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Strengthening and Evaluating the "Preventing Malnutrition in Children Under Two Years of Age Approach" (PM2A) in Guatemala and Burundi

A Five-Year Research Protocol

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List of Acronyms

ABC	Activity-based costing
AIEPI	Integrated Care of Prevalent Childhood Illnesses
AINM-C	Integrated Health Care for Women and Children in Communities
BCC	Behavior Change Communication
BMI	Body Mass Index
C-IMCI	Community Integrated Management of Childhood Illness
CC	Convergence Center
CG	Care Group
CHC	Community Health Committee
CHW	Community Health Worker
CRS	Catholic Relief Services
CSB	Corn-Soy Blend
Deff	Design Effect
EBS	*Equipo Basico de Salud*
EHA	Essential Hygiene Actions
ENA	Essential Nutrition Actions
ENSMI	*la Encuesta Nacional de Salud Materno Infantil*
FA-MCHN	Food-Assisted Maternal and Child Health and Nutrition
FANTA	Food and Nutrition Technical Assistance
FFP	Food for Peace
FH	Food for the Hungry
GMP	Growth Monitoring and Promotion
HAZ	Height-for-Age Z-score
Hb	Hemoglobin
HH	Household
ICC	Intracluster Correlation Coefficient
IFPRI	International Food Policy Research Institute
IMC	International Medical Corps
IMCI	Integrated Management of Childhood Illness
IYCF	Infant and Young Child Feeding

LM	Lead Mother
LNS	Lipid-based Nutrient Supplement
MC	Mercy Corps
MCHN	Maternal and Child Health and Nutrition
MICS	Multiple Indicator Cluster Survey
MMN	Multiple micronutrients
MN	Micronutrients
MoH	Ministry of Health
MSF	Maize-soy flour
MUAC	Mid-Upper Arm Circumference
MYAP	Multi-Year Assistance Program
NFP	No Food in Pregnancy
NS	Nutritional Status
OR	Operations Research
PM2A	Preventing Malnutrition in Children under Two Years of Age Approach
PPS	Probability proportional to size
PPT	Percentage point
PROCOMIDA	*Programa Comunitario Materno Infantil de Diversificación Alimentaria* (Maternal and Child Community Food Diversification Program)
PVO	Private Voluntary Organization
SAM	Severe Acute Malnutrition
SD	Standard Deviation
SIAS	*Sistema Integral de Atención en Salud*
TBA	Traditional Birth Attendants
THP	*Tubaramure* Health Promoter
TPS	Public Health Technician
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WAZ	Weight-for-Age Z-score
WHO	World Health Organization
WHZ	Weight-for-Height Z-score
WMD	Weighted Mean Difference
WSB	Wheat-Soy Blend

1. Introduction

The third paper of the *Lancet Series on Maternal and Child Undernutrition* concludes that effective nutrition interventions to tackle maternal and child undernutrition exist; and that if implemented at scale during the window of opportunity (pregnancy and up to the child's second birthday), these interventions could reduce undernutrition-related mortality and disease burden by 25 percent in the short term (Bhutta et al. 2008). By far the most consistent message across the five papers of the series is the need to focus on the *prevention* of undernutrition by intervening as early and as aggressively as possible during the short interval from pregnancy to 24 months of age. This authoritative guidance, combined with the first programmatic evidence from Haiti that targeting nutrition interventions during this critical period leads to greater reductions in child undernutrition than interventions aimed at reversing undernutrition (Ruel et al. 2008) led the Office of Food for Peace of the United States Agency for International Development (USAID) to adopt a new policy for food assisted maternal and child health and nutrition (FA-MCHN) programming. The new Food for Peace Act Title II program policies and proposal guidelines for 2009 (USAID 2009a) specifically encourage Title II Awardees to design their FA-MCHN program on the basis of preventive action and to use the *Preventing Malnutrition in Children Under Two years of Age Approach* (PM2A), which targets all mothers during pregnancy and infants and young children up to two years of age.

The Haiti study, funded by USAID through Food and Nutrition Technical Assistance (FANTA) between 2002-2006, was the first rigorous evaluation conducted under real programmatic conditions, which showed that the blanket targeting of a FA-MCHN program to all children 6-24 months of age (preventive approach) was more effective at reducing the community prevalence of stunting, wasting, and being underweight than the traditional approach based on targeting underweight children (WAZ < -2) (recuperative approach). Pregnant and lactating women up to 6 months postpartum were also targeted in both program models, as ensuring optimal health and nutrition of mothers is critical for their own as well as their offspring's health and nutrition. The study, however, was carried out in one country (Haiti) and in one particular context (Central Plateau), which was characterized by moderate levels of stunting (37 percent) and significant household food insecurity (Ruel et al. 2008; Menon et al. 2007a). It is not clear whether the same benefits would be obtained in populations with different levels of poverty, food insecurity, and undernutrition. Overall, the results were impressive and convincing, but begged replication in other contexts and in different operational environments.

Based on the evidence from Haiti, Food for Peace invited proposals to replicate the *preventive* approach (PM2A) in two other countries: Guatemala and Burundi. The two countries were selected because of their excessively high levels of child stunting. FANTA-2 considered that it would be important to incorporate a strong action-oriented research and development program linked to the implementation of PM2A in the two countries, to allow learning and refinement of the approach and to generate lessons learned for future PM2A programming.

This proposal lays out the research and development activities that will be implemented by the International Food Policy Research Institute (IFPRI) in the next five years, in partnership with FANTA and with the two key implementing institutions, Mercy Corps (MC) in Guatemala, and a Catholic Relief Services-led consortium of private voluntary organizations (PVOs) in Burundi.

