeeding	453	80%	510	80%	523	80%	595	79%	2,081	80%
Season of enrollment										
Rainy season	363	63%	421	66%	399	60%	441	57%	1,624	61%
Transferred from SAM	114	20%	174	27%	166	25%	218	28%	672	25%
Twin at birth	23	4%	32	5%	39	6%	20	3%	114	4%
Mother is caregiver	546	95%	589	92%	608	92%	700	91%	2,443	92%
Caregiver is married	490	85%	541	85%	571	86%	647	85%	2,249	85%
Caregiver's age, in years	28.1±8.2	27 (16,80)	27.1±7.4	25 (17,65)	28.3±8.4	27 (17,65)	27.5±8.2	26 (16,69)	27.7±8.1	26 (16,80)
Level of education										
None	321	56%	340	54%	369	56%	389	51%	1,419	54%
Some or completed primary	141	24%	146	23%	146	22%	200	26%	633	24%
Some, completed, or more than secondary	116	20%	150	24%	145	22%	176	23%	587	22%
SES and HFIAS										
HFIAS category (mild/moderate collapsed)										
Food Secure	134	23%	148	23%	178	27%	220	29%	680	26%
Mildly or Moderately Food Insecure Access	80	14%	93	15%	77	12%	124	16%	374	14%
Severely Food Insecure Access	365	63%	395	62%	406	61%	424	55%	1,590	60%
SES Wealth Index (quintiles of score derived from PCA)										
Lowest	123	22%	115	18%	122	19%	162	21%	522	20%
Mid-Low	138	24%	105	17%	115	18%	165	22%	523	20%
Medium	110	19%	122	20%	123	19%	164	22%	519	20%
Mid-High	111	19%	133	21%	145	22%	134	18%	523	20%
Highest	89	16%	152	24%	148	23%	135	18%	524	20%

[1]Percentages are of non-missing values, < 2% missing for each variable

Figure 5: Reasons for Exclusion and Enrollment and Outcome Figures by Study Arm

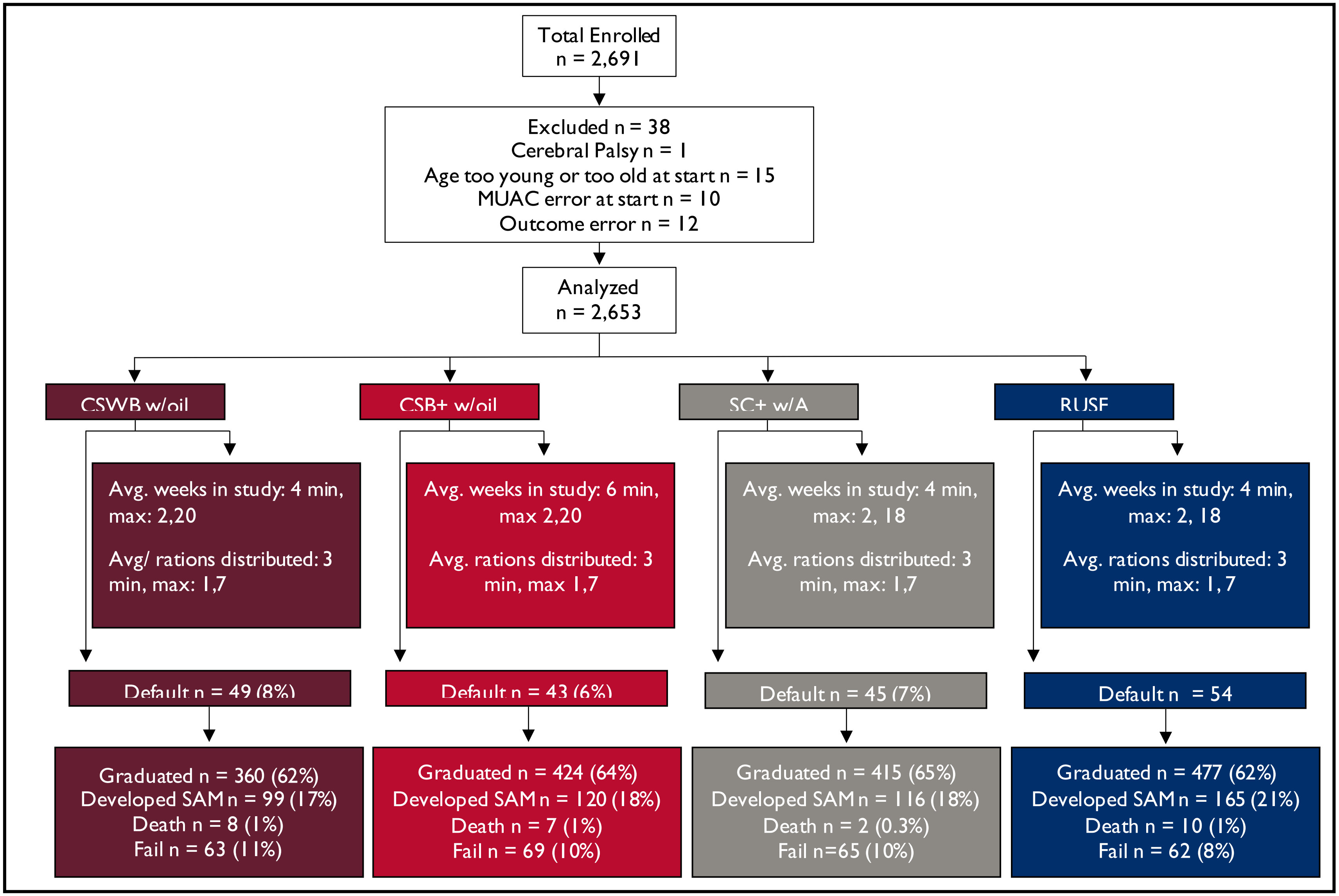
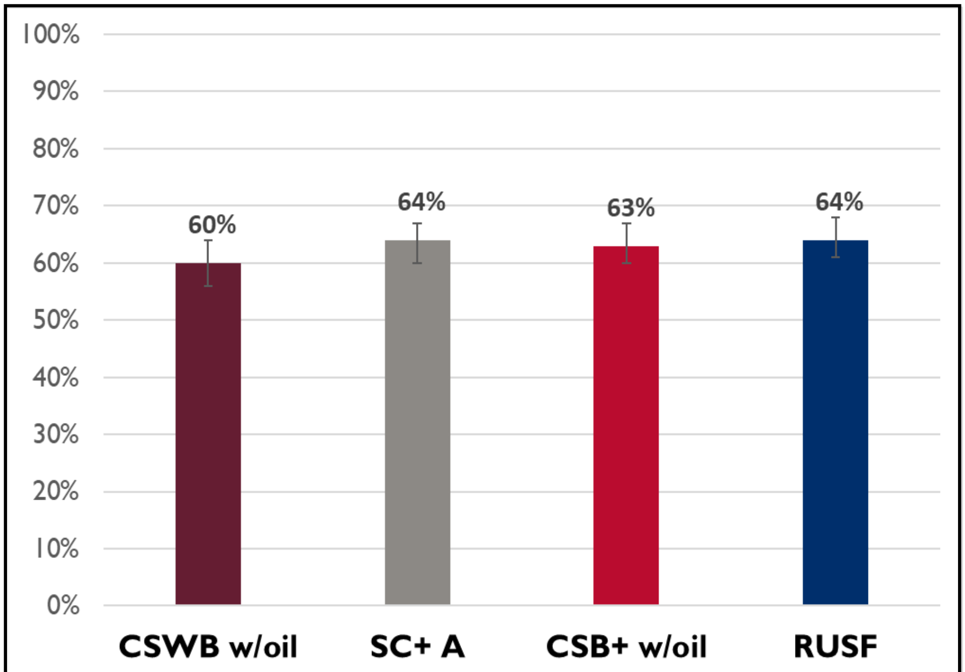


Figure 6: Percentage Graduated Within 12 Weeks, Adjusted Marginal Predictions[1]



[1]Error bars represent 95% CIs

Several variables were significantly associated with graduation from SFP. Children with the following enrollment characteristics had significantly higher odds of graduation: higher average MUAC, higher length-for-age Z-score, enrolled in the rainy season, presence of females age 65 or older within the household, and presence of diarrhea within prior two weeks. Among those who were transferred from SAM, having a zinc roof type and having had a fever within the prior two weeks were associated with significantly lower odds of graduation. Odds ratios and 95% confidence intervals from the adjusted model are displayed in **Table 5.**

Mean time to graduation (for those that graduated) was 35.8 days overall (SD=22.9) and ranged from 34.9 to 36.6 days by study arm, with the shortest mean time to graduation in the RUSF arm and the longest in the CSB+ w/oil arm. However, none of these differences was significant. **Table 6** shows the Hazards Ratios (HR) from Cox Proportional Hazards models for time to graduation, and **Figure 7** shows Kaplan-Meier curves for time to graduation by study arm.

Average weight gain velocity (g/kg/day) throughout the study period ranged from 12.6 in the CSB+ w/oil arm to 14.1 in RUSF (12.8 and 13 in CSWB w/oil and SC+A, respectively), with no statistically significant differences among arms. Similarly, average MUAC gain throughout the study period was the same for all four study arms, at 0.4 cm with no statistically significant differences detected.

Table 5: Odds Of Graduation From SFP[1], Adjusted Mixed-Effects Logistic Regression

	OR	95% CI	P-value
CSB+	Ref.		
CSWB w/oil	0.83	(0.64, 1.08)	0.16
SC+ w/A	1.01	(0.78, 1.3)	0.95
RUSF	1.05	(0.82, 1.34)	0.69
Child's sex (male)	1.26	(0.97, 1.64)	0.09
Child's age (in months)	1.02	(1, 1.04)	0.07
Breastfeeding	0.93	(0.69, 1.26)	0.65
Enrolled during dry/hot season	Ref.		
Rainy season	1.55	(1.29, 1.87)	<0.01
Child transferred from SAM	0.56	(0.45, 0.7)	<0.01
Received supplementary food last month	0.90	(0.62, 1.31)	0.59
Child had twin at birth	1.11	(0.7, 1.74)	0.66
Caregiver's age	1.01	(0.99, 1.02)	0.21
No formal education	Ref.		
Some or completed primary	0.93	(0.74, 1.16)	0.51
Some, completed, or more than secondar	0.98	(0.76, 1.27)	0.91
Child has no living siblings	Ref.		
One	0.89	(0.69, 1.16)	0.40
Two	1.20	(0.9, 1.6)	0.20
Three or more	1.04	(0.78, 1.38)	0.79
No males aged 0-5 years in household	Ref.		
One	0.94	(0.74, 1.19)	0.59
Two or more	0.97	(0.74, 1.28)	0.83
No females aged 0-5 years in household	Ref.		
One	0.79	(0.61, 1.04)	0.09
Two or more	0.82	(0.61, 1.1)	0.18
One or more females aged 65+ in household	1.43	(1.08, 1.9)	0.01
Radio	1.04	(0.87, 1.26)	0.65
Mattress with bed	1.00	(0.82, 1.23)	0.98
Motorcycle/scooter/okada	0.97	(0.74, 1.26)	0.81
Agricultural land	0.94	(0.74, 1.2)	0.63
Private household toilet	Ref.		
Shared/public	0.96	(0.79, 1.17)	0.71
Unprotected well as drinking water source	1.52	(0.94, 2.48)	0.09
Zinc roof type	0.81	(0.66, 1)	0.05
Average MUAC at enrollment	11.76	(8, 17.29)	<0.01
Length-for-age Z-score at enrollment	1.17	(1.06, 1.28)	<0.01
BMI-for-age Z-score at enrollment	1.27	(0.85, 1.9)	0.24
Weight-for-length Z-score at enrollment	0.99	(0.68, 1.44)	0.96
Fever at enrollment (within prior 2 weeks)	0.78	(0.61, 0.99)	0.04
Diarrhea at enrollment (within prior 2 week:	1.67	(1.12, 2.48)	0.01
Cough at enrollment (within prior 2 weeks)	1.15	(0.89, 1.49)	0.27

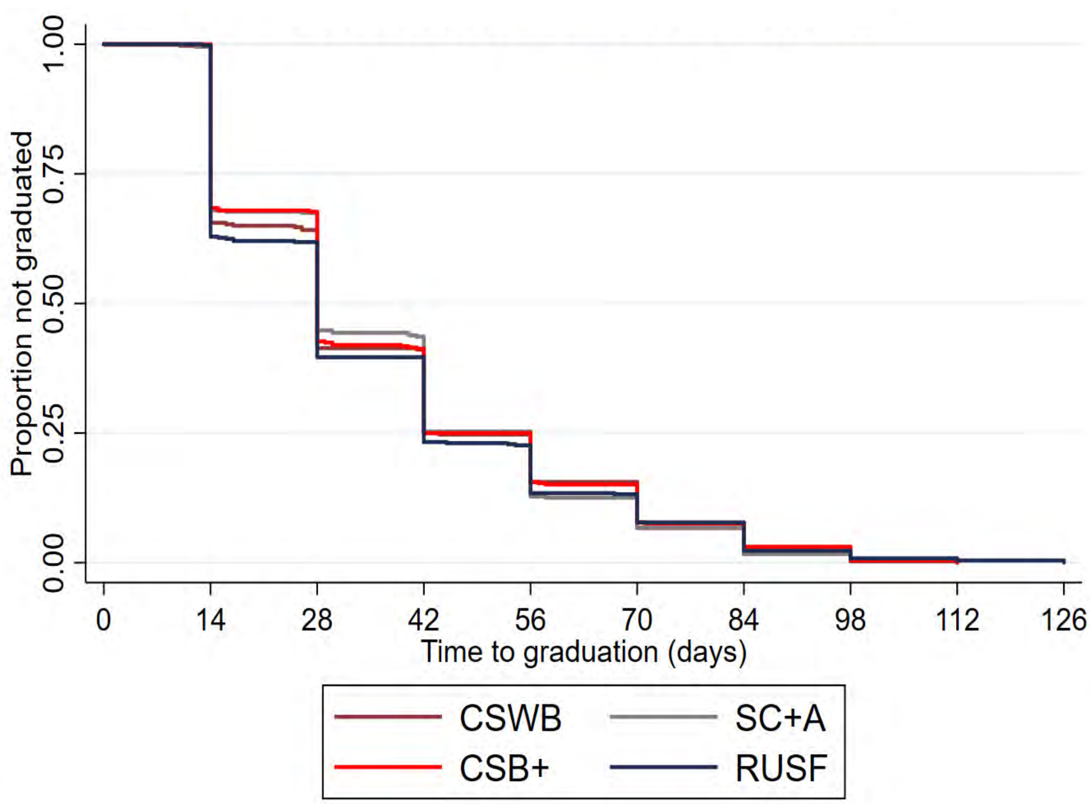
[1]Graduation defined as reaching a mid-upper-arm circumference ≥ 12.5 cm within 12 weeks

Table 6: Cox Proportional Hazards Models Assessing Time to Graduation by Study Arm

Graduation rate per day[1]	Crude HR	95% CI	Adjusted[2] HR	95% CI
	n=1,676		*n*=1,644	
Study arm (Ref = CSB+ w/oil)				
CSWB w/oil	1.03	0.90, 1.19	1.02	0.89, 1.18
SC+ A	1.02	0.89, 1.17	1.04	0.91, 1.20
RUSF	1.05	0.92, 1.19	1.09	0.96, 1.25

Notes: CSB+ = Corn Soy Blend Plus, CSWB = Corn Soy Whey Blend, SC+ A = SuperCereal Plus with amylase, RUSF = Ready-to-Use Supplementary Food
[1]Graduation defined as reaching a mid-upper-arm circumference ≥ 12.5 cm within 12 weeks
[2]Adjusted models control for: gender, breastfeeding, season, transfer from program for severe-acute-malnutrition, child age, weight at enrollment, muac at enrollment, bmi z-score at enrollment
*$p<0.05$

Figure 7: Kaplan-Meier Survival Estimates: Time to Graduation by Study Arm



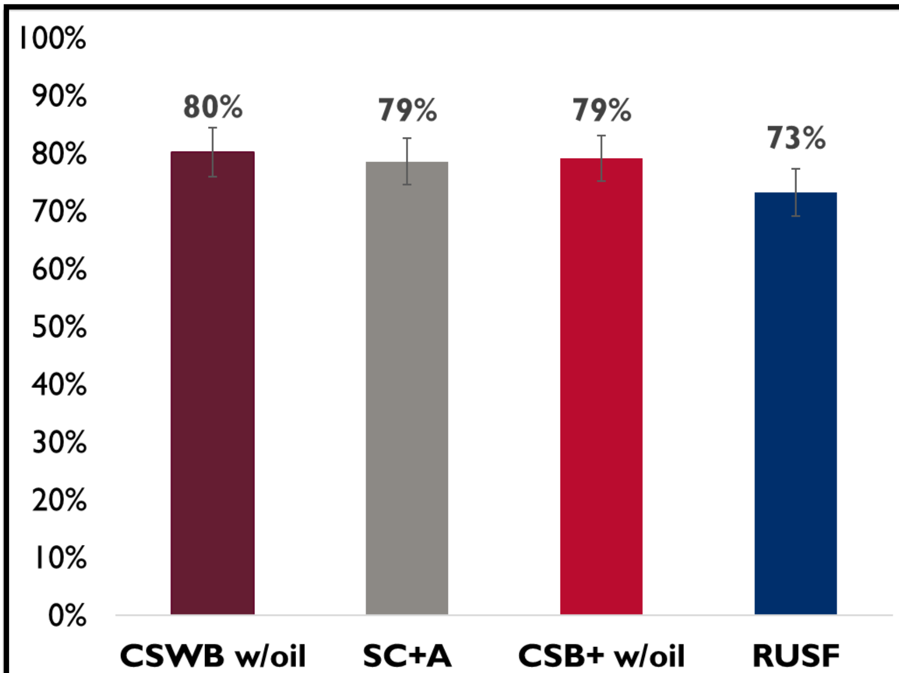
b. Sustained recovery at one-month follow-up

A total of 1,676 beneficiaries graduated from the SFP based on MUAC. Of these, most (91.3%) returned to clinic for a one-month follow-up appointment. The number of recovered beneficiaries that missed the one-month follow-up visit was proportionately lower among CSB+ w/oil beneficiaries (5.9%) than among the other three arms. **Table 3** illustrates differences in attendance at one-month post-graduation by arm.

In unadjusted analysis, all 1,531 beneficiaries that came for a one-month follow-up appointment were included; individuals that missed the one-month appointment were excluded. As covariates were included, beneficiaries with incomplete data were dropped, for a final sample of 1,489 in adjusted analysis. In total, 22.14% of the 1,531 beneficiaries that came for one-month follow-up relapsed to MAM. In both adjusted and unadjusted models, there were no statistically significant differences in the odds of sustained recovery between any of the FBFs and CSB+ w/oil. A significant difference between RUSF and CSB+ w/oil existed in both adjusted and unadjusted models, though this was attenuated in the adjusted model. Overall, the odds of sustained recovery were lower for RUSF than for CSB+ w/oil. **Figure 8** displays the adjusted marginal predictions for both adjusted and unadjusted models.