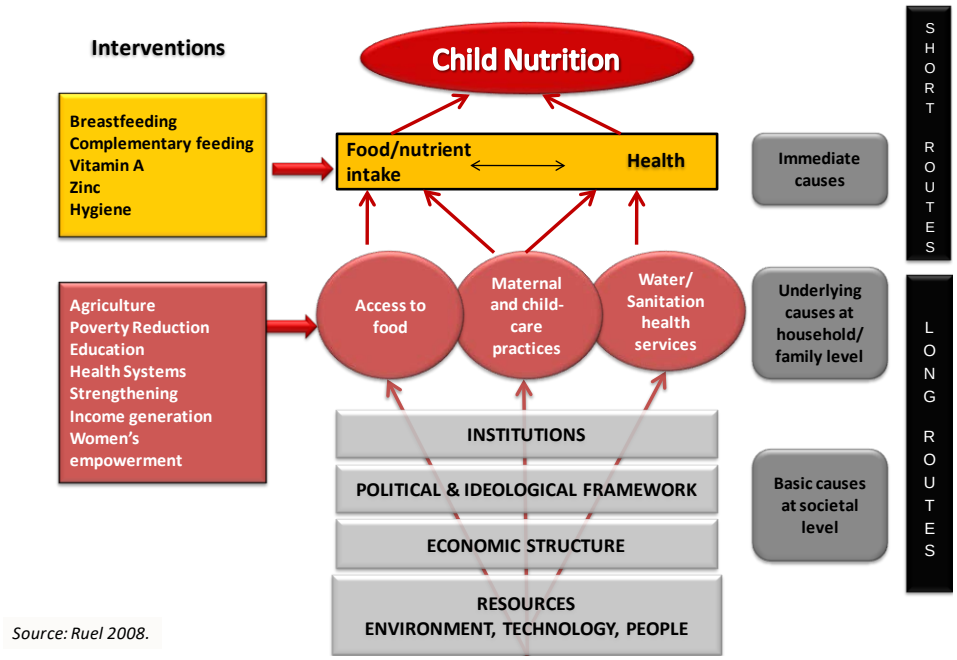
The proposal is structured as follows: Section 2 presents a short overview of the PM2A concept and of the rationale for preventing undernutrition in children under two; Section 3 presents the overall objectives of the research and the specific questions that will be addressed in the two country studies and their justification; Section 4 describes the program theory framework used to guide the impact and process evaluations; Section 5 describes how IFPRI plans to work with the implementing PVOs in the two countries; Section 6 and Section 7 describe the two country programs—Guatemala and Burundi—and presents the specific research and development objectives, the evaluation design, the comparison groups and research questions, the activities and methods, and the time line for the two studies; Section 8 describes the approach for the cost and cost-effectiveness study; Section 9 presents the overall time frame and a list of project deliverables and outputs; and Section 10 presents the budget and budget justification.

2. The "Preventing Malnutrition in Children under 2 Years of Age Approach" (PM2A): Description and Rationale

2.1. Brief Description of PM2A

The Preventing Malnutrition in Children under 2 years of Age Approach (PM2A) is a package of health and nutrition interventions aimed at preventing child undernutrition using food rations as one of the key intervention components. The approach targets pregnant and lactating women during the first 6 months postpartum, and children 6 to 24 months of age. Targeting is based on the mothers' physiological status and the child's age, rather than on the child's nutritional status as traditionally done in most FA-MCHN programs. The key principle underlying PM2A is that mothers and children receive the intervention *before* the child becomes undernourished[1] rather than after s/he has been identified as underweight (WAZ < -2 or other similar criteria). The main goal of PM2A is to prevent child undernutrition by addressing the key underlying determinants of nutrition: access to sufficient **food**, being in good **health**, and receiving adequate feeding and **care** (also referred to as Food, Health, and Care). Figure 2.1 illustrates that all three of these key determinants need to be addressed simultaneously in order to effectively improve child nutrition (Ruel 2008). It shows that access to food, maternal and childcare practices, and water/sanitation and health services (circles in the middle of the figure) are the most critical inputs to ensure adequate food and nutrient intake and health of the child, the two immediate determinants of child nutrition.

Figure 2.1: Conceptual framework of the determinants of child nutrition



Source: Ruel 2008.

[1] Note that this does not imply that none of the beneficiaries of PM2A are undernourished. PM2A targets all children regardless of nutritional status and not only children before they are malnourished.

The core package of interventions in PM2A thus includes three main components, each of which addresses one of the underlying determinants of nutrition:

1. **A food ration** (*Food*), which usually includes a family ration as well as an individual ration. The family ration aims at improving household food security and access to greater quantities of food, and to foods of higher quality (e.g., when using micronutrient-fortified foods). The individual ration directly targets pregnant or lactating women and/or children 6-23 months of age and aims at increasing their energy, protein, and micronutrient intake. The food ration thus serves the dual purpose of increasing household food security and improving energy and micronutrient intake among mothers and children.

2. **A behavior change and communication (BCC) strategy** *(Care)***:** beneficiary mothers are required to participate in BCC activities, which focus on the promotion of optimal infant and young child feeding practices, and care, hygiene, nutrition, and health seeking behaviors for mothers and children. The purposes are to improve maternal knowledge, stimulate adoption of recommended practices and use of available services, teach mothers how to use the donated and local foods, and ensure that greater food availability and access at the household level translates into greater energy and nutrient intake among targeted beneficiaries (mothers and children).

3. **Preventive health services and referral of children with severe acute malnutrition (SAM)** *(Health)*: beneficiaries are required to comply with regular visits to health centers to seek preventive and curative health and nutrition services. These include pre- and postnatal care, with prenatal care beginning as early as possible after conception, assisted delivery at birth, and postnatal controls as per national protocols. For children, preventive and primary health-care services usually include immunization, vitamin A supplementation, deworming, prevention and management of diarrheal diseases, malaria prevention strategies (if applicable), prevention and treatment of iron deficiency, growth monitoring and promotion, and identification and referral of children with severe acute malnutrition (SAM).

It is important to note that the three core components of PM2A are the same as those included in traditional FA-MCHN programs. The key differences are in the targeting mechanism (age of the child in PM2A and being underweight in traditional FA-MCHN), and in the focus of the BCC and health inputs, which are on the prevention of undernutrition in PM2A and on recuperating undernourished children in traditional FA-MCHN programs.

2.2. Rationale for Preventing Undernutrition in Children under Two

Global evidence regarding the timing of growth retardation was provided in 2001 by Shrimpton and colleagues, who analyzed data from 39 countries from three regions of the developing world (Shrimpton et al. 2001). The powerful figures presented in this paper make two key points. First, they show a striking consistency in the timing of growth faltering across countries and regions of the developing world. Second, they show that growth faltering occurs in the first two years of life for height-for-age, and in the first 12-18 months of life for weight-for-age, as seen by the rapid drop in the mean anthropometric indicators during these periods and the overall

flattening of the curves thereafter. These graphs thus illustrate the increased vulnerability to growth faltering and undernutrition of developing country children during their first 12-24 months of life. Complementary evidence is provided by the Oriente study in Guatemala, which shows the *greater benefits* of a high-protein/high-energy food supplement on child growth among children who were exposed to the intervention during their first 2-3 years of life, compared to those exposed at older ages (Burger 1993; Schroeder et al. 1995; Rivera and Habicht 1996, 2002). The findings are consistent across several outcomes and hold true even for long-term outcomes such as adult economic productivity, as measure by increased income and wages (Hoddinott et al. 2008). For both growth velocity in childhood (Schroeder et al. 1995) and wages at adulthood (Hoddinott et al. 2008), the benefits of the supplementation declined with child age, even within the first three years of age. In other words, benefits were greater among children exposed before two years of age than they were for children exposed between two and three years of age. No impacts on these outcomes were found among children exposed to the intervention at older ages.

The importance of preventing stunting in early childhood cannot be overemphasized; stunting in childhood is associated with increased risks of morbidity and mortality, delays in motor and cognitive development, lower schooling performance, and reduced cognition and economic productivity at adulthood (Hoddinott et al. 2008; Maluccio et al. 2009; Martorell 1993; Granthan-McGregor et al. 2007; Victora et al. 2008). The second paper of the *Lancet Series* (Victora et al. 2008) presents new analyses of five cohort studies that look at the consequences of maternal and child undernutrition for adult health and human capital formation. This new body of evidence corroborates that malnutrition *in utero* and stunting in the first two years of life lead to irreversible damages in key human capital outcomes, including adult height, schooling, and income, and under certain postnatal circumstances, increases the risk of obesity and chronic diseases. Globally, malnutrition in early childhood stunts human capital formation, hinders economic productivity, and perpetuates the cycle of poverty and malnutrition; it produces generations of adults who do not reach their full educational potential, who are at greater risk of poor health and who have limited physical, cognitive, and reproductive capacity; finally, it wastes resources in increased health-care costs due to poor population health and nutrition (Ruel 2009).

3. Overall Objectives of the Research on PM2A in Guatemala and Burundi

As described above, the Haiti study provided the first programmatic evidence, using a cluster randomized evaluation design, that preventing child undernutrition through an integrated program providing food rations, BCC, and preventive health and nutrition services is both feasible and highly effective. The study's principal aim was to compare a newly designed preventive approach with the traditional (recuperative) food-assisted MCHN program approach, and therefore included only two comparison groups: one group of communities that was randomly assigned to the preventive approach and another group assigned to the recuperative approach. For logistical and financial reasons, the study did not include a randomized control group receiving no intervention. As such, the study design was well-suited to achieve its main goal—i.e., to test whether the preventive approach was more effective than the recuperative approach at preventing child undernutrition—but it left a number of questions unanswered. For instance, the absence of a control group prevented the assessment of the absolute impact and cost-effectiveness of the two approaches compared to no intervention. The study was also not designed to assess the contribution of different components of the package, such as the food ration or the BCC, or the additional benefits of including a family ration in addition to an individual food ration. Other questions that remain relate to the optimal size, timing and composition of the food ration, and the duration of exposure to the program for children (e.g., would the same impact be achieved if children were in the program until 18 months of age rather than 24?).

The present study will address several of these design and operational questions, which will allow further refining of the PM2A, facilitate its replication in different contexts, and maximize its impact and cost-effectiveness in future programming. The key research questions that will be addressed in the present study can be organized around three broad objectives:

1. **Impact and cost-effectiveness**: Assess the impact and cost-effectiveness of PM2A on child nutritional status (Burundi and Guatemala).

2. **Optimal composition, size, and timing of food rations in PM2A:** Assess the differential and absolute impact of varying the size and types of foods incorporated in the food ration of the PM2A. More specifically, assess the effect of different sizes of family food rations, and assess the impact of substituting the individual food ration with new micronutrient-rich products such as lipid-based nutrient supplements (LNS) or micronutrient Sprinkles (Guatemala).

3. **Optimal duration of PM2A:** Assess the differential and absolute impact of varying the duration and timing of exposure to PM2A on child nutritional status.

Table 3.1 presents an overview of the broad objectives of the study and related research questions. It also indicates which comparison groups will be used to answer the different research questions and in which country(ies) the specific research questions will be addressed. More details on the objectives and research questions that will be addressed in the two country case studies are provided in Sections 6 and 7.

Table 3.1: Summary of overall study objectives and research questions (all impacts are on child nutritional status)