Incidence of fever, vomiting, diarrhea, and cough at graduation were found to be collinear; only incidence of diarrhea was therefore chosen for inclusion as a proxy for comorbidities at graduation. Variables associated with significantly higher odds of sustained recovery in the adjusted model included the child's age, weight gain velocity over treatment period, MUAC at graduation, graduation in rainy season, and being severely food insecure at enrollment.

Figure 8: Percentage Sustained Recovery at 1-month Follow-up, Adjusted Marginal Predictions[1]



1Error bars represent 95% CIs

Table 8: Odds of Sustaining Recovery[1] After Graduation from SFP, Adjusted Mixed Effects Logistic Regression

	Unadjusted			Adjusted (exclude missed)			Missed visits = relapse			Missed visits = sustained		
	OR	**95% CI**	**P-value**	**OR**	**95% CI**	**P-value**	**OR**	**95% CI**	**P-value**	**OR**	**95% CI**	**P-value**
CSB+ w/oil (ref.)												
CSWB w/oil	1.11	(0.77, 1.61)	0.57	1.08	(0.73, 1.6)	0.71	0.94	(0.67, 1.34)	0.75	1.12	(0.76, 1.65)	0.56
SC+A	0.96	(0.68, 1.36)	0.83	0.96	(0.67, 1.4)	0.85	0.85	(0.61, 1.19)	0.35	0.98	(0.68, 1.41)	0.91
RUSF	0.70	(0.51, 0.96)	0.03	0.70	(0.49, 0.99)	0.04	0.64	(0.46, 0.88)	0.01	0.74	(0.52, 1.04)	0.08
Child's age (in months)				1.04	(1.02, 1.06)	0.00	1.02	(1, 1.03)	0.01	1.04	(1.02, 1.06)	0.00
Breastfeeding				0.995	(0.98, 1.01)	0.55	0.993	(0.98, 1.01)	0.39	0.996	(0.98, 1.01)	0.62
Child transferred from SAM				0.996	(0.97, 1.02)	0.71	0.993	(0.97, 1.01)	0.51	0.997	(0.97, 1.02)	0.77
Child admitted to hospital in 2 weeks preceding enrollment				1.57	(0.71, 3.46)	0.26	1.55	(0.8, 3)	0.19	1.48	(0.68, 3.24)	0.32
Diarrhea at graduation (within prior 2 weeks)				0.94	(0.65, 1.37)	0.75	1.01	(0.99, 1.02)	0.47	0.94	(0.64, 1.37)	0.73
Weight gain velocity during treatment period (kg/day)				1.03	(1.01, 1.04)	0.00	1.02	(1.01, 1.03)	0.00	1.02	(1.01, 1.04)	0.00
Average MUAC at graduation				15.03	(6.5, 34.75)	0.00	3.93	(2.14, 7.21)	0.00	15.59	(6.82, 35.63)	0.00
Caregiver's Age				1.002	(0.99, 1.01)	0.55	1.004	(1, 1.01)	0.26	1.002	(0.99, 1.01)	0.59
Household Food Insecurity												
Moderately Food Insecure				1.18	(0.78, 1.8)	0.43	1.15	(0.8, 1.65)	0.46	1.20	(0.79, 1.8)	0.39
Severely Food Insecure				1.38	(1.02, 1.85)	0.03	1.28	(0.99, 1.67)	0.06	1.40	(1.05, 1.87)	0.02
Socioeconomic Status												
Mid-Low				0.73	(0.49, 1.1)	0.13	0.86	(0.61, 1.23)	0.42	0.73	(0.49, 1.09)	0.12
Medium				1.01	(0.67, 1.52)	0.97	1.13	(0.79, 1.63)	0.50	0.96	(0.64, 1.44)	0.85
Mid-High				1.09	(0.71, 1.66)	0.70	1.01	(0.71, 1.46)	0.94	1.08	(0.71, 1.64)	0.73
Highest				0.89	(0.58, 1.37)	0.61	0.80	(0.56, 1.15)	0.24	0.95	(0.63, 1.44)	0.80
Season of Graduation												
Rainy season				1.39	(1.05, 1.82)	0.02	1.29	(1.01, 1.63)	0.04	1.35	(1.03, 1.77)	0.03

1 Sustained Recovery defined as maintaining a MUAC ≥12.5 for 1-month after graduation

As detailed in **Table 3**, the proportion of missed visits at the one-month follow-up visit varied across arms. To understand whether these differences in attendance at the one-month follow-up could have influenced conclusions of the analysis, sensitivity analysis was conducted. **Table 8** details adjusted models for two scenarios: [A] all missed visits categorized as having relapsed to MAM or [B] all missed visits categorized as having sustained recovery post-graduation. The direction of the effect in both models was consistent with the main model that excluded missed visits. While RUSF had significantly lower sustained recovery than CSB+ w/oil in the main model and in model B, it was only marginally significant (p=0.08) for model A.

8.3 Summary

The four SNFs performed similarly across measures of effectiveness. Though the total sample size was lower than expected, the effectiveness differences between the foods were small, making it unlikely that a statistical difference would have been detected even if the full sample size had been achieved. Compared to CSB+ w/oil, the odds of sustained recovery at one-month post-treatment were lowest among children receiving RUSF.

9. Costs & Cost-effectiveness

9.1 Methods

a. <u>Costs</u>

Five costing perspectives are shown in **Figure 9**, with more detail found in **Appendix 3**. The figure details costs incurred by different stakeholders related to implementation of the SFP. Two combined perspectives were used in the cost-effectiveness analyses: the *program perspective* (combining donors, implementers, government, and lead mother volunteers [i.e., entities associated with the provision of services]) and the *combined program and caregiver perspective,* which incorporates the cost to caregivers of participating in the program.

Figure 9: Five costing perspectives and the included stakeholders

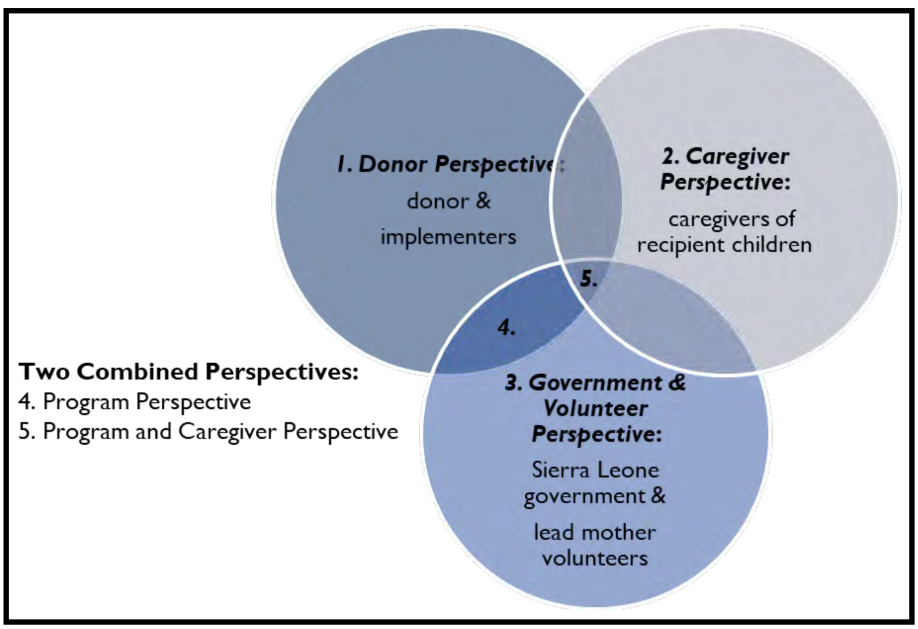


Figure 10: Cost components, summary cost measures, and cost-effectiveness measures

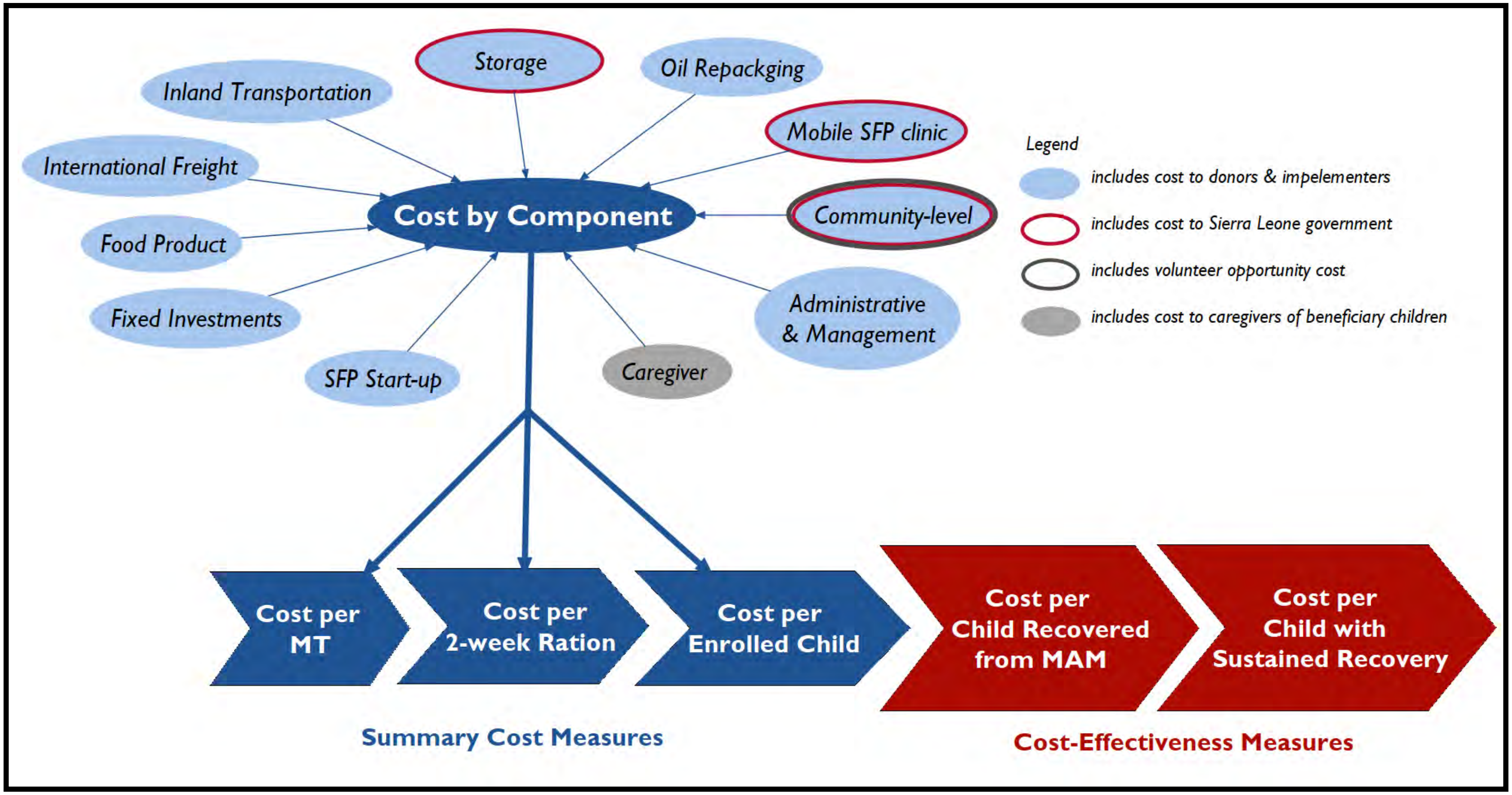


Table 9: Definition of cost components and corresponding data sources

Cost Component	Definition	Study Instruments & Data Sources
Start-up Activities	Cost to set up the supplementary feeding program during the start-up period (between 09/2016 and 03/2017), including setting up Pujehun food storage, clinic scoping, supplies purchasing, clinic staff training, community health worker outreach.	Accounting records from PPB- Sierra Leone
Fixed Investment	Cost of fixed investments for the supplementary feeding program, including equipment/technology, fixed materials, vehicles, and PPB Pujehun office space.	Accounting records from PPB- Sierra Leone
Food Product	Cost of the specific specialized nutritious food and fortified vegetable oil	Realistic price quotes for experimental products from Didion Milling; Historical procurement price data for standard products from FFP and WFP
International Freight	Cost of international shipping from the United States to Freetown, Sierra Leone	Realistic quotes from BKA Logistics
Inland Transportation	Cost of food transportation and loading/unloading from Freetown to Kenema WFP Warehouse, and from Kenema Warehouse to Pujehun Storage. (transportation and labor)	Observation[1] (2) instruments from the study; Accounting records from WFP-Sierra Leone and PPB- Sierra Leone
Storage	Cost of storing the foods at the WFP warehouse in Kenema and at the Pujehun Storage. (government-provided space, labor, relevant services, and variable supplies)	Accounting records from WFP-Sierra Leone and PPB- Sierra Leone
Repackaging (fortified vegetable oil ONLY)	Cost of repackaging fortified vegetable oil 4L cans into small bottles (labor and materials)	Observation[1] (2) instruments from the study; Accounting records from PPB- Sierra Leone
Mobile Supplementary Feeding Program Clinic Activities	Cost of staff and food transportation between PPB Pujehun office and 28 PHUs and distribution of food and other MAM treatment activities at the PHUs. (labor, accommodation, transportation, and variable supplies)	Observation[1] (~2 per PHU for 28 PHUs) instruments from the study; Accounting records from PPB- Sierra Leone, and government salary information
Community-level Activities	Cost of conducting community-level activities including IEC, screening of MAM cases, outreach for missed visits, training etc. (labor cost of staff and CHWs, and opportunity cost of lead mothers' time)	Interview (193 CHWs and 178 lead mothers) instruments from the study; Accounting records from PPB- Sierra Leone, and government salary information
Administrative and Management Activities	Cost of managing the supplementary feeding program (labor, transportation, relevant services, and variable supplies)	Accounting records from PPB- Sierra Leone
Caregiver Activities	Monetary and opportunity cost of caregivers' time participating in the program, including transportation spending and time, clinic time, time for community activities, and household study food preparation/serving and feeding time	Observation (373 caregivers at PHUs and 269 caregivers at households) and interview (957 caregivers, 193 CHWs, and 178 lead mothers) instruments from the study

CHW: community health workers; MAM: Moderate Acute Malnutrition; IEC: Information, Education, and Communication; L: liter; PHU: Peripheral Health Unit; PPB: Project Peanut Butter; WFP: World Food Programme

[1] *In most cases, one observation took place in 2017 and the other took place in 2018.*

An activity-based with ingredients costing approach was used which identified 11 cost components.[44] These cost components are shown in **Figure 10** and defined in **Table 9. Figure 10** describes in more detail which stakeholders contributed to each cost component. Cost data were collected using a variety of study instruments and data sources (see **Table 9**). In addition to using data on costs actually incurred in the study, more realistic cost estimates for product procurement and international freight were obtained externally from historical cost data or price quotes from suppliers so that data could be generalized to other contexts. This was necessary because two of the foods were novel and procured only for the present study; the unit price was higher for the small quantities required than would have been the case if the foods had been ordered for a full-scale program.
Details on how product and international freight costs were derived are explained in the footnotes of

Figure 11: Methods Used to Assess Cost-Effectiveness for Each Arm

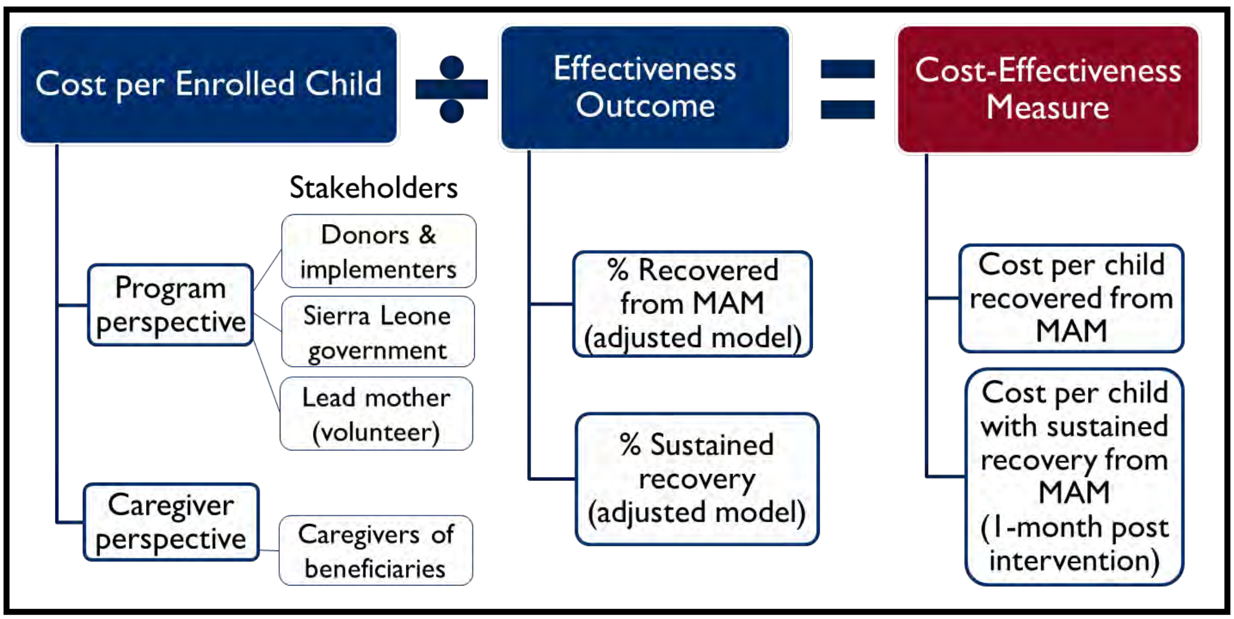


Table 10 and **Table 11**.

Cost data for each component were summarized into one of three summary cost measures for each arm (**Figure 10**):

- Cost per MT
- Cost per biweekly ration
- Cost per enrolled child

For each arm, cost per MT and cost per biweekly ration were converted to cost per enrolled child by either biweekly ration size or number of rations received. Differences in adherence to food collection or treatment duration by arm were accounted for in the cost comparisons.

Total cost per enrolled child was calculated by summing the cost components for each of the five costing perspectives separately. To represent variation in total cost from the caregiver perspective, uncertainty ranges were constructed using distributions of time for activities that differed by arm (e.g., preparation time or time spent at the first clinic visit). (See **Section 7.2** and **Appendix 3** for more details.)

All cost results presented in "$" are 2018 USD based on annual exchange rates between Sierra Leone leones (SLL) and USD and adjusted for inflation (annual rates of US GDP implicit deflator). The opportunity cost for lead mothers and caregivers was valued at $0.38 per hour based on the Sierra Leone minimum wage of SLL 500,000 per month, assuming five workdays per week, eight hours per day, and 10 national holidays per year.