Objective	Research Question	Groups compared		Country B=Burundi G=Guatemala
Objective 1. Assess the impact and cost-effectiveness of PM2A on child nutritional status (NS)				
a) Evaluate the impact of PM2A compared to a control group	Does PM2A improve child NS compared to a control group?	**PM2A**	**Control**	B, G
b) Evaluate the cost-effectiveness of PM2A	What is the cost-effectiveness of PM2A?	**PM2A**	**Control**	B, G
Objective 2. Determine the optimal size and composition of food rations in PM2A				
a) Evaluate the impact of PM2A *with a reduced family ration* (providing about half of the energy (239 kcal/capita/day) of the PM2A ration used in Guatemala (445 kcal/capita/day), compared to a control group	Does PM2A with a reduced family ration improve child NS?	**PM2A *with a reduced family ration***	**Control**	G
b) Assess the differential impact of a *reduced family ration* compared to the family ration size used in the PM2A program in Guatemala	Do large family rations (e.g., 445 kcal/capita/day) have a greater impact on child NS than reduced family rations (239 kcal/capita/d)	**PM2A *with a reduced family ration***	**PM2A**	G
c) Evaluate the impact of PM2A *without a family ration* compared to a control group	Does PM2A without a family ration improve child nutritional status?	**PM2A *without family ration***	**Control**	G
d) Assess the differential impact of a PM2A program *without a family ration* compared to the PM2A with family ration	Are family rations necessary for PM2A to have an impact on child NS?	**PM2A *without family ration***	**PM2A**	G
e) Evaluate the impact of PM2A *with a lipid-based nutrient supplement (LNS)* instead of CSB as the individual ration compared to a control group	Does PM2A *with LNS* as the individual ration improve child nutritional status?	**PM2A *with LNS as the individual ration***	**Control**	G
f) Assess the differential impact of *substituting LNS for CSB* as the individual ration in PM2A	What is the differential impact of PM2A *with LNS* compared to PM2A with CSB as the individual ration?	**PM2A *with LNS as the individual ration***	**PM2A**	G
g) Evaluate the impact of PM2A *with MN Sprinkles* instead of CSB as the individual ration compared to a control group	Does PM2A *with MN Sprinkles* as the individual ration improve child nutritional status?	**PM2A *with MN Sprinkles as the individual ration***	**Control**	G
h) Assess the differential impact of *substituting MN Sprinkles for CSB* as the individual ration	What is the differential impact of PM2A *with MN* compared to PM2A with CSB as the individual ration?	**PM2A *with MN Sprinkles* as *the individual ration***	**PM2A**	G

	Objective	Research Question	Groups compared		Country B=Burundi G=Guatemala
i)	Evaluate the differential impact of *PM2A with MN Sprinkles* vs. *PM2A with LNS* as the individual ration	Does PM2A + LNS (instead of CSB) have a similar or greater impact than PM2A + MN Sprinkles (instead of CSB)?	**PM2A *with MN Sprinkles***	**PM2A *with LNS***	G
	Objective 3. Determine the optimal duration and timing of exposure to PM2A				
a)	Evaluate the impact of PM2A keeping children in the program *up to 18 months of age* compared to a control group	Does a PM2A program that stops providing benefits to children at 18 months of age have an impact on child NS?	**PM2A *until child is 18 mo***	**Control**	B
b)	Evaluate the differential impact of PM2A keeping children in the program up to the age of *24 vs. 18 months*	Is program eligibility up to 24 mo of age necessary for impact on child NS, or is 18 months sufficient?	**PM2A *until child is 18 mo***	**PM2A**	B
c)	Evaluate the impact of PM2A providing *no food rations during pregnancy* compared to a control group	Does PM2A without food (family + individual rations) during pregnancy improve child nutritional status?	**PM2A *without food during pregnancy***	**Control**	B
d)	Evaluate the differential impact of PM2A providing *food or no food during pregnancy*	Are food rations (family + individual) necessary during pregnancy to improve child NS?	**PM2A *without food during pregnancy***	**PM2A**	B

This study is clearly more ambitious than the Haiti study and will go far beyond the comparison of two program approaches. It will validate the proof of concept of PM2A in two more countries with different social, political, and cultural environments, and with two different programmatic delivery systems. The inclusion of a valid, randomized control group will allow an assessment of the absolute impact and cost-effectiveness of the program in these two contexts. The research will also generate strong evidence-based recommendations on how the PM2A should be designed to maximize its impact on the prevention of childhood undernutrition in the most cost-effective way. This will include critical information regarding the optimal composition and size of food rations, the best timing and duration of exposure to the PM2A, and the role of new products, such as micronutrient sprinkles and lipid-based nutrient supplements in Title II programs.

The remainder of this section provides a brief overview and justification of the broad research questions that will be addressed in the study.

3.1. Overall Impact of PM2A on Child Nutritional Status and Cost-effectiveness

The first group of study objectives will look at the overall impact of PM2A in Burundi and Guatemala on child nutritional status as the main outcome. Other secondary outcomes that will be studied include child feeding practices, morbidity, anemia and selected child development outcomes, and household food security. The two studies will also assess the overall cost-effectiveness of PM2A, using child height-for-age Z-scores and stunting as the effectiveness measure. In order to assess the overall impact and cost-effectiveness of PM2A, the two evaluation designs will use randomization to assign clusters of communities to intervention (PM2A) and control groups. Nonrandomized, purposively selected control groups are easier to manage programmatically, but they are often not useful because of their lack of comparability with the intervention group(s) on aspects that are difficult to measure and control for. All too often nonrandomized control groups end up not being used in final analyses and publication of findings because they are deemed unacceptably different from the intervention group. We will therefore use cluster randomization for all intervention and control groups in both countries.

3.2. Optimal Composition and Size of Food Rations for PM2A: Large, Reduced, or No Family Rations; Individual Rations, Lipid-based Nutrient Supplements, or Micronutrient Sprinkles?

The second set of study objectives aims at identifying the best mix of and size of food rations that will ensure the maximum impact and cost-effectiveness of PM2A. When the Haiti results were released, the most commonly asked question was, What is responsible for the greater impact of the preventive compared to the recuperative approach? Is it the food? Is it the BCC? Is it the longer exposure to the program? As indicated earlier, the Haiti evaluation design was not set up to answer these questions, and therefore the relative contribution of the different program components to the impact on nutrition remains unanswered. The present study will look at some of these questions in Guatemala and will focus on aspects related to ration size and composition, and the use of new micronutrient supplement products. Although we had intended to test the question of which specific component—food, BCC, or both—was responsible for the impact on child nutrition, the PM2A implementer (Mercy Corps in Guatemala) felt that a BCC only (no food) group was unfeasible. Details regarding the design and comparison groups that

will be used in Guatemala are provided in Section 6. A brief summary of the approach is provided here along with a justification for the specific questions addressed.

The PM2A will follow Haiti's model and will include the three components described above: food rations (family + individual rations); required participation in preventive BCC; and required use of preventive and primary health and nutrition services. All pregnant and lactating women up to 6 months postpartum will be eligible for the program as well as all children 6–24 months of age. The questions of family rations *vs*. reduced family rations *vs*. no family rations and of individual CSB (fortified blended food) rations vs. lipid-based nutrient supplements vs. micronutrient sprinkles will be addressed in Guatemala. In Burundi, we will also compare no food (either family or individual) during pregnancy *vs.* micronutrient sprinkles to assess the contribution of food rations during pregnancy to achieving nutritional impact on the child at 24 months of age. In both countries, the research questions will be addressed by creating different comparison groups (study arms), which will be compared among themselves and with a control group (see Table 3.1, comparisons groups for research questions 2a-2k).

The question of whether take-home food rations are necessary to achieve an impact on child nutritional status in the context of food-assisted maternal and child health and nutrition programs is an important one, and has not been carefully studied. Most of the evidence regarding the impact of food supplements on child nutrition comes from controlled efficacy trials—where food intake of the target child is precisely controlled and measured (e.g., Oriente study in Guatemala) (see TRMs [FANTA2 2009] for brief overview). Food aid programs providing take-home food rations are much more complex to analyze because the food is often distributed to mothers who then decide how they distribute the food within—and sometimes outside—their household. Programs often provide a "family ration" in addition to an individual ration, recognizing the potential problem of sharing of food, and they urge mothers to use the individual ration for the targeted household member (either themselves or their young child). In spite of these measures, the problem of donated food sharing is widespread. In Haiti, the vast majority of mothers reported having shared some of the program food, either from time to time or regularly, and more than half of the mothers reported sharing with neighbors or relatives outside the household. As a result none of the food commodities lasted the whole month, although the fortified corn (or wheat) soy blend targeted to the child (8 kg/month) was reported to last the longest (on average about three weeks). The oil, on the other hand, which was also targeted to the child or the pregnant/lactating woman (2 kg/month), lasted, on average, only two weeks (Loechl et al. 2004). These results were obtained in the context of a program that provided particularly large amounts of food (8 kg of fortified blended cereals and 2 kg of oil per month for the targeted child; and 10 kg of soy-fortified bulgur and 2.5 kg of lentils as family ration).

Given the problems of sharing, it is difficult to predict the amount of food—and of energy, protein, and micronutrients—that actually gets to the targeted individual within the household. It is therefore difficult to assess adequate ration size, because the magnitude of leakage is unknown and is likely to depend on various factors, including the severity of poverty and household food insecurity, family size and demography, and cultural factors. It is also unclear whether providing more food actually triggers even more sharing and leakage inside and outside the household, or whether it results in more of the donated food being consumed by the individual(s) targeted by the program.

From a theoretical point of view, we could assume that family rations would be needed—in addition to effective BCC—in contexts where food insecurity is severe and households cannot afford a high quality diet. In such circumstances, family rations could help relieve the household "food access" constraint to improved nutrition, as well as help reduce the sharing of the individual ration with non-beneficiaries, and facilitate the adoption of recommended infant and young child feeding practices. The reverse situation, where food security is adequate (at least in terms of quantities of food and energy), could lead to another type of problem: excess energy consumption by some household members and an increased risk of overweight and obesity, as found in Mexico. A poverty-alleviation program providing monthly food baskets to households in poor rural communities in Southern Mexico (The *Programa de Apoyo Alimentario* [PAL]) was found to increase household energy consumption by 6–10 percent, in a population that already had more than adequate energy intake at baseline (2,650 kcal/adult equivalent/day), in spite of being extremely poor. The program also increased women's body weight by 0.5 kg on average after 18 months of participation, a dangerous outcome in a population where 73 percent of the women were overweight or obese at baseline (Jef Leroy, personal communication). These results highlight the potential risks associated with providing energy-rich food rations in populations that are not energy-deficient at baseline. In these situations, it is likely that even infants and young children would not need the extra energy, but would benefit from high quality, micronutrient-rich foods.[2]

To address some of these questions, the Guatemala study will compare a PM2A providing a full family ration (272 kcal/household member, assuming average household size of 6.3 members) with a PM2A providing a reduced family ration (154 kcal/household member, corresponding to 57 percent of the full family ration) and a PM2A without a family ration (i.e., providing only an individual ration) (see Table 3.1, research questions 2a-d). The family ration in Guatemala consists of rice, beans, and oil (see Section 6.2 for details on ration size provided in Guatemala).

The other question we will examine in Guatemala is whether replacing the individual food rations (CSB in this case) with lipid-based nutrient supplements or micronutrient Sprinkles would achieve the same impact on child nutritional status as the PM2A with the individual ration. The rationale for looking at this issue is that poor diet quality is a much more widespread problem globally than lack of food (or calories). So, while it is possible for example that the population in Alta Verapaz has sufficient calories available at the household level, they may not have diets that include a variety of foods or foods that are rich in bioavailable micronutrients such as fruits, vegetables, and animal source foods. The same is true for infants and young children, who may be fed foods of adequate energy-density in the right amount and frequency, but may not consume the right types of foods to meet their micronutrient needs. Infants and young children, especially during their first year of life, have particularly high requirements for certain micronutrients and need to consume either animal source foods, or adequately fortified foods or micronutrient supplements on a daily basis (PAHO/WHO 2003). The Haiti study documented that porridges made with donated fortified cereal blends, such as CSB and WSB, could not ensure adequate intake of iron and zinc in children 6–12 months of age, even when

[2] Another potential negative consequence of providing large amounts of food in nonfood-insecure populations is the risk that it affects local markets. This has led the U.S. government to promulgate a law (called "Bellmon amendment"), which regulates food donations to avoid negative effects on local production and consumption markets. Fears that too much food may have a disincentive on local production have not been substantiated by existing studies (e.g., Barrett and Maxwell 2005), but the sale of donated food on local markets is a well known phenomenon.

complemented by locally available, acceptable, and affordable foods (Ruel et al. 2004). The fortified cereal blends (CSB and WSB) do not have sufficiently high levels of bioavailable iron and zinc fortificants to completely close the gap in these nutrients in young children who have small gastric capacity and high iron and zinc requirements. So, in the present study, we will test whether substituting the individual ration of CSB with LNS or multiple micronutrient Sprinkles would have the same (or a greater) impact on child nutrition (Table 3.1, research questions 2e-h). We will also compare the differential impact of LNS and multiple micronutrient Sprinkles as substitutes for the individual CSB ration (Table 3.1, research question 2i).