Each of the three FBFs procured for this study was in some way a novel specification (in packaging and/or formulation), while RUSF and FVO were standard specifications. The FBFs and FVO were imported from the United States, while RUSF was procured locally in Sierra Leone. Novel formulations could affect the product cost, while novel packaging and procurement channels could affect both product cost and international freight cost. To explore the cost implications of different specifications and procurement channels in comparable conditions across arms, four policy-relevant scenarios were constructed and described in **Appendix 3**. Scenario 1 served as the primary scenario used for cost-effectiveness analysis for the following reasons:

- Package specifications other than those used in the study could result in an unobserved impact on effectiveness.
- Assuming the same procurement channel improves comparability across arms.
- Data sources for imported products are more available and more comparable than data sources for Local and Regional Procurement (LRP) products. For example, only RUSF and FVO have been procured from West African suppliers by WFP in recent years.
- USAID/FFP procures most SNFs from the United States, making it the procurement channel most immediately relevant to policy.

Results for scenarios 2-4 can be found in **Appendix 3**.

Table 10: Comparing Product Cost ($ Per MT) Based on Different Product Specifications and Procurement Channels.

		CSB+			CSWB			SC+			RUSF			Oil (FVO)		
Specification	Procurement channel	Detail	Cost/ MT	Data source	Detail	Cost/ MT	Data source	Detail	Cost/ MT	Data source	Detail	Cost/ MT	Data source	Detail	Cost/ MT	Data source
Standard	imported from USA	25kg bag	556 (443, 700)	USAID[1]	25kg bag	1000	Didion[2]	SC+ 1.9kg bag	1555 (1406, 1657)	USAID[1]	100g sachet	2,835	USAID[4]	4L can	1256 (1123, 1534)	USAID[1]
Experimental	imported from USA	1.2kg bag	1,204	Didion[2]	1.2kg bag	1,442	Didion[2]	SC+ with amylase (SC+A)	1,886	Didion[2]	N/A	N/A	N/A	N/A	N/A	N/A
Standard	LRP	Suppliers in Africa	642	WFP[3]	N/A	N/A	WFP[3]	SC+ Suppliers in Africa	1,407	WFP[3]	Suppliers in West Africa	3,107	WFP[3]	Suppliers in West Africa	1,487	WFP[3]

1 Mean (Min, Max) of USAID 2016 -2017 historical transaction prices for products imported from USA to West Africa, with additional in-country inspection cost provided by WFP-Sierra Leone for imported foods. * West Africa as defined by USAID Food For Peace trading route regions.*

2 Price quotes for experiemental specifications (with initial captial cost) at scaled production of >500 MT from Didion, a major US food aid supplier (to mimic common program procurement scale), with additional in-country inspection cost provided by WFP-Sierra Leone for imported foods.

3 Only mean was provided by WFP based on WFP's 2016-2018 historical transaction prices for products locally or regionally procured in Africa, with additional in-country inspection cost provided by WFP-Sierra Leone for locally procured foods. All LRP products were in standard specifications. No suppliers in West Africa had produced CSB+ and SC+ for WFP in the past, so LRP cost data for CSB+ and SC+ came from suppliers outside of West Africa in the continent.

4 Only one historical transaction available for RUSF throughout USAID 2016 -2017 which was imported from USA to Burundi, with additional in-country inspection cost provided by WFP-Sierra Leone for imported foods.

Table 11: Comparing International Freight Cost ($ per MT) from USA to Freetown, Sierra Leone

Flag Vessel	CSB+ & CSWB. (25 kg Bag)	SC+A (1.9 kg Bag), CSB+ & CSWB (1.2 kg Bag) 3	RUSF. (100 g)	FVO (4 L Can)
P2[1]	130	137	145	150
P3[2]	110.5	117.5	125.5	131.5

Data source: BKA Logistics.

Acronyms: CSB+: Corn Soy Blend Plus; CSWB: Corn Soy Whey Blend; SC+A: Super Cereal Plus with Amylase; RUSF: Ready-to-Use Supplementary Food; FVO: Fortified Vegetable Oil;

1 P2: US flag vessel from USA with a foreign flag vessel relay to final discharge port. P2 rates took an average between shipments from US Gulf and from US East Coast. P2 rates were used to estimate international freight cost in the cost and cost-effectiveness analyses of this study.

2 P3: foreign flag vessel entire ocean transport. P3 rates took an average between shipments from US Gulf and from US East Coast.

3 International freight rate for SC+ (1.9kg bag) was used as proxy for SC+A(1.9kg), CSB+ (1.2 kg), and CSWB (1.2kg) because of similarities in packaging size.

4 International freight rate for RUTF(100g) was used as proxy for RUSF(100g) because of similarities in packaging size.

b. Cost-effectiveness

As shown in **Figure 10** and **Figure 11**, there are two effectiveness measures: 1) recovery from MAM, and 2) sustained recovery at one month post-intervention. The formulas below describe how each cost-effectiveness measure was calculated:

Per Arm – Cost per Child Recovered from MAM

$$= \frac{Number\ of\ Enrolled\ Children * Cost\ per\ Enrolled\ Child}{Number\ of\ Enrolled\ Children * \%\ Recovered\ from\ MAM}$$

$$= \frac{Cost\ per\ Enrolled\ Child}{\%\ Recovered\ from\ MAM}$$

Per Arm – Cost per Child Who Sustained Recovery

$$= \frac{Number\ of\ Enrolled\ Children * Cost\ per\ Enrolled\ Child}{Number\ of\ Enrolled\ Children * \%\ Recovered\ from\ MAM * \%\ Sustained\ Recovery}$$

$$= \frac{Cost\ per\ Enrolled\ Child}{\%\ Recovered\ from\ MAM * \%\ Sustained\ Recovery}$$

Cost-effectiveness uncertainty ranges corresponding to cost per child recovered were constructed using the following process:

- Marginal mean effects of recovery and sustained recovery were estimated based on predicted probabilities of the adjusted effectiveness models (see **Section 7.2** for more details).
- Uncertainty ranges for recovery rates across arms were constructed based on 95% CIs of marginal mean effects from the adjusted model.

Cost-effectiveness uncertainty ranges corresponding to cost per child who sustained recovery were constructed using the following process:

- Depending on the specific model for sustained recovery, a recovered child who missed the one-month visit was included in the analysis by simulating his or her outcome as either all relapsed or as all sustained recovery.
- The average point estimate from the imputation simulations of the adjusted model provided point estimates of the arm-specific sustained recovery rates used to construct uncertainty ranges.

In addition to uncertainty around effectiveness, uncertainty around cost to caregivers as described in the previous section was also included in the cost-effectiveness uncertainty ranges for combined program and caregiver perspectives.

All cost and cost-effectiveness analyses were conducted using Microsoft Excel 2016 and R version 3.4.1.

9.2 Results

a. Costs – Program Perspective

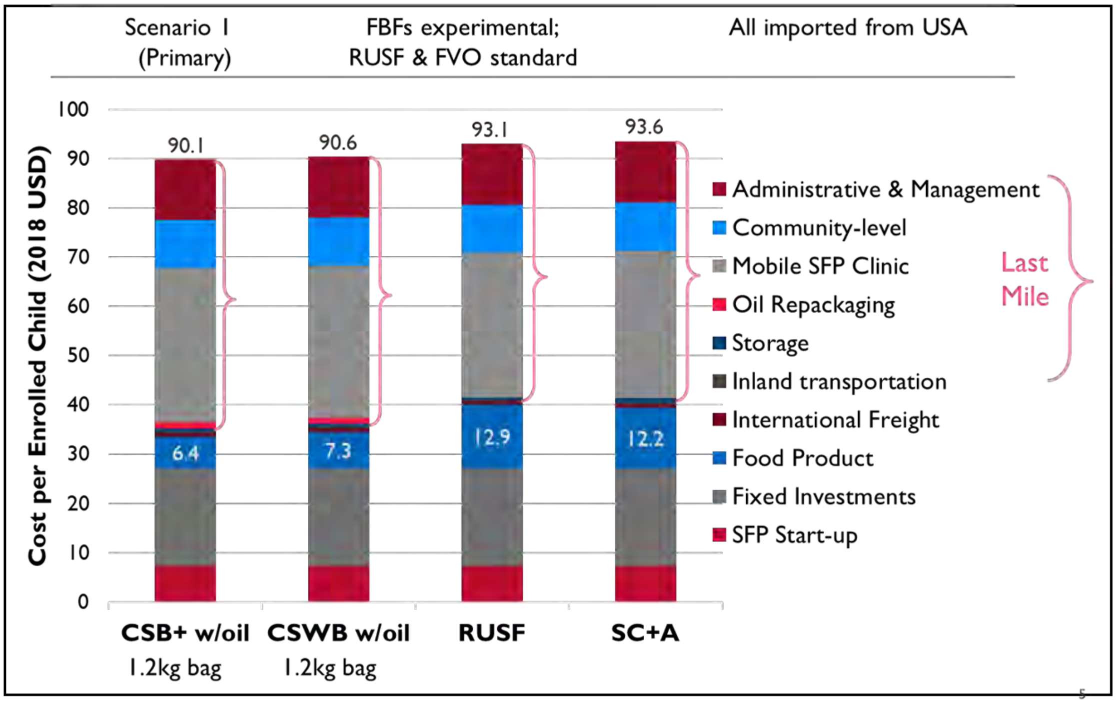
Product Cost and International Freight Cost

To mimic procurement sizes used in typical programming contexts, the price quotes for novel specifications (formulation and/or packaging) were estimated at scaled production >500 MT as shown in **Table 11**. Assuming all foods were imported from the United States, the product cost per MT was much higher for novel specifications compared to their standard counterparts. This seemed to be because some amount of initial capital cost per MT was applied to all novel specifications in the price quotes provided by Didion Milling. At a more realistic program scale, these costs would be amortized over a larger quantity, and the cost per MT would be lower. After deducting the initial capital cost from the price quotes, the absolute cost difference between the two packaging specifications (novel versus standard) was the same for both CSB+ and CSWB flours. Similarly, the absolute difference between the two was the same for packaging in 25 kg bags compared to 1.2 kg bags. For both CSB+ and CSWB, switching packaging into better material and smaller sizes increased overall product cost more than modifying the formulation.

Another arm-specific factor was the cost difference between international and locally procured foods. Product cost per MT was higher when a standard product was locally procured than when imported from the United States (**Table 10**). Of the four foods, RUSF had the most comparable local procurement data obtainable, resulting in a reported product cost difference (local versus international) of $272/MT. There were two elements driving this higher cost: higher local procurement costs and higher in-country inspection costs. The mean procurement price for RUSF paid by WFP to West African suppliers from 2016 to 2018 was approximately $100/MT higher than RUSF procured by USAID from American suppliers from 2016 to 2017. This is despite the U.S.-based commodity price including inspection costs from a U.S.-based lab. Inspection costs of locally procured RUSF were $1,630 per tranche in addition to the product price. Products imported from the United States only incurred additional inspection fees of $25 per shipping container. A major USAID freight forwarder provided international freight quotes for standard products on two types of flag vessels. These quotes served as proxies for the cost of shipping novel products with similar packaging specifications from the United States to Sierra Leone. Shipping via U.S. flag vessels was approximately $20/MT more expensive than via foreign vessels (**Table 11**). Comparing across the study foods' different specifications, packaging differences did not substantially affect international freight cost per MT.

Cost from the Program Perspective

Figure 12: Program Perspective Cost per Enrolled Child.



The primary scenario analysis considers all foods with the product specifications used in the study and imported from the United States. Cost per enrolled child in this scenario was similar across the four arms, with CSB+ w/oil being the lowest at $90 per child and SC+A the highest at $94 per child (**Figure 12**).

On average, children collected 3.3 to 3.4 rations during treatment in each arm. The largest *difference* in cost across arms was product cost. Other minor sources of cost difference included oil repackaging cost (~$1 per child for CSB+ w/oil and CSWB w/oil only) and supply chain costs per enrolled child including international freight, inland transportation, and storage (~$0.60 per child difference between the lowest [RUSF] and highest [SC+A] arms).

The CSB+ w/oil and CSWB w/oil arms had about $2 per child higher mobile SFP clinic-attributable costs than RUSF and about $1 per child higher than SC+A. Food-specific differences in the amount of time spent at clinic arising from the cooking demonstration and oil distribution likely account for these differences in clinic-attributable costs (see "last mile" section of **Figure 12**).

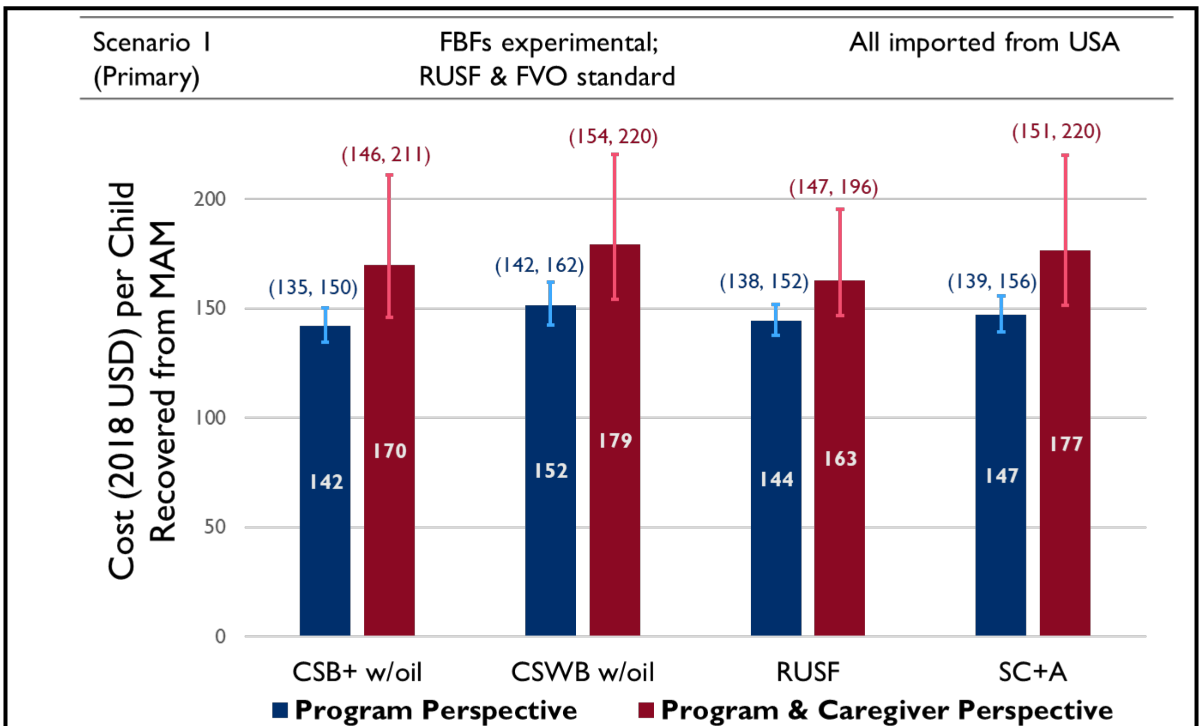
Though product cost drove cost *differences* across arms, product cost was not the largest *component* of the total cost. The largest component of total cost in this context was the cost associated with the mobile SFP clinic (see **Section 3.1** for more details). The mobile-based SFP may have had higher transportation costs than site-based or integrated models due largely to the biweekly Land Cruiser usage.

The mobile SFP clinic cost is also part of the last mile costs, defined as in-country costs including inland transportation, storage, oil repackaging, distribution/clinic, community-level activities, and administrative and management activities (**Figure 12**). Last mile costs constituted more than half of the total cost across arms, contrasting with FAQR findings in another report about last mile costs in other types of food aid programs (e.g., blanket supplementary feeding).[33] Additionally, lower-than-expected caseload in the catchment areas increased the last mile costs per enrolled child because full capacity of input resources was not reached.

b. Cost-effectiveness – Program Perspective

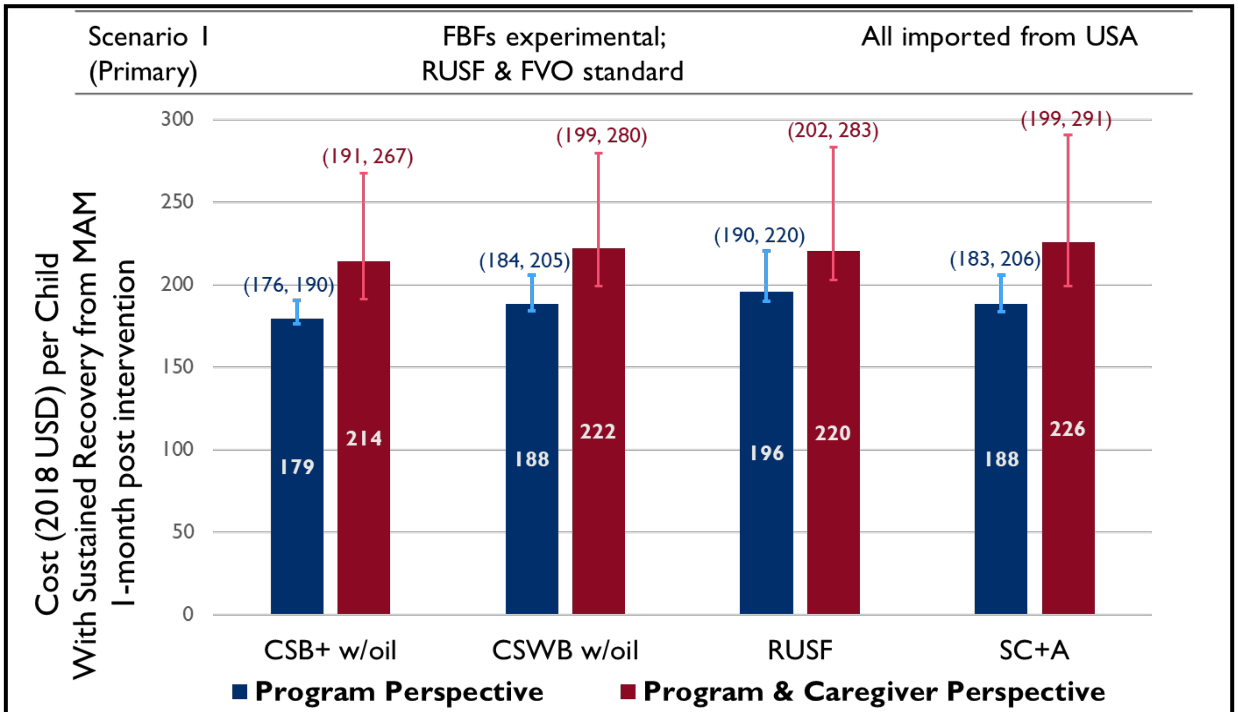
The cost-effectiveness results are shown for cost per child recovered from MAM in **Figure 13** and for cost per child with sustained recovery in **Figure 14**. From the program perspective, CSB+ w/oil had the most cost-effective point estimate for both recovery and sustained recovery. For cost per child recovered from MAM, all arms were similarly cost-effective, with mostly overlapping uncertainty ranges. While CSB+ w/oil was only $2 less than RUSF in cost *per child recovered from MAM*, CSB+ w/oil was $18 less than RUSF in cost *per child with sustained recovery,* with barely overlapping uncertainty ranges. This suggests that RUSF was significantly less cost-effective than CSB+ when considering cost-effectiveness based on sustained recovery.