The main rationale for testing LNS in this study is that it could provide the additional micronutrients needed by infants and young children, which the donated food commodities in their current formulation (even CSB and WSB) cannot provide for this age group. LNS also contains energy, protein, and essential fatty acids, which are essential for the utilization of micronutrients and for optimal growth. LNS is also easy to use and preserve and well accepted by mothers and children. There is some preliminary evidence to support that LNS improves growth among children 6 to 18 mo of age (Adu-Afarwuah et al. 2007; Phuka et al. 2008) and that these benefits persist up to two years after the end of supplementation (Phuka et al. 2009). However, this evidence is limited to two relatively small trials. The first one in Ghana compared the provision of LNS to children from 6 to 12 mo of age to the provision of two different micronutrient formulations (sprinkles containing six micronutrients [the anemia-formulation]; and crushable multiple micronutrient tablets similar in micronutrient content to the LNS) (Adu-Afarwuah et al. 2007). The second study, conducted in Malawi, compared the provision of a fortified maize-soy flour (MSF) to children 6 to 18 mo of age with two different LNS supplements (high energy LNS [FS50] and low energy LNS [FS25]) (Phuka et al. 2008). In this study, the MSF and high energy LNS (FS50) were designed to provide approximately the same amount of energy (282 and 256 kcal/d), and the two formulations of the LNS were designed to have a similar micronutrient content but different energy and protein content (256 vs. 127 kcal/d and 7.0 vs. 3.5 g/d, respectively).

The study in Ghana found a greater impact of the LNS compared to the crushable tablets in both weight and length gain, and of the LNS compared to the two other micronutrient supplements combined (tables and sprinkles). The authors hypothesized that the greater growth impact of LNS may be due to its fatty acid content, rather than its energy content (Adu-Afarwuah et al. 2007).

In Malawi, both of the LNS groups had a lower prevalence of severe stunting compared to the fortified flour (MSF) group at the end of the supplementation period (Phuka et al. 2008). Two years later, however, the FS25 group actually fared significantly worse in terms of weight gain than the children in the MSF group (Phuka et al. 2009). The differences between the FS50 and MSF groups remained consistent with the FS50 group having better growth outcomes throughout. It is unclear why the FS25 group did not fare as well over time, but it could be that additional energy and/or protein is necessary to improve growth in this food-insecure population.

While both of these studies have demonstrated the potential of LNS to improve children's growth, it is still unclear what is responsible for these improvements in growth (e.g., energy, protein, essential fatty acids, micronutrients, population factors, etc.) and what the optimal dose and duration of LNS is for improving growth. The specific formulation of the LNS that will be

used in Guatemala is still to be decided, but it will aim to address multiple micronutrient deficiencies. The study will compare replacing the individual CSB ration with LNS (Table 3.1, research questions 2e and 2f).

Micronutrient Sprinkles are another attractive option for improving the micronutrient intake and status of mothers and children. Daily doses of Sprinkles are at least fourfold cheaper than LNS, and like LNS, they have been found to be easy to use and well accepted by mothers and children (Loechl et al. 2009). In Haiti, most mothers reported using Sprinkles only for the targeted child, an important advantage over food rations, which mothers reported to share widely with other family members.

The anemia-formulation of Sprinkles (with five micronutrients) has been shown to be highly effective at reducing the prevalence of anemia in children in short periods of time (Zlotkin et al. 2003; Menon et al. 2007a). In Haiti, for example, approximately half of the children receiving fortified cereals blends were anemic, and sprinkles supplementation reduced anemia prevalence to 24 percent in two months (Menon et al. 2007). There is no evidence to date, however, to support the use of micronutrient Sprinkles to improve growth. This could be due to many reasons, including wrong micronutrient mix (the anemia formulation was originally designed to address anemia, not growth), too short duration of supplementation, inadequate amount of zinc provided in the supplement, and a low prevalence of stunting in the populations tested. The Ghana study, which compared LNS with Sprinkles (also anemia formulation) is inconclusive relative to the differential impact of LNS and Sprinkles on growth. The study found that LNS had a greater impact on height and weight *only* when the Sprinkles and the micronutrient crushable tablet groups were combined; differences in growth between the LNS and the Sprinkles groups were not statistically significant (Adu-Afarwuah et al. 2007).

We therefore believe that it is still important to examine the relative benefits of LNS and Sprinkles for child growth, especially since the Sprinkles are a much cheaper option. In Guatemala, we will compare LNS and Sprinkles, and use a multiple micronutrient formulation of Sprinkles rather than the anemia formulation to ensure greater comparability between the two products. We will provide the supplements both to mothers (pregnancy and up to 6 months of lactation), and to children during the entire period from 6-24 months of age.

There is also evidence to support the provision of multiple micronutrients (MMN) to pregnant women to reduce the risk of low birth weight (RR = 0.83), small-for-gestational age newborn babies (0.91), and maternal anemia (0.61) when compared to no supplementation or a placebo (Haider and Bhutta 2006). Overall the provision of MMN to pregnant women has modest benefits for birth outcomes, however; these outcomes may be improved through the provision of MMN in a lipid-based supplement as was found in a recent study conducted in Burkina Faso (Huybregts et al. 2009). In this study, pregnant women who received MMN in a lipid-based supplement gave birth to longer babies than women who received the supplement as a pill and the effect was greater among the children of women who were undernourished (BMI < 18.5 kg/m^2) or anemic (Hb < 11 g/dL) at baseline (Huybregts et al. 2009). Although these results are promising, it is important to further explore the provision of MMN supplements during pregnancy on maternal and birth outcomes in a programmatic setting compared to both a control group, a group that receives a fortified food ration as well as to a group that receives the MMN in a LNS.