Figure 13: Cost per Child Recovered from Moderate Acute Malnutrition (MAM): Program Perspective Versus Program & Caregiver Perspective



Error bars for both perspectives use 95% confidence intervals of recovery rate from the adjusted effectiveness model. Error bars for program & caregiver perspective also incorporate uncertainty around time cost of caregivers (±1 SD).

Figure 14: Cost per Child Sustained Recovery 1-month post intervention: Program Perspective Versus Program & Caregiver Perspective



Error bars for both perspectives used point estimates of sustained recovery from two adjusted models that treated missed visits at 1-month post intervention as all sustained recovery and as all relapsed.
Error bars for program & caregiver perspective also incorporate uncertainty around time cost of caregivers (±1 SD).

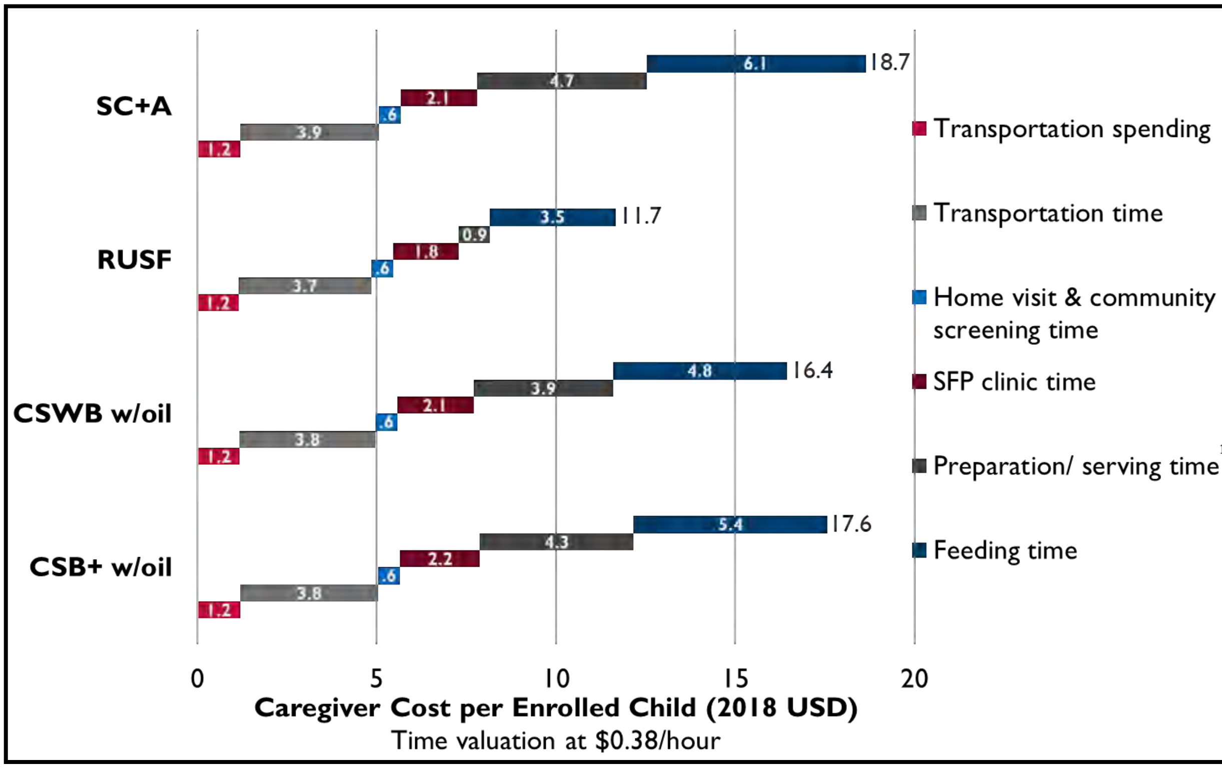
c. Costs – Caregiver Perspective

Total cost per enrolled child from the caregiver perspective varied across arms. As the only ready-to-use product of the four SNFs, RUSF had the lowest total cost for caregivers: about $5-7 per enrolled child lower than the FBF arms (**Figure 14**), though this figure is dependent on the valuation of time chosen for the analysis.

From the caregiver perspective, across-arm cost differences resulted from differences in time that caregivers devoted to relevant activities both during the SFP and in the home. Among these activities, the largest driver of cost differences was the observed caregivers' time spent on study food preparation/serving and feeding at home. Even though 32% of caregivers in the RUSF arm were observed to use RUSF as an ingredient to cook a home meal for the children, the average cost attributable to time over the entire sample in the RUSF arm remained lower than in the FBF arms. Caregivers in the RUSF arm also spent less time feeding the beneficiary child than in the FBF arms. Among the three FBF arms, caregivers receiving SC+A consistently spent the most time preparing and feeding per meal.

The opportunity cost of caregivers' time spent at the SFP clinic was a minor source of cost differences across arms, which was about $0.30 per enrolled child lower in the RUSF arm. During the first visit, where children were enrolled into the program, caregivers in the RUSF arm spent about 36-53 minutes less at

Figure 15: Caregiver Perspective Cost per Enrolled Child



the SFP clinic than those receiving any of the FBFs. This difference occurred because the individual taste test for RUSF took less time than the group cooking demonstration for FBFs at the first/enrollment visit.

Relating to food-specific differences in caregivers' opportunity costs at the intake visit, one theme identified during focus group discussion was "forgetfulness" due to factors such as the time-intensive nature of the demonstration and a generalized lack of attention as a result. This is described in more detail in **Section 9.2.b**.

Caregivers' monetary and time costs for transportation and community-level activities were not arm-specific (**Figure 15**). About 16 to 17% of caregivers who completed an in-depth interview (IDI) reported having to pay on average $1.10 for transportation each way to collect a single biweekly ration of study foods. Therefore, the average transportation spending for the whole sample was about $0.40 per enrolled child. Regarding opportunity costs related to transportation time, caregivers reported traveling on average of three hours round-trip to collect a biweekly ration of study foods, which totaled about $3.80 per enrolled child. The opportunity cost of caregivers' time spent in community-level activities, including home visits and community screening, was $0.60 per enrolled child. Other transportation and travel challenges included the long distance to get to the clinic and environmental obstacles such as rain, flooding, rough terrain, and hot sun. Travel by foot was the only mode of transportation reported across all arms. This was confirmed during FGDs; those who walked to the clinic explained that their personal limited resources were a constraint to paying for transportation, which resulted in spending the majority of the day getting to and from the clinic.

> *I walked with my naked foot to come. If you ask anybody to bring you, to leave his own business, he will ask you to pay big money, and my husband is bankrupt; even me, I am hard-up. What I do is walk with my naked foot. (FGD #7, Respondent 6)*

To assess variability in caregivers' time, uncertainty ranges for total cost per enrolled child were estimated from the caregiver perspective (**Table 12**). The values for the upper and lower bounds of the RUSF uncertainty ranges were consistently smaller than the corresponding bounds of uncertainty ranges for the FBF arms. However, due to the large variation within each arm, the uncertainty ranges for RUSF still overlapped with those for the FBF arms.

d. Cost-effectiveness - Cost from All Stakeholder Perspectives
Different sets of stakeholders contributed to the cost of the SFP in several components. **Table 12** shows the summarized cost per enrolled child from each of the five perspectives defined in **Figure 9**. Cost per enrolled child from the donor and implementer perspective was the highest, regardless of the arm. Meanwhile, cost per enrolled child from the caregiver perspective had the largest differences across arms. Opportunity cost of lead mother volunteers and free space provided by the government was $7 per child for each arm.

Comparing the two combined perspectives (program versus program and caregiver) in **Table 12**, SC+A remained the most expensive arm in both. While RUSF was about $3 per child more than CSB+ w/oil and CSWB w/oil from the program perspective, RUSF was about $3 per child less than these two arms when the program and caregiver perspectives were combined.

e. Cost-effectiveness – Combined Program and Caregiver Perspective
The cost-effectiveness results are shown in **Figure 13** for cost per child recovered and in **Figure 14** for cost per child with sustained recovery.

From the combined program and caregiver perspective, RUSF had the most cost-effective point estimate for cost per child recovered from MAM, while CSB+ w/oil had the most cost-effective point estimate for cost per child with sustained recovery. From the combined perspective, all uncertainty ranges for the two cost-effectiveness measures (program and caregiver) overlapped across all four arms.

9.3 Summary

Table 12: Cost per Enrolled Child Corresponding to Each Perspective

Perspective	CSB+ w/oil	CSWB w/oil	RUSF	SC+A
Donor & Implementer	83	83.5	86	86.5
Government & Volunteer[1]	7.1	7.1	7.1	7.1
Caregiver	17.6	16.4	11.7	18.7
	(7.6, 36.4)[2]	(7.5, 32.7)[2]	(6.1, 26.7)[2]	(8.0, 38.6)[2]
Program	**90.1**	**90.6**	**93.1**	**93.6**
Program & Caregiver	**107.7**	**107**	**104.7**	**112.3**
	(97.7, 126.5)[3]	**(98.1, 123.3)[3]**	**(99.2, 119.8)[3]**	**(101.6, 132.2)[3]**

[1] Includes storage space provided by government, community health worker Base Pay by government, and volunteer opportunity cost of lead mothers involved in community-level activities.
[2] Constructed based on mean ± 1 SD of time per occasion for caregiver activities that were sources of across arm differences
[3] Constructed by incorporating the ranges for caregiver perspective cost

From the program perspective, cost per enrolled child and cost per child recovered from MAM were similar across the four foods when they were imported from the United States. Cost per child with sustained recovery was lowest for the CSB+ w/oil arm, and RUSF was less cost-effective than CSB+ w/oil.

Cost per enrolled child from the caregiver perspective was lower for the RUSF arm mostly due to its ready-to-use nature. However, the addition of this perspective to the analysis did not alter conclusions that the four foods performed similarly in terms of cost per recovered child. CSB+ w/oil remained lower in cost per child with sustained recovery with overlapping uncertainty ranges.

The only out-of-pocket spending for caregivers was about $0.40 per enrolled child on average to pay for transportation. The majority of the caregiver costs was the opportunity cost of caregivers' time spent in relevant activities such as transportation, SBCC, SFP clinic, and study food preparation/serving and feeding at home. The largest drivers of caregiver cost differences across arms were preparation/serving and feeding, especially between RUSF and the three FBFs. Among the three FBFs, SC+A was observed to have the highest preparation and feeding time. Differences in total caregiver perspective cost per enrolled child was $7 between the lowest cost option, RUSF, and the highest cost option, SC+A.

10. Other Factors Influencing Effectiveness

10.1 Methods

Quantitative outcomes related to factors influencing the effectiveness of the four foods were based on data from the subsamples of households who underwent in-home observation (IHO) for five consecutive days and/or participated in an IDI and linked with the clinic data for outcomes. Qualitative information was from either enumerator notes recorded during in-home observations or from FGDs.

a. Consumption and Sharing

The following descriptive statistics were calculated: observed consumption of the study food ration by the target child and others, and observed sharing of the study food ration, by both study arm and day of observation; self-reported sharing of the study food ration and reasons for sharing; self-reported dietary diversity. In addition, displacement of household complementary foods was assessed through a 24-hour dietary diversity recall using bivariate logistic regressions. Food groups consumed by children were reported by caregivers based on a 24-hour reference period, determined based on the IYCF minimum diet diversity (MDD) score, and regressed on assigned study arm.

b. Recipe Adherence Behavior

All caregivers received counseling regarding the correct quantities and proportions of water, flour, and, where relevant, FVO (see **Figure 1**). The unit of measurement was a standard baby feeding cup that was readily available in every village and most households (see **Section 5.2**). In all households surveyed, this common unit was available.

The recommendations for the quantity of FVO and FBF were made in grams (g). However, the unit of measurement at the household and for data collection was milliliters (ml). The target quantities of flour for the FBF arms were therefore 85.7 g = 150 ml for CSB+ w/oil; 85.7 g = 150 ml for CSWB w/oil; and 135.7 g = 210 ml for SC+A. Caregivers were categorized as reporting the “correct” amount of flour if they were within ±10 ml of the target amount. In the CSWB w/oil and CSB+ w/oil arms, the target quantity of FVO was 26 g = 30 ml. Caregivers were categorized as reporting the correct amount of FVO if they were within ± 5 ml of the target amount.

The target ratio of flour to water in the CSB+ w/oil and the CSWB w/oil arms was 0.33 and 0.4 for SC+A. The same lower and upper bounds used to categorize correct flour measures were applied to water (450 ml ± 10 ml) in the CSB+ w/oil and CSWB w/oil arms and in the SC+A arm (525 ml ± 10 ml). The upper bound of the correct flour to water ratio was therefore set at 160/440 (~0.36) and the lower bound at 140/460 (~0.30) in the CSB+ w/oil and the CSWB w/oil arms. In the SC+A arm, the upper bound was set at 200/535 (~0.43) and the lower bound at 220/515 (~0.37).

Care and feeding practices observed during IHOs were compared to self-reported information in the IDIs. Following guidance correctly was defined as when caregivers reported using the correct ingredients and no other ingredients. For RUSF, the definition of adherence was defined as eating it straight out of the packet and not mixing it with other foods. Caregivers observed cooking the FBFs using only the recommended ingredients were categorized as correctly adhering to the recipe guidance. Similarly, caregivers observed feeding the beneficiary child the RUSF without mixing it with other foods were categorized as adhering to the recipe guidance.

Descriptive summary data reported the percentage of respondents self-reporting or the percentage of households in which the behavior was observed. Descriptive statistics included the percentage of respondents *reporting* to use of correct ingredients compared to percentage of households *observed* to use the correct ingredients at least once during the five-day period; the percentage of respondents accurately reporting the quantity of ingredients used at last preparation for the FBF arms; and the percentage of households observed to measure all the ingredients at least once during the five-day observation.

10.2 Results

a. Demographic Characteristics of Interviewed and Observed Households

In the subsample, a total of 962 caregivers were interviewed (IDI), of whom 321 households were also observed (IHO). Demographic differences between the two subsamples are detailed in **Table 13**: caregivers were generally married, uneducated, and in their late 20s across arms and subsamples. Beneficiary children were generally still breastfeeding (>75%) and had similar MUAC at enrollment (12 cm ± 0.3) and similar graduation rates, illustrating that the subsample was comparable to the full study sample.

Consumption and Sharing

Figure 16: Observed consumption of the study food at least once during the 5-day observation period

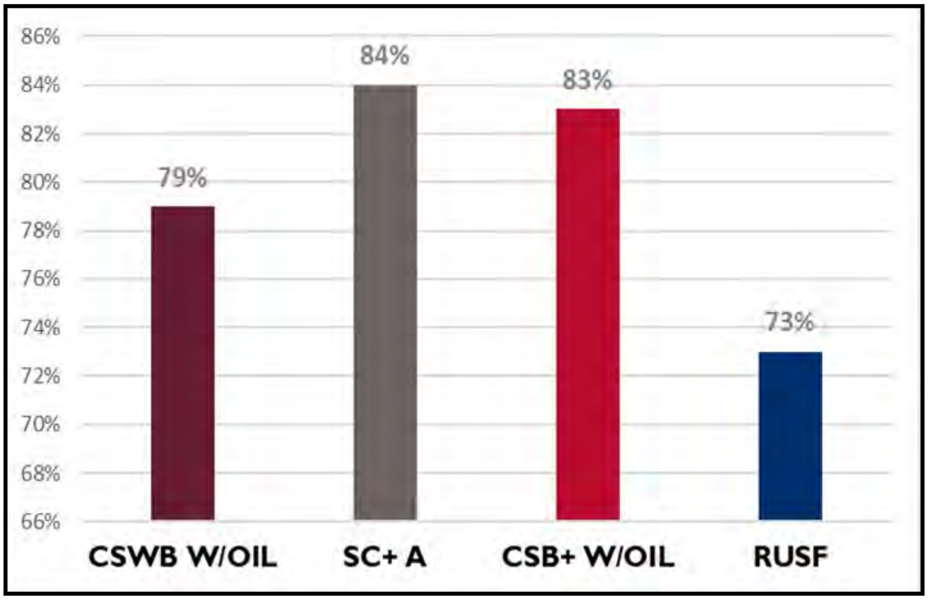
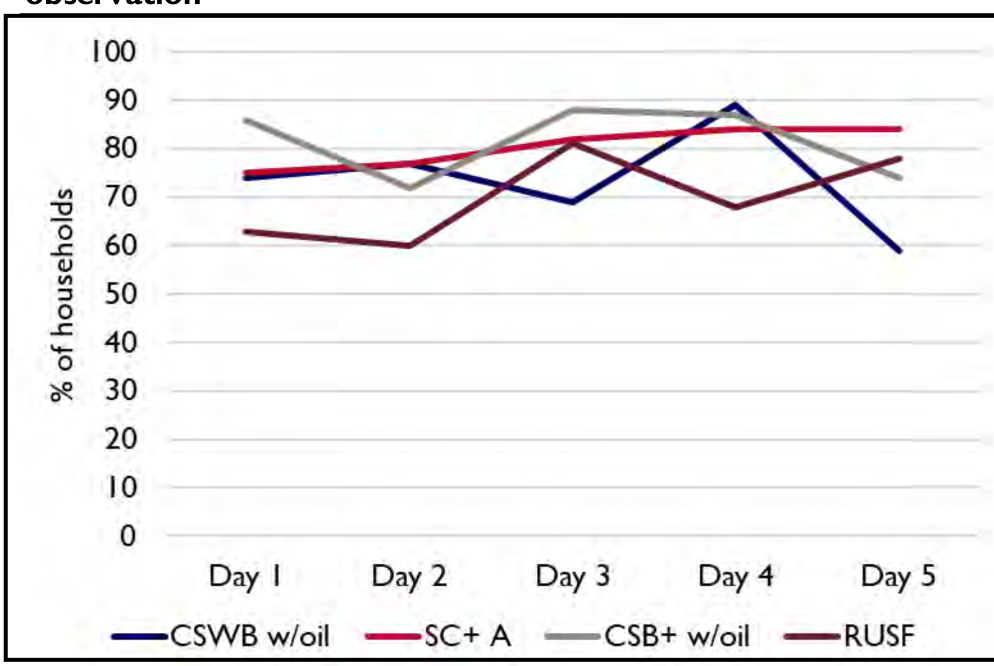


Figure 17: Observed consumption by study arm and day of observation



Overall, the target recipients were observed consuming the study foods at least once during the five-day observation period in 80% of observed households. **Figure 16** shows the percentage of households in which the target child was observed eating the study food at least once during the five-day observation period, by study arm. There were no discernable consumption trends by day of observation **Figure 17**.

Consumption was also discussed among caregivers in FGDs. Overall and within each arm, nearly all of the respondents reported that the beneficiary child consumed the ration normally. When asked about daily ration consumption, respondents across arms reported serving the study food more than once per day, with some in the CSB+ w/oil and RUSF arms reporting serving the food only once. Having leftovers was evident in all FBF arms, with the largest number in the CSB+ w/oil arm. Leftovers were not mentioned in the RUSF arm during FGDs.

> *She eats it [the SC+A] three times, but I cook it only one time. I only cook the one that will be enough for her. (FGD #8, Respondent 6)*

Other consumption and utilization patterns emerged during FGDs. In the RUSF and CSWB w/oil arms, the ration was consumed by caregivers. Respondents in the RUSF arm reported tasting or consuming the food during feeding times. “Testing” the food prior to giving it to children was a perceived common behavior. Consumption of the food by the caregivers occurred in the CSWB w/oil arm when children refused to consume the entire portion and leftovers remained. No respondents indicated that their consumption of the study affected the 14-day ration supply.

> *I also tasted it [the RUSF], because as a mother whenever you are feeding a child you have to taste it first. (FGD #9, Respondent 5)*

> *For me, I give the food [CSWB w/oil] to my child and after she has eaten a little, I take the rest [of the food] in my own pan and we go to the farm. (FGD #11, Respondent 6)*

Giving the FBFs foods to the beneficiary children raw, without cooking it, was a theme that arose among the SC+A and CSB+ w/oil study arms. This was expressed as an act of appeasing a crying child by one caregiver in the CSB+ w/oil arm.

> *My child started eating the raw/dry blended [CSB+] when I received the last supply. she eats it [raw] once a day, only when she cries for it while I am preparing to cook it [the food]. (FGD #7, Respondent 1)*

Table 13: Demographic Characteristics of Respondents and Observed Households

	CSWB		SC+		CSB+		RUSF		Total	
	IDI	IHO	IDI	IHO	IDI	IHO	IDI	IHO	IDI	IHO
Child enrollment characteristics	*n (%) or mean ± SD*		*n (%) or mean ± SD*		*n (%) or mean ± SD*		*n (%) or mean ± SD*		*n (%) or mean ± SD*	
n	**213 (22.14%)**	**69 (21.5%)**	**249 (25.88%)**	**83 (25.86%)**	**251 (26.09%)**	**90 (28.04%)**	**249 (25.88%)**	**79 (24.61%)**	**962**	**321**
Male gender	82 (38.5%)	22 (31.9%)	96 (38.6%)	33 (39.8%)	108 (43%)	37 (41.1%)	116 (46.6%)	39 (49.4%)	402 (41.8%)	131 (40.8%)
Age, months	12.5 ± 8.1	11.9 ± 6.1	13.1 ± 8.7	12.6 ± 8	12.6 ± 7.8	11.5 ± 5.9	14 ± 8.9	13.1 ± 7.3	13.1 ± 8.4	12.3 ± 6.9
Breastfeeding	172 (80.8%)	55 (79.7%)	195 (78.3%)	65 (78.3%)	205 (81.7%)	77 (85.6%)	188 (75.5%)	58 (73.4%)	760 (79%)	255 (79.4%)
Transferred from SAM	40 (18.8%)	15 (21.7%)	66 (26.5%)	22 (26.5%)	62 (24.7%)	25 (27.8%)	71 (28.5%)	22 (27.8%)	239 (24.8%)	84 (26.2%)
Twin (at enrollment)	9 (4.2%)	3 (4.3%)	10 (4%)	3 (3.6%)	10 (4%)	5 (5.6%)	0 (0%)	0 (0%)	29 (3%)	11 (3.4%)
Admitted to hospital (past 2 weeks)	2 (0.9%)	1 (1.4%)	9 (3.6%)	0 (0%)	10 (4%)	4 (4.4%)	8 (3.2%)	2 (2.5%)	29 (3%)	7 (2.2%)
Morbidities (presence of in past 7 days)										
Fever	76 (35.7%)	17 (24.6%)	83 (33.3%)	21 (25.3%)	72 (28.6%)	16 (17.6%)	66 (26.5%)	20 (25.3%)	297 (30.8%)	74 (23%)
Diarrhea	19 (8.9%)	5 (7.2%)	18 (7.2%)	3 (3.6%)	15 (6%)	4 (4.4%)	11 (4.4%)	4 (5.1%)	63 (6.5%)	16 (5%)
Vomit	13 (6.1%)	4 (5.8%)	16 (6.4%)	2 (2.4%)	13 (5.2%)	3 (3.3%)	11 (4.4%)	2 (2.5%)	53 (5.5%)	11 (3.4%)
Cough	57 (26.8%)	18 (26.1%)	59 (23.7%)	14 (16.9%)	56 (22.2%)	11 (12.1%)	61 (24.5%)	18 (22.8%)	233 (24.2%)	61 (18.9%)
Average weight (kg)	6.6 ± 1	6.6 ± 1	6.6 ± 1.1	6.6 ± 1	6.6 ± 1	6.5 ± 1	6.7 ± 1.1	6.6 ± 1	6.6 ± 1	6.6 ± 0
Average length (cm)	67.4 ± 5.9	67.4 ± 5.7	67.8 ± 6.6	67.2 ± 6	67.6 ± 6	67 ± 5.4	68.1 ± 6.4	67.8 ± 6.1	67.7 ± 6.2	67.3 ± 5.8
Average MUAC (cm)	12 ± 0.3	12 ± 0.3	11.9 ± 0.3	11.9 ± 0.2	12 ± 0.3	12 ± 0.3	12 ± 0.3	11.9 ± 0.3	12 ± 0.3	12 ± 0.3
Weight-for-age z-score	-2.8 ± 0.8	-2.7 ± 0.8	-2.8 ± 0.7	-2.8 ± 0.7	-2.8 ± 1	-2.7 ± 0.7	-3 ± 0.9	-3 ± 0.8	-2.8 ± 0.9	-2.8 ± 0.8
Length-for-age z-score	-2.7 ± 1.2	-2.5 ± 1.3	-2.7 ± 1.2	-2.8 ± 1.2	-2.7 ± 1.2	-2.6 ± 1.2	-2.7 ± 1.2	-2.9 ± 1.3	-2.7 ± 1.2	-2.7 ± 1.3
Weight-for-length z-score	-1.7 ± 0.7	-1.6 ± 0.7	-1.7 ± 0.7	-1.6 ± 0.7	-1.7 ± 0.7	-1.6 ± 0.7	-1.7 ± 0.7	-1.6 ± 0.7	-1.7 ± 0.7	-1.6 ± 0.7
Caregiver & household characteristics										
Caregiver's age, years	28.6 ± 8.9	28.5 ± 8.1	26.8 ± 6.8	26.1 ± 6.3	29.2 ± 8.7	28.1 ± 6.8	28.1 ± 8.9	27.4 ± 8.1	28.2 ± 8.4	27.5 ± 7.3
Marital status										
Married	183 (85.9%)	61 (88.4%)	205 (82.3%)	70 (84.3%)	219 (87.3%)	79 (87.8%)	217 (87.1%)	67 (84.8%)	824 (85.7%)	277 (86.3%)
Separated	2 (0.9%)	0 (0%)	5 (2%)	1 (1.2%)	4 (1.6%)	1 (1.1%)	3 (1.2%)	0 (0%)	14 (1.5%)	2 (0.6%)
Single	28 (13.1%)	8 (11.6%)	37 (14.9%)	10 (12%)	28 (11.2%)	10 (11.1%)	29 (11.6%)	12 (15.2%)	122 (12.7%)	40 (12.5%)
Level of education										
None	122 (57.3%)	40 (58%)	130 (52.2%)	42 (50.6%)	147 (58.6%)	51 (56.7%)	136 (54.6%)	39 (49.4%)	535 (55.6%)	172 (53.6%)
Some or completed primary	47 (22%)	15 (21.7%)	57 (22.9%)	16 (19.3%)	56 (22.3%)	23 (25.5%)	62 (24.9%)	22 (27.9%)	222 (23.1%)	76 (23.7%)
Some, completed, or more than second	44 (20.6%)	14 (20.2%)	61 (24.5%)	24 (28.9%)	48 (19.1%)	16 (17.8%)	51 (20.5%)	18 (22.8%)	204 (21.2%)	72 (22.4%)
1 or more Females age 65+	27 (12.7%)	7 (10.1%)	36 (14.4%)	11 (13.2%)	29 (11.6%)	12 (13.3%)	26 (10.4%)	13 (16.5%)	118 (12.2%)	43 (13.4%)
HFIAS category										
Food Secure	51 (23.9%)	18 (26.1%)	63 (25.3%)	27 (32.5%)	78 (31.2%)	37 (41.1%)	67 (26.9%)	28 (35.4%)	259 (27%)	110 (34.3%)
Mildly Food Insecure Access	0 (0%)		1 (0.4%)		0 (0%)		1 (0.4%)		2 (0.2%)	
Moderately Food Insecure Access	27 (12.7%)	10 (14.5%)	37 (14.9%)	12 (14.5%)	21 (8.4%)	11 (12.2%)	30 (12%)	9 (11.4%)	115 (12%)	42 (13.1%)
Severely Food Insecure Access	135 (63.4%)	41 (59.4%)	148 (59.4%)	44 (53%)	151 (60.4%)	42 (46.7%)	151 (60.6%)	42 (53.2%)	585 (60.9%)	169 (52.6%)
SES quintiles										
Lowest	50 (23.7%)	16 (23.5%)	52 (21.3%)	20 (24.7%)	60 (24.2%)	26 (28.9%)	53 (21.4%)	14 (17.7%)	215 (22.6%)	76 (23.9%)
Mid-Low	44 (20.9%)	16 (23.5%)	36 (14.8%)	12 (14.8%)	48 (19.4%)	16 (17.8%)	57 (23%)	19 (24.1%)	185 (19.5%)	63 (19.8%)
Medium	39 (18.5%)	11 (16.2%)	49 (20.1%)	16 (19.8%)	47 (19%)	15 (16.7%)	57 (23%)	20 (25.3%)	192 (20.2%)	62 (19.5%)
Mid-High	43 (20.4%)	14 (20.6%)	52 (21.3%)	19 (23.5%)	42 (16.9%)	14 (15.6%)	44 (17.7%)	12 (15.2%)	181 (19%)	59 (18.6%)
Highest	35 (16.6%)	11 (16.2%)	55 (22.5%)	14 (17.3%)	51 (20.6%)	19 (21.1%)	37 (14.9%)	14 (17.7%)	178 (18.7%)	58 (18.2%)
Outcomes										
Graduate	143 (67.1%)	44 (63.8%)	163 (65.7%)	52 (62.7%)	177 (70.2%)	58 (63.7%)	164 (65.9%)	54 (68.4%)	647 (67.3%)	208 (64.6%)
Developed SAM	30 (14.1%)	11 (15.9%)	33 (13.3%)	14 (16.9%)	31 (12.3%)	10 (11%)	37 (14.9%)	11 (13.9%)	131 (13.6%)	46 (14.3%)
Default	6 (2.8%)	1 (1.4%)	9 (3.6%)	5 (6%)	4 (1.6%)	2 (2.2%)	13 (5.2%)	5 (6.3%)	32 (3.3%)	13 (4%)
Death	0 (0%)	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	0 (0%)	3 (1.2%)	1 (1.3%)	4 (0.4%)	1 (0.3%)
Fail	34 (16%)	13 (18.8%)	42 (16.9%)	12 (14.5%)	40 (15.9%)	21 (23.1%)	32 (12.9%)	8 (10.1%)	148 (15.4%)	54 (16.8%)

Explanations among the SC+A arm were offered, which included preventing sickness or vomiting, while others said that the child did not like the cooked pap and preferred it raw.

> *When I am cooking it, he [the child] may be eager to eat it [SC+A] and I give him the raw one, it does not harm him or give him sickness. (FGD #6, Respondent 4)*
>
> *She loves the dry/raw [SC+A] more than the pap or the cooked one. (FGD #8, Respondent 3)*

In all of the FGDs, there were no mentions of mixing the raw food with any other ingredients, and some expressed that they served the food to the child alone.

> *I came to a point where I no longer cooked the blended. I added a little oil on the raw/dry blended [CSB+ flour] and mix it in a cup to give to my child to eat it alone. (FGD #7, Respondent 1)*
>
> *In the morning I just put some raw flour [SC+A] in the cup and water and she will eat it all…she just eats the raw flour [SC+A]. (FGD #4, Respondent 1)*

Sharing the study foods with those other than the intended recipient was both observed and reported in all study arms. Information on observed and self-reported sharing of the ration is presented in **Figure 18** by study arm. Although there were no major differences among study arms in reported sharing, observed sharing was highest in the RUSF arm and lowest in the SC+A arm. Unsurprisingly, self-reports of sharing were lower than direct observations.

Figure 18: Self-reported vs observed sharing of the study food by study arm

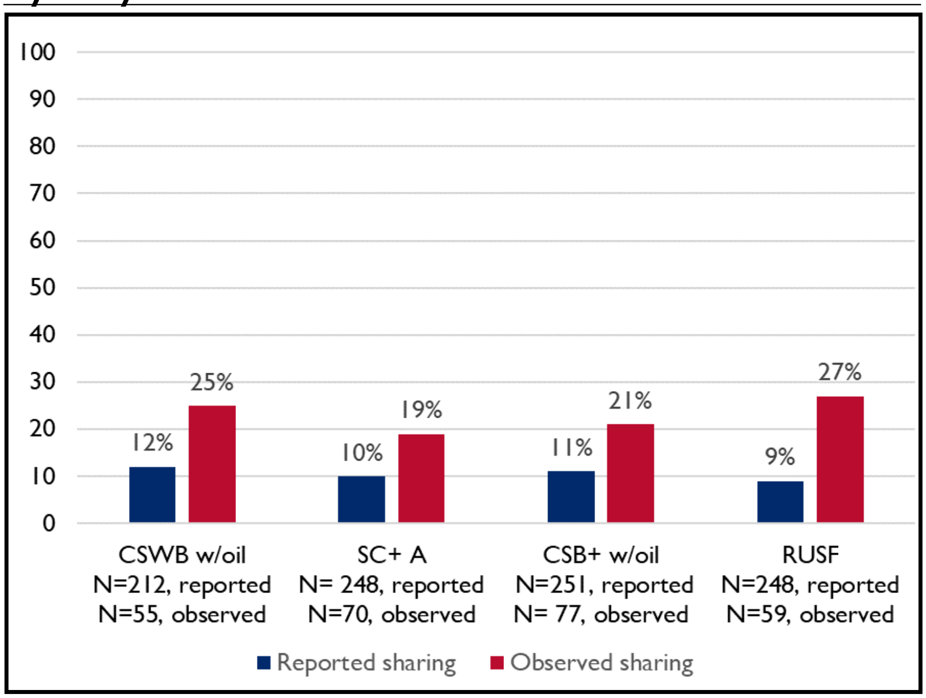


Figure 19: Observed sharing by study arm and day of observation

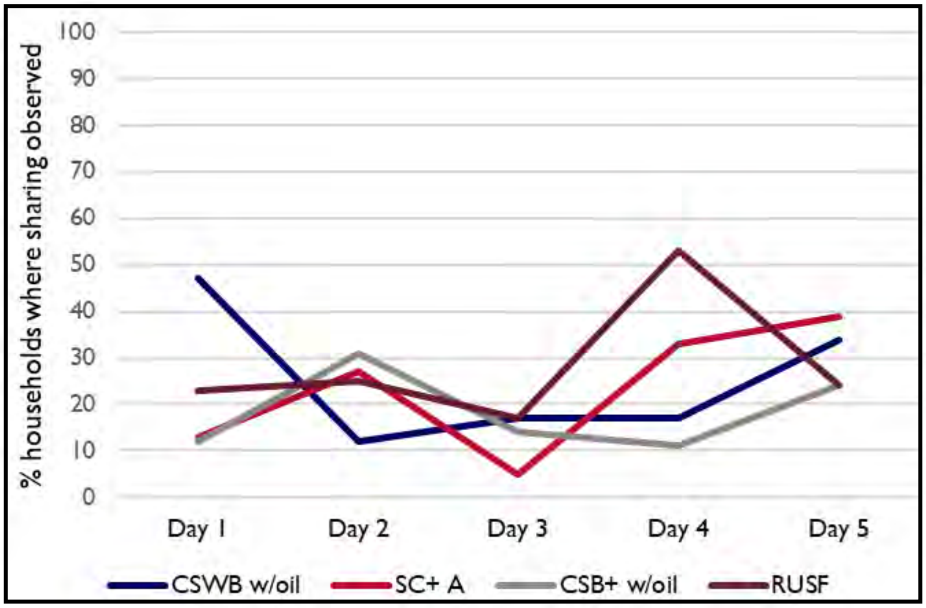


Table 14: Observed sharing by study arm and day of observation

Reported Reason	N (%)
It is good for health	330 (34)
It treats illness	291 (30)
Other children need or want	263 (27)
Other adults need or want	97 (10)
Other reason	53 (6)
Caregiver is breastfeeding the child	47 (5)
Not enough other food in the house	25 (3)
Receive more than child needs	18 (2)
Morally obligated to share	20 (2)
Not enough money to buy food	11 (1)

No discernable trends were seen in observed sharing by day of observation **Figure 19**. Additional descriptive statistics support the finding that sharing is common: 56% of respondents across all four study arms reported running out of the ration before receiving the next distribution. Very few people reported giving away (1%) or selling (0.21%) the ration to people outside of their households. Reported reasons for sharing the study food are shown in **Table 14**.

By outcome, there were few differences in observed sharing of the study foods, with less sharing observed among those who failed to graduate; however, there were differences in observed consumption by outcome. Those who graduated were observed consuming the food the most often (82% of households observed consuming the food at least once over the five-day observation), and those who failed were observed consuming the food least often (46% of households observed consuming the food at least once over the five-day observation), but this was not tested for statistical significance. These findings are summarized in **Figure 20**.