The findings related to the impact of combining or substituting new products with traditional blended cereals (CSB and WSB) to provide essential micronutrients in the context of Title II programs targeted to mothers and children will be particularly important for Food for Peace (FFP), as they continue to explore best alternatives for future programming. FFP has recently commissioned a study on the quality of food aid, which is tasked with revisiting the current formulation of fortified blended cereals. The results of our study will feed into this renewed effort to improve the quality of food aid, and to identify most cost-effective solutions. It will allow FFP to be at the cutting edge of these new developments and lead the way in what may constitute an important future trend in development assistance.

3.3. Optimal Duration and Timing of Exposure to PM2A

The optimal timing of exposure to PM2A will be addressed only partially in the study. In Burundi, we will test whether not providing the food ration (family + individual) during pregnancy (as discussed above) has the same impact on child growth as the full PM2A, which provides food rations during pregnancy in addition to BCC and prenatal services. Thus, we will assess the role of food assistance during pregnancy in improving child nutritional status during the first two years of life. We will not, however, include a group of pregnant women who receive no program benefits at all during pregnancy, except for the control group. Therefore, the question of "timing" of exposure will be answered only as it refers to the "timing" of exposure to food assistance, and not the timing of exposure to the whole PM2A program. The control group will help assess the absolute impact of the different program models, but it will not help answer the "timing" question related to whether or not the regular PM2A during pregnancy confers an additional benefit on child growth from 0-23 months of age.

The question of duration of exposure for the child will be addressed in Burundi, where we will test the absolute and differential impact of the PM2A where children exit at 24 months of age with a PM2A with children exiting at 18 months (see Table 3.1, research questions 3a-3b). There is no information about the optimal duration of participation in these types of programs, but the growth curves in both Guatemala and Burundi suggest that children in these two countries might actually continue to benefit from exposure to nutrition interventions between 18 and 24 months of age, since their growth continues to deteriorate beyond 18 months of age. To our knowledge, this will be the first study to systematically compare two different lengths of exposure to a food assisted maternal and child health and nutrition program.

4. Program Theory Framework

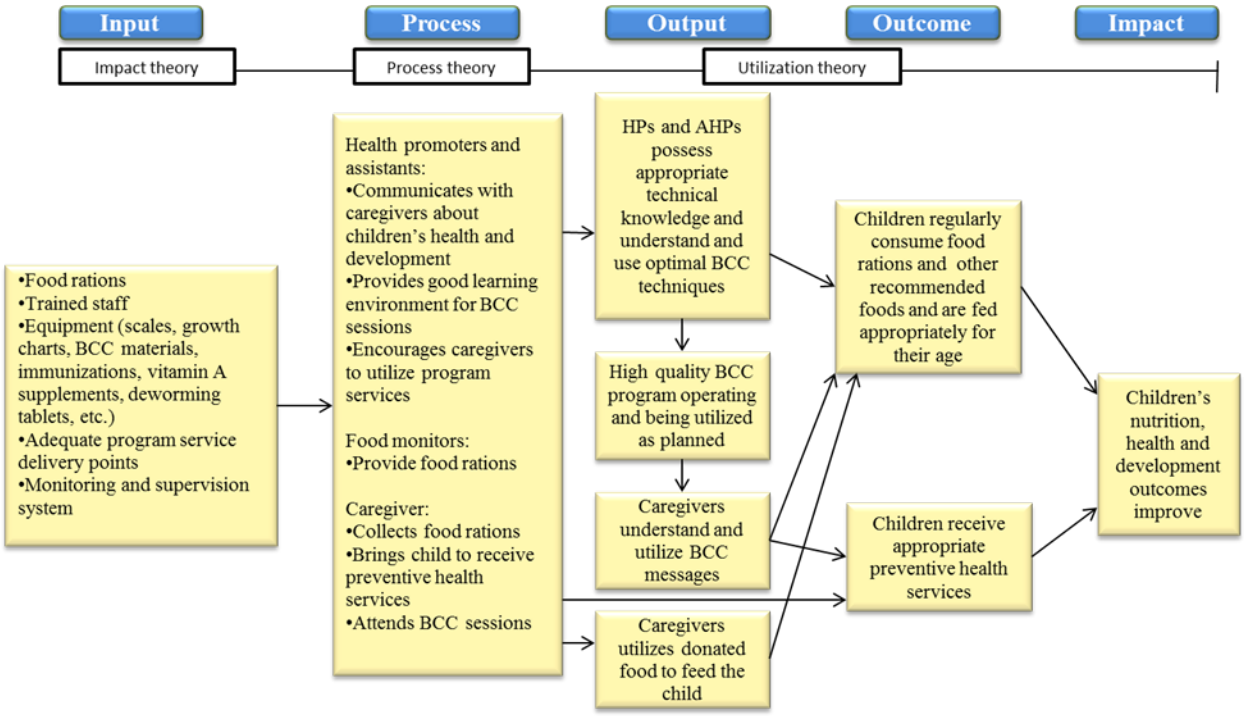
In the two countries, we will use a program theory framework as the foundation for program design and implementation and for the operations research (OR) and impact evaluation. Program theory is the conceptualization by those involved in and affected by the program (e.g., implementers, beneficiaries, and partners) that may potentially be evaluated objectively by outsiders. Inherent in program theory is the rationale for its existence and implementation approaches. If the program theory is adequate and the program is implemented according to the outlined plan, then the desired outcomes should be achieved (see Figure 4.1).