Figure 20: Percent of households observed consuming food at least one day in five by outcome

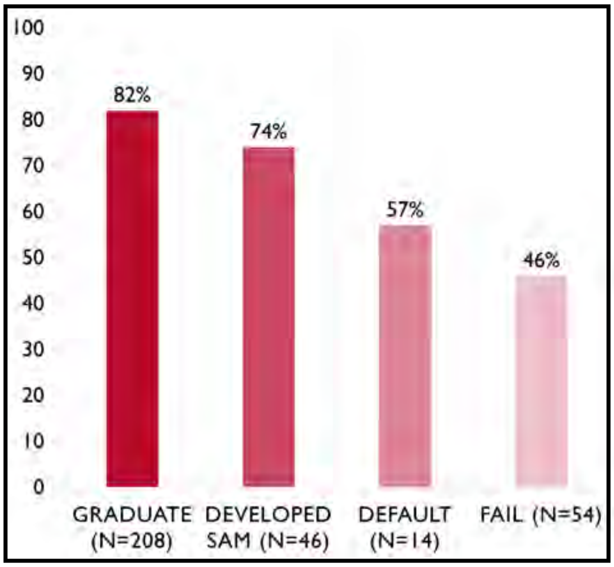
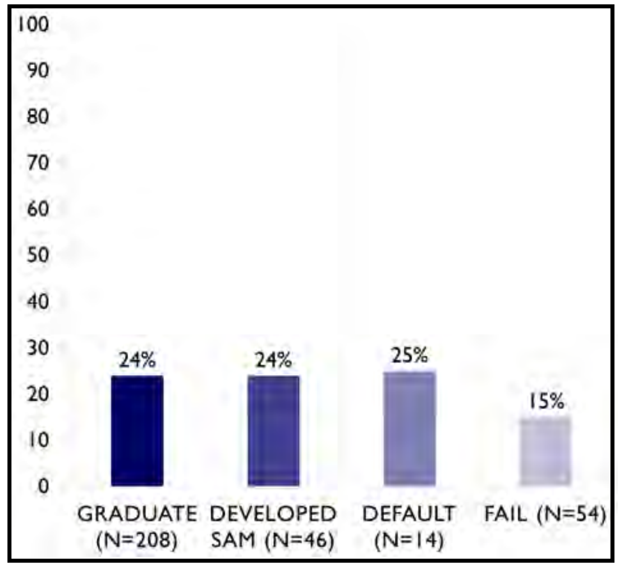


Figure 21: Percent of households observed sharing food at least one day in five by outcome



When prompted about sharing during FGDs, caregivers across all arms expressed that they did not sell or share the food outside the household, even when under social pressure from community members. Caregivers in the FBF arms reportedly shared the food with nonbeneficiary children. The sharing most often occurred with siblings or other children in the household. One caregiver went on to explain that instead of throwing away leftovers, she gave the food to the other child living in the house.

> *[Will not share] unless [for] my sister's younger child because maybe when she eats it [beneficiary child] and leave leftover, she [sister's child] will eat it. So she is the only one. (FGD #14, Respondent 1)*

Another commented:

> *I have [another] kid that does ask for the pot and I give it to her. She will eat the pap [porridge] in it.* (FGD #4, Respondent 5)

When prompted about sharing outside of the house, no respondents reported selling or exchanging their ration for other goods or services. Participants in the CSB+ w/oil arm indicated a sense of moral obligation to share with others in the community, specifically to thin children or pregnant women who had not received a ration (see **Figure 1**).

> *Besides malnourished children, I don't remember of giving this food to other people besides malnourished children and pregnant women that have skinny children in their wombs. (FGD #15, Respondent 4)*

> *If a colleague mothers' child is thin in structure and not actually the beneficiary child, if the mother request by saying please, let me have some of the blended to give to my child I will measure some of the blended and give it to her for her to cook it for her child. (FGD #3, Respondent 3)*

One respondent receiving CSB+ w/oil expressed willingness to buy the food if she saw it being sold because her child loved the food and cried for it.

> *Even my child now, when she sees the food with a colleague mothers' child, she will cry for the food and if I see where they are selling the food, I will buy it. (FGD #2, Respondent 3)*

Overall and within each arm, almost all caregivers reported not sharing because they viewed the food as "only for the beneficiary child" and pertinent to the child's development. In the CSWB w/oil and SC+A arms, sharing the food with other children was not considered acceptable—that sharing the food could transfer the "illness" to the other children.

> *The leftover [SC+A food], you should not give it to others to eat because if you do, the sickness that the beneficiary child has will transfer to the other children. (FGD #4, Respondent 7)*

> *The sickness that this child has, the other child doesn't have it, if you give the other child it [the CSWB w/oil food], it will transfer to him. That is why I don't give to other child except this child (FGD #11, Respondent 3)*

In one CSWB w/oil FGD, one caregiver stated that she did not share because she knew someone was observing them. Others in the CSB+ w/oil arm expressed they did not share because this behavior was counseled against in the photos and through scenarios used during the counseling sessions at the SFP clinic. Embedded in these descriptions were instances of knowledge translation regarding the food handling instructions, such as "we were told not to [share or sell the study food]."

> *The food is for her [beneficiary child] alone, they told me not to give to others. (FGD #4, Respondent 2)*

> *For me I don't have another thinking on this, just as they have told me, I don't cook the food for another person except for the child. (FGD #10, Respondent 7)*

These references to the caregivers' dialogue demonstrate how multiple avenues of instruction were important for knowledge translation and adherence to the recipe. For example, many caregivers, within all arms, recognized the connection of the strict instructions and their child's well-being.

> *They are not giving it to us to go and sell it, they are giving it to us for our children to develop. (FGD #14, Respondent 4)*

However, despite the willingness of caregivers to follow guidance discouraging sharing, this had drawbacks. For example, in the CSB+ w/oil and SC+A arms, not sharing within the household was described as creating potential conflicts, specifically that the food caused quarrels within the family. Others reported pressure to share in order to limit turmoil within the household.

> *This food has caused hate issues on me in the home. (FGD #4, Respondent 7)*

> *For this food that they give, my husband and I have dispute for it. (FGD #14, Respondent 8)*

> *There is somebody, when you collect this and you don't give them, they would not be happy. That is why some people do share it. She would share to her household members for them not to disagree with her. (FGD #6, Respondent 7)*

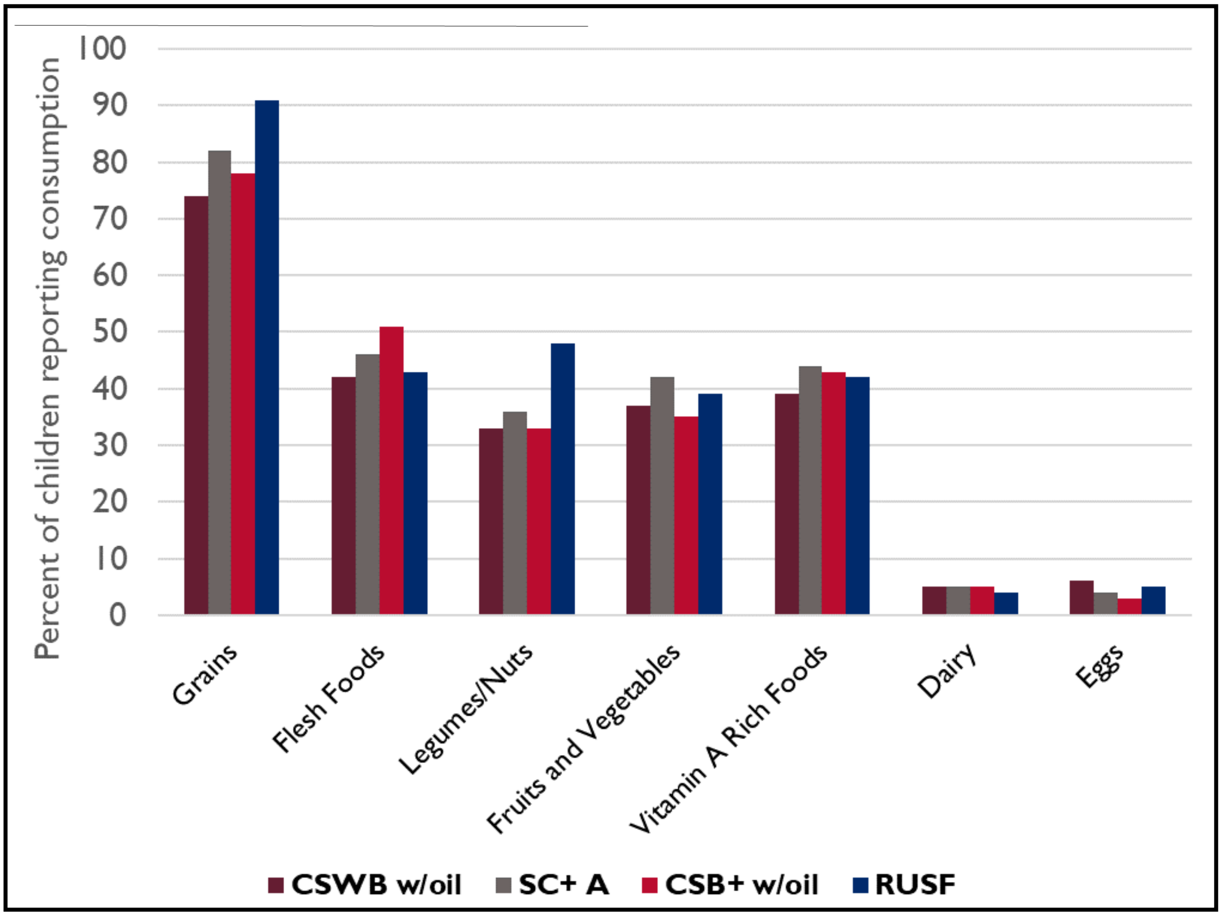
Similar sentiments were expressed in cases of sharing outside of the household in the CSB+ w/oil and SC+A arms. In two FGDs, caregivers expressed concerns about arguments among community members, especially in situations where social pressure was present.

> *If you tell someone that [you cannot share], you will have a quarrel with her. (FGD #1, Respondent 4)*

Displacement of Complementary Foods

There was minimal displacement of household complementary foods by the study foods in intention-to-treat analyses. In bivariate logistic regressions, children in the RUSF arm were significantly more likely to eat household grains (OR=3.55; 95% CI=2.02, 6.25) and legumes and nuts (OR=1.88; 95% CI=1.26, 2.80) than those in the other three arms. There were no significant differences in consumption of any of the other food groups by study arm. Reported food group consumption by study arm is shown in **Figure 22.**

Figure 22: Reported Food Group Consumption by Study Arm



General acceptability of the study foods among the caregivers and beneficiary children was illustrated by the lack of displacement of other foods, which was discussed across all arms in FGDs. Respondents discussed that the rationale for feeding the beneficiary child with other foods besides the study food was simply "doing as they were told." Other foods not mixed in with the study food but given in addition to it included rice, Bennimix[d] , cassava and mango. Breastfeeding was also seen as another form of feeding and was not omitted once the child was given the study food.

They said I should also serve my child with the food [CSB+] she normally eats, that is the only thing I add. (FGD #2, Respondent 2)

[d] Bennimix is a sesame-based flour manufactured in Sierra Leone: http://bennimixsl.com/

Displacement did occur minimally within the CSB+ w/oil and SC+A arms but was not evident in the other arms. In one SC+A FGD, when asked about the benefits of the study food, one caregiver responded with the benefit of not having to buy other food because the child can eat the study food.

> *Firstly, that food [the SC+A] has helped me, because I don't have to buy rice again, groundnut, benni, beans, and all those things. So I really take care of that food [the study food]. (FGD #8. Respondent 6)*

The main reason for giving the beneficiary child only the study food was because of shortages of other foods available in the house. One caregiver in the CSB+ w/oil arm expressed concern for not having any other available food in the house.

> *For me, if that happen [displacing other food], meaning there is no other food for my child, that is the time I will cook the pap [CSB+] again for my child because there is no other food. (FGD #15, Respondent 1)*

Food as Medicine
Across all study arms, caregivers perceived the study food as "medicine food." This was especially apparent among caregivers in the RUSF arm. Caregivers discussed that they believed the food would heal their child if they adhered to the instructions given. Many expressed their worry that mixing the food with other things would affect its medicinal qualities.

> *They [study staff] told us not to mix the food with other foods because you don't want the power of the drugs in the food to be destroyed or become less. (FGD #9, Respondent 1)*

Others used the foods' "medicinal qualities" as an excuse for not sharing the food with other children. Many caregivers believed that they were given medicine from the clinic, in the form of the study foods.

> *That one is a medicine food, so you should give it only to your child. (FGD #5, Respondent 3)*

> *It is already mixed with the ingredients…with medicines. The medicine that it was mixed with in the clinic. (FGD #4, Respondent 1)*

This perception was also visible throughout the preparation and cooking process, where many caregivers expressed their concern over the need to be very careful with the study food because of its medicinal qualities.

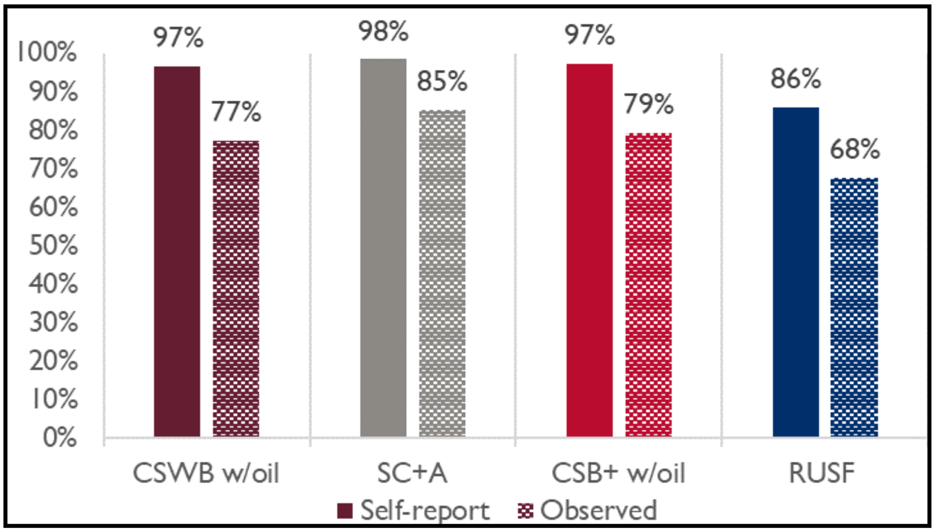
> *It should not cook too long so that the power will not die. (FGD #8, Respondent 6)*

The perception of the food as medicine is apparent throughout the caregivers' experience with the program. The perception of the food as medicine is displayed in **Appendix 4**.

b. Recipe Adherence Behavior

Figure 23 illustrates the differences between self-reported and observed behaviors in adhering to the recipe guidance. Self-reported was higher than observed adherence in all arms, varying from 13 to 20 percentage points between self-reported and observed behaviors. Though adherence to the recipe was overstated in the self-report compared to observed behavior, the general trends were consistent in both data collection methods. As expected, the CSB+ w/oil and CSWB w/oil arms performed similarly. The RUSF arm had the lowest rates of adhering to ingredient guidance, as a result of mixing the RUSF with rice porridge as a complementary food.

Figure 23: Percent of Caregivers Self-Reporting Adherence to Recipe Guidance Compared to Percent of Households Observed to Adhere at Least One Day in Five



Caregivers in the CSWB w/oil and CSB+ w/oil arms consistently reported using too much flour for an individual/daily ration. This contrasted with the SC+A study arm, where equal numbers of caregivers reported using too much, too little, and recommended quantities of flour (**Figure 24**). However, when comparing the ratio of water to flour, the pattern reversed (**Figure 25**): caregivers reportedly used too much flour in the SC+A arm, whereas caregivers receiving CSB+ w/oil and CSWB w/oil tended to use too much water. However, these variations did not influence recovery.

Figure 24: Percent of Caregivers Self-Reporting Using Correct Amount of Flour at Last Preparation Time

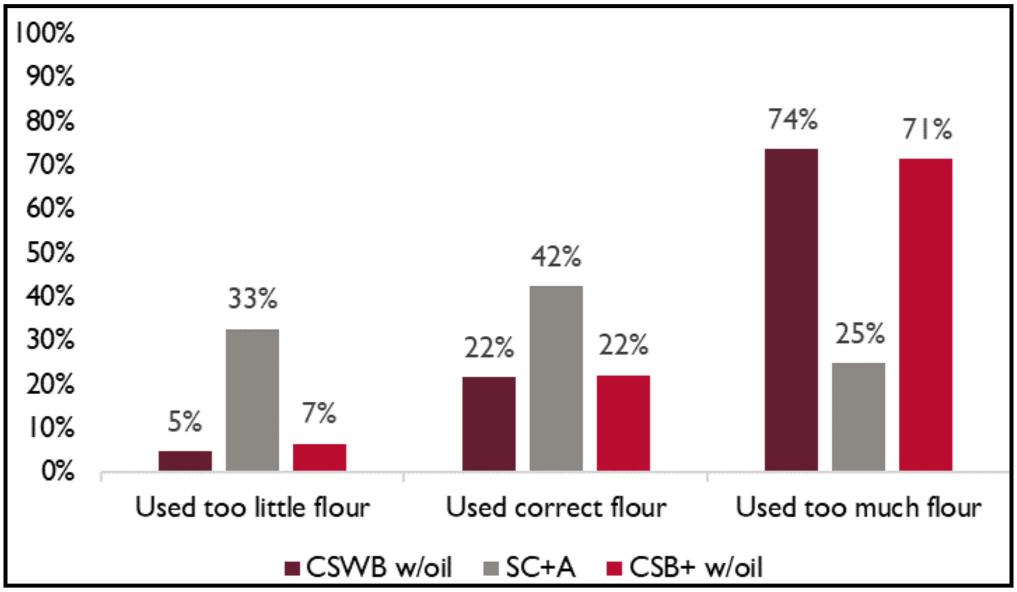
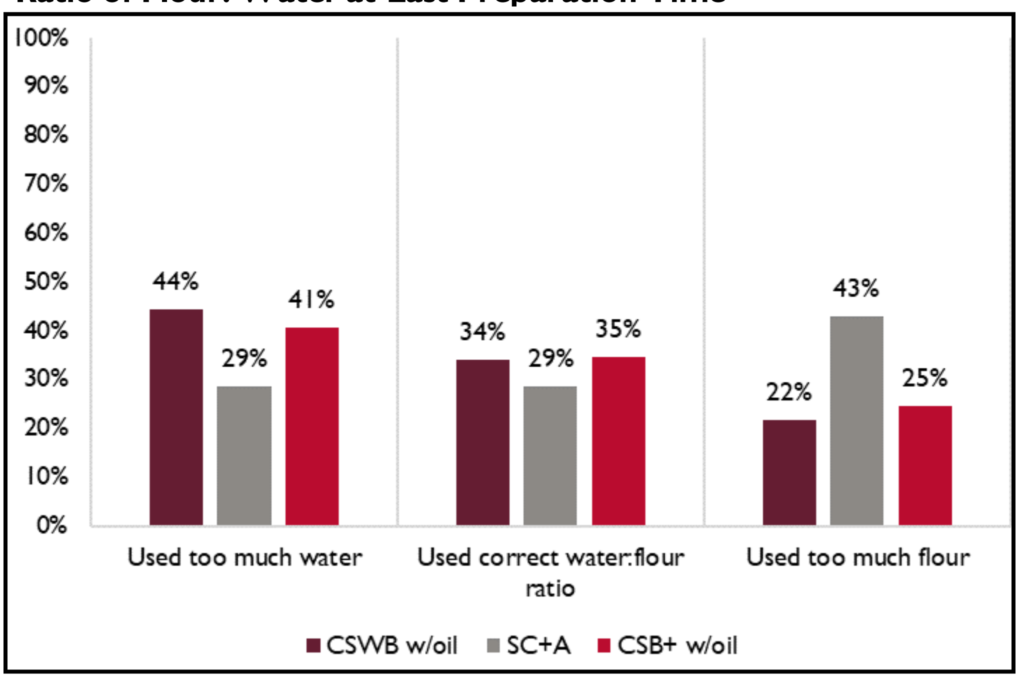
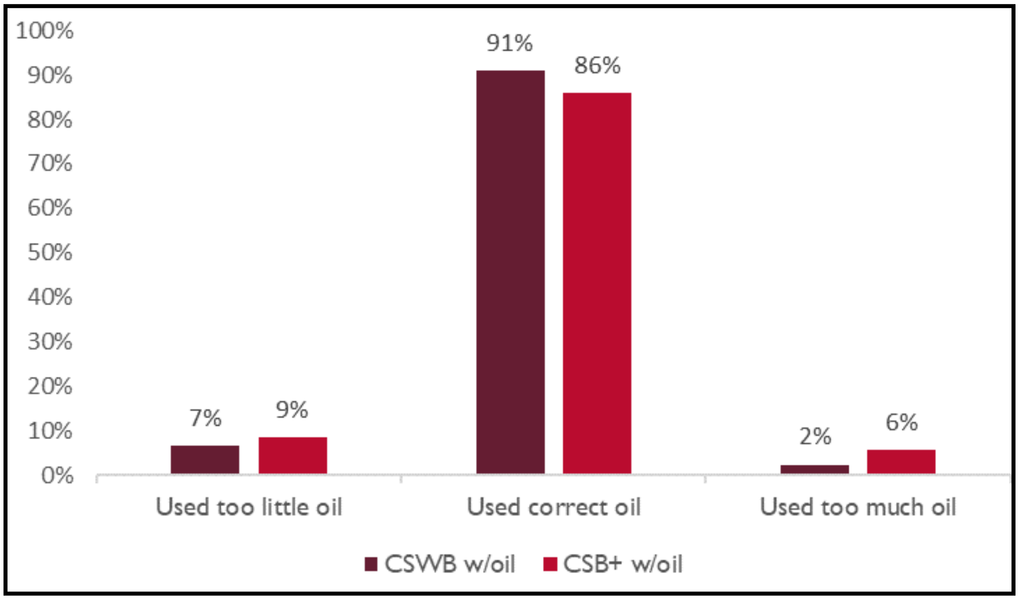


Figure 25: Percent of Caregivers Self-Reporting Using Correct Ratio of Flour: Water at Last Preparation Time



Among caregivers in the CSB+ w/oil and CSWB w/oil arms, nearly all caregivers reported using the correct amount of oil (**Figure 26**). Generally, as illustrated in **Figure 23**—in which more than 75% of households were observed to measure flour, oil, or water—caregivers did seem to be trying to adhere to the recipe. No differences were observed between older and younger children or between those breastfeeding and not breastfeeding, suggesting that differences in recipe adherence were dependent on factors other than child's age. There were also no distinguishable differences in recipe adherence by outcome.

Figure 26: Percent of Caregivers Self-Reportedly Using Correct of Oil at Last Preparation Time



Knowledge Transfer

During FGDs, multiple themes emerged as either facilitators or barriers to recipe adherence. Main themes surrounding the caregivers' ability to adhere to the instructions included familial and community support, images of cooking steps on the packaging, and the recipe demonstrations. These themes helped facilitate knowledge translation of the instructions. Knowledge translation is most often defined in the literature as "the methods for closing the gaps from knowledge to practice".[45] For this analysis, knowledge translation included any references showcasing caregiver knowledge of how to cook the study food; verbalized actions that illustrated adherence to those instructions; or knowledge of other influencing practices such as intrahousehold sharing or food hygiene. Varying levels of familial and community support were also found to be an important facilitating factor. Familial support, both positive and negative, was defined as any household member that encouraged or hindered the caregiver's ability to adhere to and succeed in the program. Community support was also apparent. Community support was defined as support from any person outside the participant's immediate household that had a useful or obstructive effect on the caregiver's ability to succeed in the program.

Verbal instruction helped to reinforce the caregivers' ability to prepare the food as recommended. The use of photos to help with the caregivers' preparation process was most commonly expressed among the SC+A arm.

> *The packet that the blended [SC+A] is in, it has cups drawn on it, it is three and those cups directed us how to go about the food prepared, that is why they drawn on it, how we should go about it (preparing the food). (FGD #6, Respondent 2)*

> *If you do it [prepare the food] twice then you can boast of saying it so (that you are confident). If only you are a quick learner, just as the way the photos are explained, you can do it. (FGD #4, Respondent 1)*

Language or literacy as a barrier to understanding the photos was only apparent in the CSB+ w/oil arm. When asked about challenges related to the packaging, a few caregivers responded with individual strategies that could have helped them better understand the instructions, including utilizing positive community support as a resource. One went on to explain:

> *If you take the blended packet to someone who is educated and that person explains to you, you will understand. (FGD #7, Respondent 4)*

Husbands providing reminders to pick up the study food from the clinic was only reported in one SC+A FGD; the other FGDs discussed encouragement generally.

> *When I will be sleepy, my husband will shout at me saying, [caregiver name] don't you know you should go [pick up the food] today? (FGD #8, Respondent 2)*

Within each arm, husbands were seen as a resource for encouragement to follow the recipe. When asked about ways in which the caregivers felt supported, caregivers reported that husbands were useful for understanding the instructions and photos on the packaging because their literacy was higher.

> *My husband also did Mende and English learning. As soon as I reach home, then he removes the document [the packaging instructions] from my hand and sit on the veranda and read it for me. (FGD #8, Respondent 7)*

Caregivers in the FBF arms identified the recipe demonstration at enrollment to be the major facilitator for adhering to recipe guidance and understanding the preparation process. A common theme was the participants' ability to "boast" of their confidence in preparing the food the way they were instructed.

> *I will be confident to cook my child's pap at home just as how they taught me, that is how I am doing it at home. (FGD #6, Respondent 1)*

In the FBF arms, respondents offered explanations such as reasons why they felt confident in their ability to adhere to the demonstration instructions.

> *I have seen that my child is eating this pap [CSB+] after I cook it and she has improved. I am preparing it just as I was taught, she has been eating it and her body has changed. If that is the case, I can tell you that I know how to cook the food. (FGD #15, Respondent 5)*

In contrast, across all arms, there were barriers to adhering to instructions and food preparation shared by respondents. The most common theme identified was forgetfulness due to factors such as the duration of the demonstration and a general lack of attention during it. As expected, this was explicit in the FBF arms but not discussed in the RUSF arm. One caregiver, from the CSWB w/oil arm, explained that she could not remember the instructions because of the long duration of the demonstration.

> *I cannot really remember what they said because the explanation they gave us was very timely [long]. (FGD #12. Respondent 9)*

When asked about their initial visit to the clinic, one caregiver [CSB+ w/oil] discussed the length of the process, explaining that the long demonstration was not a good use of their time.

They took some time to teach us how to cook the blended before they gave it to us. This is what wasted our time. (FGD #7, Respondent 4)

10.3 Summary

Neither sharing, displacement, nor recipe adherence was associated with differences in recovery. Sharing was prevalent in all arms but highest among recipients of RUSF and lowest for SC+A. Similarly, differences between reported and observed sharing were highest in the RUSF arm. There were few differences in displacement among the four foods. Children who recovered were observed to consume the food most often compared to children who failed, who were observed to consume the food least often. Reported reasons for low rates of sharing included perceptions of the study food as medicine and of disease transference. Adherence to cooking instructions was high for flour and oil usage across FBFs. In SC+A, caregivers generally used less water or more flour than recommended. Reported facilitators to adherence were the recipe instructions and male/husband support in the home.

11. Challenges/Limitations

11.1 Logistical/Implementation Challenges

Lower than expected sample sizes meant that detectable differences were greater than originally anticipated. This occurred because of inaccurate data used at the scoping stage of the study indicating a higher MAM caseload than existed. This does not seem to have affected interpretation of the effectiveness analysis, in which the observed differences were small enough to suggest that they would not have been significant even if the planned sample size had been achieved.

Sierra Leone generally has a poor road infrastructure, and this was particularly true in Pujehun District. During the rainy season, roads would be underwater, and communities could be isolated from the rest of the district. This created challenges for the mobile SFP to reach clinics regularly during the rainy season and made data collection for the study challenging given the remote location of many caregivers. Though the teams worked diligently to reach and interview all sampled caregivers, it is possible that during the rainy season, the most remote potential respondents were not always reached.

Picture of enumeration team members crossing the Moa River during the dry season. Photo courtesy of Caritas Bo

11.2 Electronic Data Collection

Using tablets and electronic forms helped to decrease error in surveys. However, in a context such as Sierra Leone, where power is nearly nonexistent throughout the country, managing issues of device charging, data upload, and quirks of technology can leave enumerators in a situation where they are unable to collect data. These issues are easily managed with the provision of backup paper survey tools, but it can make training difficult when enumerators need to learn the same tool in multiple forms. In this study, there were only three documented cases of switching to paper forms (in one PHU observation and two IHOs).

11.3 Costing Limitations

This study was unable to collect detailed data on product losses. One objective of the smaller packaging was a reduction in losses of the FBFs, but there was no comparison to distribution from 25 kg bags often used in other settings. Absence of fumigation for the first tranche of foods at the main warehouse may have resulted in losses not captured by the study. Anecdotal evidence from caregivers showed that sometimes weevils were found in unopened bags of the FBFs. However, the frequency of these occurrences and their impact on cost-effectiveness remains unknown.

The novel packaging of CSB+ is an additional limitation of the cost-effectiveness analysis. Under traditional SFP modalities, 25 kg bags of CSB+ would have been repackaged in-country into smaller bags. This would have taken more of the staff and caregivers' time and could have resulted in spillage and spoilage losses of the FBFs. The impact on the cost-effectiveness analysis is unknown but should be considered when trying to generalize these findings to other SFP models in which the 25 kg bags would be used.

12. Summary of Findings

In this study set in southern Sierra Leone examining the relative effectiveness and cost-effectiveness of CSB+ w/oil, CSWB w/oil, SC+A, and RUSF, we found the four foods to be similarly effective and cost-effective when measured in cost per recovered child. Though caregivers' opportunity costs (caregiver perspective) were lower in the RUSF arm, the difference was not great enough to alter the comparative cost-effectiveness of the four foods when both caregiver and program perspective were combined. The mobile SFP's operational costs were the largest cost component of the SFP. This contrasts with other studies that found SNFs to be the largest cost component. [14] Unfortunately, as reported by Kennedy, et. al., are few cost-effectiveness studies of SFPs generally and even fewer that specifically report detail *on program costs*.[15]

Our findings are consistent with results from previous studies examining the effectiveness of different SNFs, in which neither RUFs nor FBFs performed systematically better than one another.[4,5] There are few studies exploring the comparative cost-effectiveness of different SNFs for MAM treatment, and they have reported different results.[6,7] Though previous studies cited lower caregiver opportunity costs as a rationale for increasing the use of RUFs in lieu of FBFs for MAM treatment, the findings of this study do not support these conclusions. [9,10]

With respect to the influence of the supply chain, we found that procuring commodities locally was not cheaper than international tenders. One novel element of this study was the use of smaller sized packaging for FBFs, which was more expensive but likely more efficient than the large paper-walled standard bags. Though there have been few formal studies examining the influence of different packaging types on the relative effectiveness of different SNFs, a recent review detailed the diverse challenges specific to SNF packaging.[16] In the review, the authors highlighted challenges with the 25 kg multiwall paper bags used in traditional settings and differences in the box sizes for the smaller, 1.25 kg bags normal for SC+. Because this study did not use 25 kg bags of CSB+, we do not know if the smaller bags mitigated the challenges reported in the earlier review. However, the differences in box size was a challenge experienced at the storage warehouse when the study switched suppliers during the second tranche shipment.

Differences in effectiveness and cost-effectiveness emerged in the analysis of sustained recovery at one month, in which FBFs performed similarly to one another but differently from RUSF. This difference affected the cost-effectiveness point estimates of cost per child who sustained recovery—with RUSF achieving a lower rate of sustained recovery than FBFs, albeit not significantly—and this interpretation did not change when the caregiver perspective was also included. There are currently no published studies that have examined sustained recovery through a cost-effectiveness lens.

Regarding factors that may be associated with recovery, intrahousehold sharing of the foods was both reported and observed among all the foods. However, neither intrahousehold sharing nor following the recommended recipe affected the likelihood of recovery. *Consumption* was observed to be important; observed consumption was highest in households where children graduated. This study also found similar perceptions of the four foods as being medicinal and of high quality for improving the nutritional status of children. This positive association was cited as a rationale for sharing with children both within the home and within the broader community.

Previous studies argued that local perceptions of RUSF as a medicine led to a lower rate of sharing compared to FBFs.[28] In some studies, higher sharing rates (not reported) of FBFs was presumed to be a consequence of higher levels of acceptability among the beneficiary children receiving the FBF. [29] Programs often measure consumption by asking caregivers to return used sachets or bags.[46] In this study, we gauged consumption using retrospective self-reporting and five-day consecutive in-home observations, which may provide more accurate measures of intrahousehold feeding practices.

Finally, guidelines detailing porridge viscosity of FBFs derive from guidance on complementary feeding practices.[5] These guidelines, however, have not been evaluated with reference to recovery from acute malnutrition. The results reported here may indicated that adherence to feeding practices does not impact recovery from MAM. The relationship between sharing and recovery from acute malnutrition has also not been empirically explored in previous studies.[28] The findings of this study reveal that these factors may be of secondary importance to ensuring that the beneficiary consumes the supplementary food.

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Appendix 1: Four Foods Formulations

Nutrients	Unit	Super Cereal Plus (SC+) (Comparison)	Corn Soy Blend Plus (CSB+) with Fortified Vegetable Oil (FVO)		Corn Soy Whey Blend (CSWB) and Fortified Vegetable Oil (FVO)		Ready-to-Use Supplementary Food (RUSF)	
Serving (grams)		135.7 g/day	85.7 g CSB+, 25.7 g FVO/day	85.7 g CSB+, 25.7 g FVO/day	85.7 g CSWB, 25.7 g FVO/day	85.7 g CSWB, 25.7 g FVO/day	RUSF 100 g/day	RUSF 100 g/day
Repackaged Bag Size (2 weeks)		1.9 kg bag SC+	1.2 kg bag CSB+ and 0.36 kg bottle of oil	1.2 kg bag CSB+ and 0.36 kg bottle of oil	1.2 kg bag CSWB and 0.36 kg bottle of oil	1.2 kg bag CSWB and 0.36 kg bottle of oil	N/A	N/A
			Min	**Max**	**Min**	**Max**	**Min**	**Max**
Energy Minimum	kcal	556.37	552.85	552.85	552.85	552.85	510.00	560
Protein	g	21.71	12.00	12.00	12.00	12.00	11.00	16
Fat	g	12.21	30.84	30.84	30.84	30.84	26.00	36
Vitamin A	IU	4,703.36	4,507.22	4,892.72	4,509.39	4,894.89	1,833.33	3833.33
Niacin	mg	10.86	6.86	6.86	6.86	6.86	13.00	_
Pantothenic Acid	mg	2.17	1.37	1.37	1.37	1.37	4.00	_
Vitamin B6	mg	1.36	0.86	0.86	0.86	0.86	1.80	1.80
Folate	mcg	149.27	94.27	94.27	94.27	94.27	_	_
Vitamin B12	mcg	2.71	1.71	1.71	1.71	1.71	2.70	2.70
Vitamin C	mg	122.13	77.13	77.13	77.13	77.13	60.00	60
Vitamin D	mcg		411.20	591.10	411.20	591.10	15.00	20
Vitamin D3	IU	599.25	378.45	378.45	378.45	378.45	_	_
Vitamin E	mg	11.26	9.22	9.22	9.22	9.22	16.00	_
Vitamin K	mcg	40.71	72.97	72.97	72.97	72.97	27.00	_
Vitamin B1 (Thiamine)	mg	0.27	0.17	0.17	0.17	0.17	1.00	_
Vitamin B2 (Riboflavin)	mg	1.90	1.20	1.20	1.20	1.20	2.10	_
Iron (Ferrous fumarate)	mg	5.43	3.43	3.43	3.43	3.43	10.00	14
Iron (Iron-sodium EDTA)	mg	3.39	2.14	2.14	2.14	2.14	_	_

			Min	Max	Min	Max	Min	Max
Zinc	mg	6.79	4.29	4.29	4.29	4.29	11.00	14
Iodine	mcg	54.28	34.28	34.28	34.28	34.28	100.00	140
Potassium	mg	189.98	119.98	119.98	119.98	119.98	900.00	1400
Phosphorus	mg	314.82	248.53	248.53	239.96	239.96	450.00	750
Calcium	mg	613.36	387.36	387.36	310.23	310.23	535.00	750
Biotin	mcg	_	7.03	7.03	_	_	60.00	_
Copper	mg	_	_	_	_	_	1.40	1.9
Magnesium	mg	_	_	_	_	_	150.00	225
Manganese	mg	_	_	_	_	_	1.20	_
Selenium	mcg	_	_	_	_	_	20.00	40
Sodium	mg	_	_	_	_	_	_	_

Appendix 2: Statistical Methods

PHU Sampling Process

The sampling frame consisted of 72% in the accessibility stratum and 27% in the inaccessibility stratum. To remain consistent with this distribution of accessible/inaccessible PHUs, the first step of the sampling process randomly selected 20 PHUs from the accessible stratum and 8 from the inaccessible stratum from the sampling frame. Next, 8 (or 20) block IDs were randomly assigned to the PHUs four copies of the sequence 1 through 2 for inaccessible, and four copies of sequence 3 through 7 for accessible, representing the individual blocks among which randomization was carried out. From the resultant sampling plan, statistics were generated using the stratification criteria above (e.g., total number of chiefdoms, total number of types of PHUs included in the plan, coefficients of variation in total MAM cases within each of the seven blocks, number of PHUs with mines).

Hundreds of thousands of potential plans were simulated through a computer program and reduced as more criteria were applied. One simulation was randomly selected from those that met all the criteria. Then, another round of sampling was carried out. For each block of 4, a group indicator was randomly assigned (ranging from 1 to 4, representing each of the four treatments). From this, the total number of types of PHUs in each group and total sum of MAM cases in each group were calculated. This process was repeated thousands of times using the same 28 selected PHUs and then pared down using the following predetermined criteria: every group had to contain all three types of PHUs, and the coefficient of variation for the MAM cases across the four groups needed to be lower than 0.1. This generated a set of 351 possible randomization schemes. From this set of 351, one was randomly selected as the sampling scheme for the study.

Further scoping was done by the field research manager to see if there were any obstacles to inclusion of each clinic. It was found that several PHUs offered outpatient therapeutic programs (OTPs) for SAM, which was determined to be of importance. Therefore, the 28 PHUs were reshuffled into the four groups in order to have a more even allocation of PHUs that offered OTPs across arms. Some clinics had to be exchanged because they were located too close to other PHUs or were only accessible by boat. Clinics were exchanged one by one by going back to the full PHU list and selecting replacements in order of descending MAM cases until no further issues were noted and the seven clinics in each study arm appeared to be balanced based on the selection criteria. Later in the study, due to low enrollment rates, expanded catchment schemes were put into place. In 2018, an eighth PHU was added to the CSWB arm to improve balance between the arms. See **Figure 3** for a map of Pujehun District with the PHU locations.

Statistical Modeling

Mixed-effect logistic regression models were fit using PHU as the random effect. The binary outcome variable was defined as achieving MUAC ≥ 12.5cm within 12 weeks of rations received versus not. Crude and adjusted models were fit. Observations with missing covariate data were dropped from the models. To evaluate whether missing data had an impact on parameter estimates, an additional model with multiple imputations was fit to predict the missing values from the rest of the data. The adjusted models with and without multiple imputations were compared. After the regression models were estimated, the intraclass correlation was calculated, and marginal predictions of the study arm variable were obtained. Crude and adjusted models were also fit to exclude those who missed three consecutive visits (i.e., defaulted) in order to evaluate whether the study foods differed among the sample who adhered to the treatment program.

Multicollinearity of model covariates was assessed using a variance inflation factor: if a covariate had a value above 15, it was removed from the model. The link test was used to determine if there was specification error. To evaluate for presence of influential observations and outliers that may have affected parameter estimates, plots of Pearson and deviance residuals and the Pregibon delta beta influence were examined.

For the Cox Hazards Models, prior to modeling, univariate analyses were conducted to check the Kaplan-Meier curves for each potential categorical predictor, checking the shapes of the survival functions and assessing proportionality. Tests of equality across strata (levels of each variable) were also conducted to identify potential variable candidates for the final model, using univariate Cox proportional hazards regressions for each continuous predictor and nonparametric log-rank test of equality to identify categorical predictor candidates. Variables for which the p-value was 0.05 or less were included in the final model. Interactions of each predictor and the time variable (days to recovery) were used to test violations of the proportionality assumption (i.e., that the ratio of hazards for any two individuals is constant over time), and final models were checked for goodness-of-fit using Cox-Snell residuals.

Appendix 3: Cost from the Program Perspective (Additional Scenarios)

As explained in **Table 15**, the research team used additional data sources to explore how costs from the program perspective compared across arms in three product specification and procurement channel scenarios. This was in addition to scenario 1, which served as the basis for cost-effectiveness analysis.

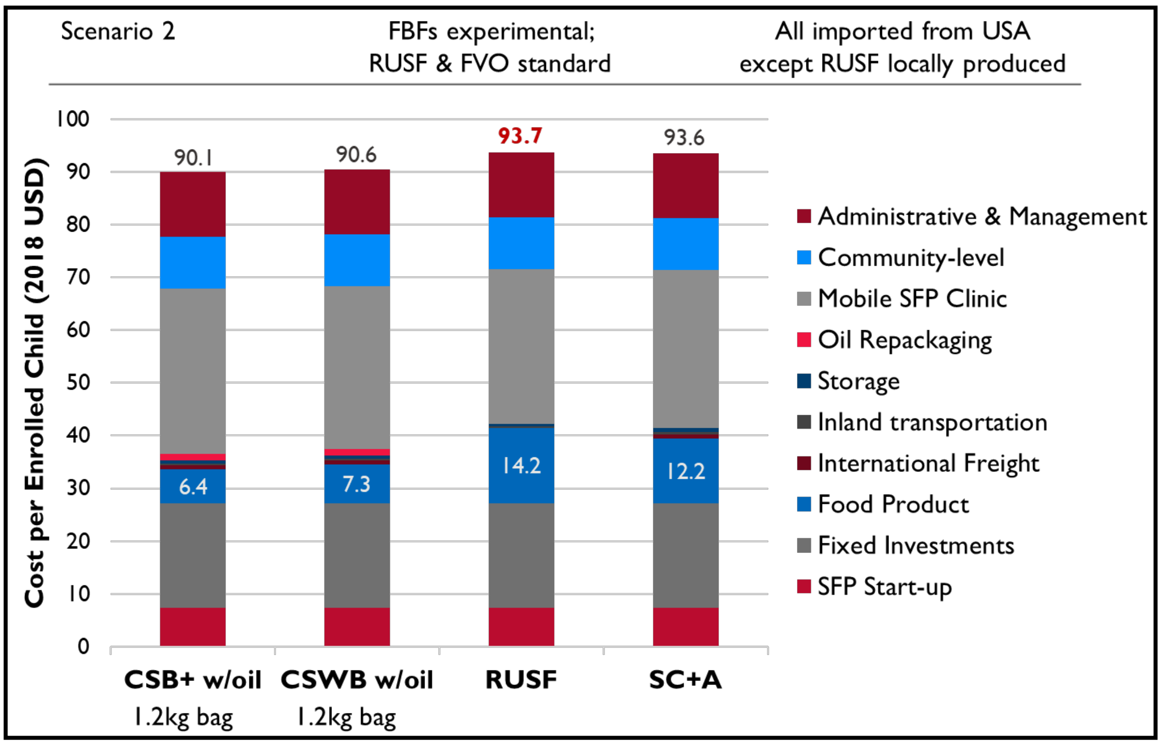
Table 15: Product Specification and Procurement Scenarios

	Product Specification: Experimental versus Standard	Procurement Channel: Imported versus LRP
Scenario 1 (Primary)	FBFs experimental; RUSF & FVO standard ı	All imported from USA
Scenario 2	FBFs experimental; RUSF & FVO standard ı	All imported from USA except RUSF locally procured ı
Scenario 3	SC+A and CSWB experimental formulation only; All standard packaging	All imported from USA
Scenario 4	All standard (exclude CSWB in this scenario)	All locally procured

Acronyms: LRP: Local and Regional Procurement; FBF: Fortified Blended Flours, CSWB: Corn Soy Whey Blend; SC+A: Super Cereal Plus with amylase; RUSF: Ready-to-Use Supplementary Food; FVO: Fortified Vegetable Oil

ı the scenario has the same product specification or channel as incurred in the study

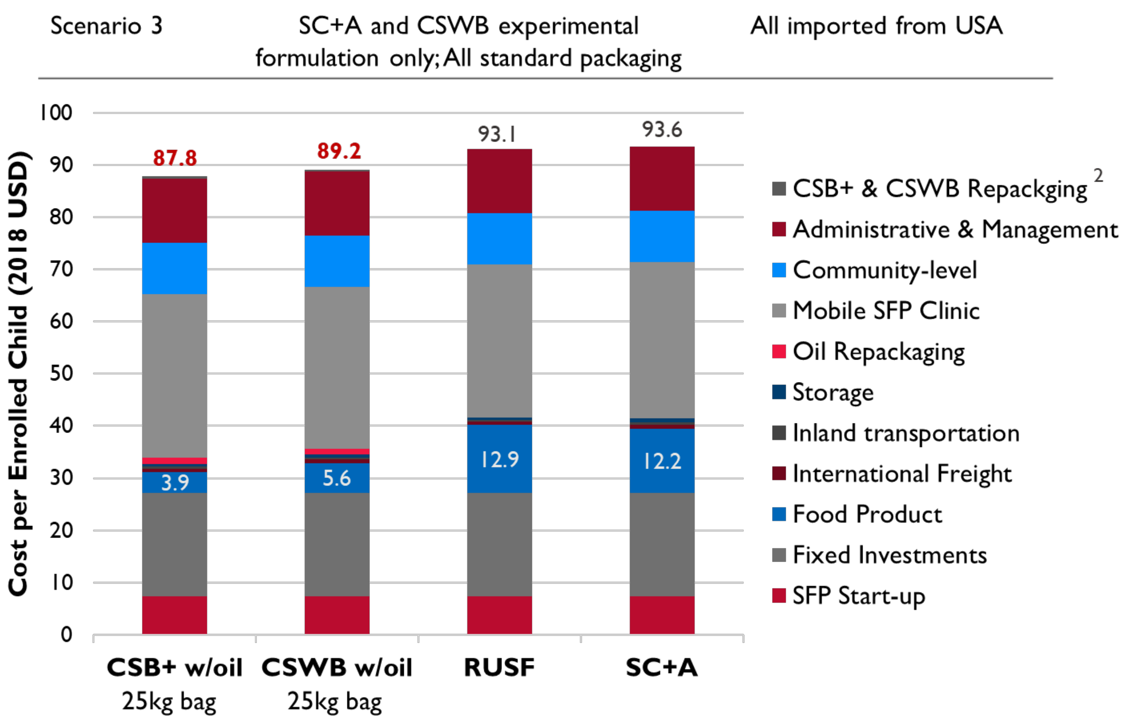
Figure 27: Program Perspective Cost per Enrolled Child (Scenario 2)



Scenario 2 compared the four arms using the actual specifications and procurement channels used for the study. For the locally produced RUSF, international freight costs dropped to zero while product costs increased (**Table 11** and **Table 12). Figure 27** shows that, compared to the primary scenario, the net difference in total cost per enrolled child for RUSF was small, amounting to about $0.60 per child increase.

Scenario 3 explored the cost impact of packaging specification changes for CSB+ and CSWB. Compared with the primary scenario using experimental 1.2 kg bags, program perspective costs per enrolled child using standard 25 kg bags decreased by about $2 per child for the two arms (**Figure 28**). This cost calculation for scenario 3 included additional in-country repackaging using cost estimates from FAQR Burkina Faso trial.[33]

Figure 28: Program Perspective Cost per Enrolled Child (Scenario 3) [1]



[1] Total cost included additional cost of in-country repackaging, but excluded potential cost due to additional product losses as a result of standard large-size packaging. Assuming 6% additional product losses due to standard packaging, we estimated that total cost per enrolled child would be $88.1/child for CSB+ w/oil and $89.5/child for CSWB.

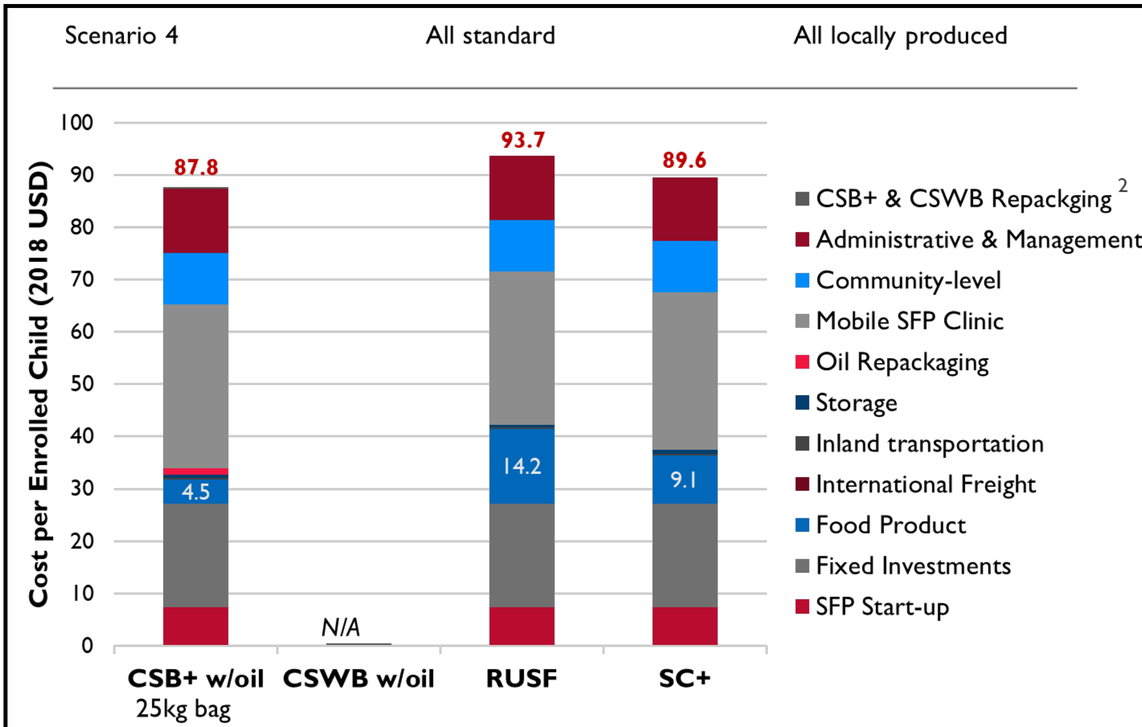
[2] As the Sierra Leone study used 1.2kg bag experimental package for CSB+ CSWB, no in-country repackaging was involved. In order to estimate in-country repackaging cost per enrolled child in a hypothetical scenario where CSB+ and CSWB are procured in 25kg standard package, we used ration size and number of rations delivered per child from the current study and then applied a per-MT cost of ~$106 from another FAQR field trial in Burkina Faso.

Additional product losses could occur due to spillage in distributions/repackaging and spoilage in storage when CSB+ and CSWB are in standard paper 25 kg packaging. To assess possible impact of food losses on cost, the research team assumed 6% losses throughout the supply chain and estimated an additional slight increase in total cost per enrolled child of ~$0.30 per child for the CSB+ w/oil and CSWB w/oil arms. We used 6% based on a previous FAQR trial in Burkina Faso that evaluated CSB+ and CSWB in standard packaging for an 18-month blanket supplementary feeding program.[33]

A total of ~2.3% losses for CSB+ and ~6.2% losses for CSWB were observed during multiple supply chain steps (we did not have data on losses during distribution). However, due to differences in supply chain conditions, local contexts, and the duration of stay for the foods between the two trials, it would be difficult to predict the exact amount of additional product losses if standard packaging had been used. Therefore, the research team calculated the turning points where total costs per enrolled child for CSB+ w/ oil and CSWB w/ oil using standard packaging would no longer be cheaper than using experimental packaging. Those turning points for percent losses were 43% for CSB+ and 25% for CSWB. As product and supply chain were not the largest components of total cost in this SFP for MAM treatment, the influence of additional losses on cost per enrolled child due to packaging was relatively small for CSB+ w/oil and CSWB w/oil.

In Scenario 4, CSB+ w/oil, RUSF, and SC+ were compared in standard specifications to explore the cost implications of local procurement (**Figure 29**). For CSB+ w/oil, total cost per enrolled child remained the same as in scenario 3, because the decrease in international freight was offset by the increase in product cost. For SC+, the total cost per enrolled child decreased by $4 per child compared to scenario 3, in part due to the lack of amylase in the LRP version. Therefore, in this scenario, total cost per enrolled child rankings changed substantially: SC+ became more comparable to CSB+ w/oil, and RUSF became the most expensive option. The price estimates for CSB+ and SC+ procured by WFP came from African suppliers outside of West Africa. It is unclear whether local capacity exists yet to produce FBFs or if they would be sold at similar price levels.

Figure 29: Program Perspective Cost per Enrolled Child (Scenario 4)[1]



[1] Total cost included additional cost of in-country repackaging, but excluded potential cost due to additional product losses as a result of standard large-size packaging. Some of the LRP prices (SC+ and CSB+) were derived from suppliers outside of West Africa, but we assumed West Africa suppliers would be able to produce these products at similar price levels. Otherwise, additional freight cost would apply.

[2] As the Sierra Leone study used 1.2kg bag experimental package for CSB+ CSWB, no in-country repackaging was involved. In order to estimate in-country repackaging cost per enrolled child in a hypothetical scenario where CSB+ and CSWB are procured in 25kg standard package, we used ration size and number of rations delivered per child from the current study and then applied a per-MT cost of ~$106 from another FAQR field trial in Burkina Faso.

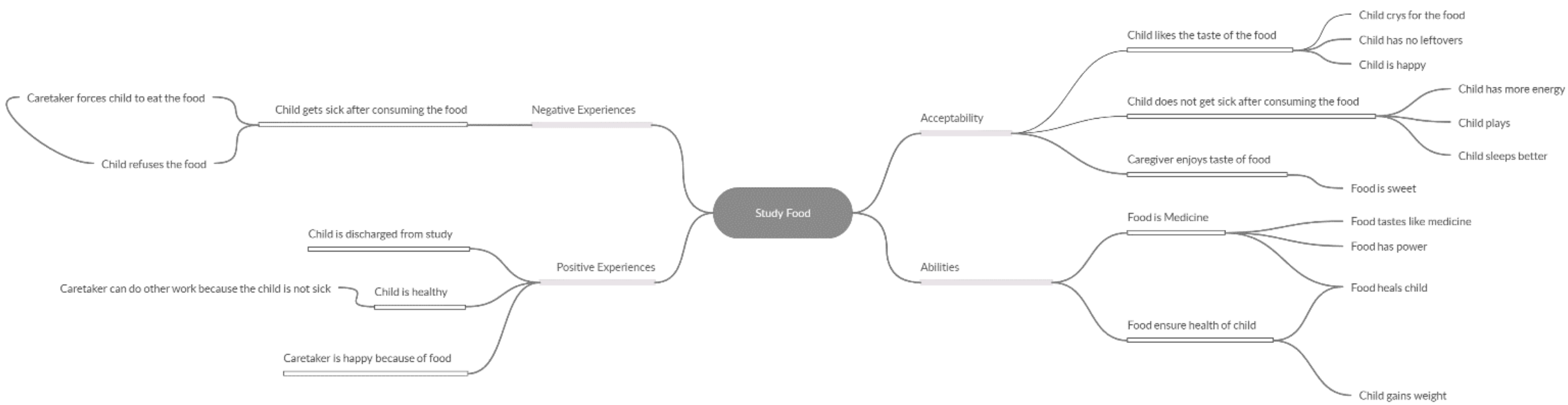
Summary

If CSB+ were packaged in standard 25 kg bag, this would have increased the cost difference (i.e., reduced the cost per enrolled child of CSB+ w/oil) compared to RUSF and SC+A. However, easier in-country handling for both implementers and caregivers as well as potential prevention of product losses should also be factored into packaging decisions for CSB+. Potential ways to reduce the cost of small packaging for CSB+ should be explored.

Product procurement channel/location did not make a substantial difference in total cost comparisons. This is because the elimination of international freight cost was mostly offset by higher in-country inspection cost of locally produced SNFs.

Appendix 4: Perceptions of Study Food (Qualitative Results)

Perception and Experiences of Study Food Mind Map



Appendix 5: Reasons for Sharing and Selling (Qualitative Results)