The first step in the use of a program theory framework is to identify the key program components, the factors that may affect the optimal delivery or utilization of each of these components, and the underlying assumptions associated with each of the key components. A clear identification and analysis of each of these aspects is critical to identify potential bottlenecks in the delivery and utilization of the different components of the program. This information can then be used to further refine the program, which will increase the potential for the program to have a significant impact on improving children's nutritional status. In addition, by using a program theory framework and clearly identifying and measuring each of the hypothesized steps in the program impact pathway, we will acquire a better understanding of *how* the impact was achieved. This information will also be particularly useful to define the key components that must be in place in order for the PM2A to be successful in improving children's nutritional status and places where the program may need to be modified or further strengthened in order to achieve maximum impacts.

The *impact theory* related to PM2A centers around the intended impacts of the three main components of the program: (1) food rations, (2) BCC intervention, and (3) preventive and primary health-care inputs (e.g., immunization, vitamin A supplementation, etc.) (Figure 4.1). The provision of the food rations is expected to improve energy and micronutrient intake and provide an incentive to participate in the program, and thus improve health and nutrition outcomes including child growth. The BCC intervention is expected to improve these same outcomes by increasing caregiver knowledge, awareness and adoption of optimal infant and young child feeding practices, best hygiene practices, and appropriate preventive and curative health-seeking behaviors. The condition of the program—that beneficiary households comply with regular health visits in order to receive their benefits—ensures that households members, especially mothers, infants, and young children, receive appropriate preventive health inputs in a timely fashion. The *process theory* involves the processes that will be put in place, such as establishing distribution points for the food rations, establishing suitable venues for the BCC intervention, and ensuring that adequate supplies and training are available to ensure that the interventions are implemented in an optimal way. Finally, *utilization theory* relates to the last important step in the framework—that the level of utilization of the different services (and adoption of practices in this case) by the targeted beneficiaries be optimal. In PM2A, mothers will have to regularly attend BCC sessions and routine preventive health-care visits in order to receive their food ration. They will also have to receive their food regularly in order to keep their eligibility for the program. Mothers will also have to adopt the infant and child feeding and care practices promoted by the program in order for children to have improved diets, reduced illnesses, and improved growth and nutritional status.

Clearly defining the program theory before a program begins is essential not only to ensure program impact, but also to allow understanding and interpretation of *how* program impacts have been achieved. This type of information is critical for replication of the program model as well as for scaling-up efforts. Thus, the program theory underlying the PM2A will serve as the foundation for the design of the study and a detailed program theory will be developed at the onset of the study for each country, in close collaboration with the implementing PVOs.

Figure 4.1: Basic program theory framework for the PM2A



5. Overview of Partnership and Coordination between IFPRI and the Implementing PVOs

In both countries, IFPRI will work in close collaboration with the PM2A implementing PVOs—Mercy Corps in Guatemala, and the consortium of PVOs led by Catholic Relief Services (with International Medical Corps [IMC], Food for the Hungry [FH], and Caritas Burundi) in Burundi. IFPRI will assist the implementing PVOs in designing their PM2A program and its implementation plan. We will pay particular attention to the BCC component of the program and in ensuring that it is designed in such a way that it is truly preventive (i.e., focusing both on the content of the BCC messages and the timeliness of their delivery). We will also design and carry out a rigorous impact evaluation and assess the cost-effectiveness of the different study arms that will be implemented in the two countries. More specifically, IFPRI will

1. Assist PVOs in doing the formative research to design the BCC messages and develop the overall implementation strategy, including defining the primary and secondary venues for the delivery of the BCC strategy.

2. Assist PVOs in developing the BCC messages and strategy and in designing the implementation plan. IFPRI will pay particular attention to the BCC messages related to infant and young child feeding practices, and to their timely delivery to mothers at their best learning moment.

3. In Guatemala, IFPRI will assist Mercy Corps in conducting formative research at the Convergence Centers (CC) in order to ensure the adequate provision of preventive health services in the program areas (see Section 5).

4. Carry out operations research to assess program operations, to gather data on perceptions of program implementers (at different levels) and beneficiaries regarding the program, and to assess quality of service delivery. The operations research will be designed based on the program theory framework described in the previous section.

5. Carry out an impact evaluation in the two countries. This will involve designing the two country-specific impact evaluations using cluster randomized designs and including a randomized control group; carrying out the fieldwork and data analysis of the impact evaluation; and writing up reports and dissemination materials for a variety of audiences.

6. Carry out the cost-effectiveness study. This will involve working with the implementing PVOs to design a cost data collection system of the different program components and analyzing the data to derive cost and cost-effectiveness estimates.

The program theory framework described in the previous section will guide all project activities listed above. For instance, it will guide the design of the formative research as well as the operations research and impact evaluation, and will help design data collection plans that include information gathering at all steps along the pathway from inputs to impact. We will use mixed methods, including a combination of quantitative and qualitative assessment methods to collect information on all the essential steps along the impact pathway. This will help improve our understanding of how the program is working and whether there are critical bottlenecks in

service delivery or utilization that could be improved. This rich set of data will facilitate interpretation of the impact results, especially our understanding of whether differences between treatment groups are due to the specific intervention components or to differences in implementation, operations, or quality of service delivery.

6. Guatemala

6.1. Country Specifics, and Patterns of Child Growth

6.1.1. Guatemala

Guatemala is located in Central America and shares borders with Mexico, El Salvador, Honduras, and Belize (Figure 6.1). In addition, it has two coastlines, one on the Pacific Ocean and the other on the Caribbean Sea. Fifty percent of the labor force is involved with agriculture and the main exports are coffee, sugar, and bananas. The per capita GDP is $5,200 and the literacy rate is 69.1 percent and is higher among men (75.4 percent) than women (63.3 percent). The population of Guatemala includes many different ethnic groups, including Mestizo (Ladino) and European, which make up the majority of the country's population (59.4 percent) as well as a number of indigenous ethnic groups of primarily Mayan descent, including K'iche, Kaqchikel, Mam, and Q'eqchi (CIA 2009a).

Guatemala ended 36 years of civil war in 1996 with the signing of Peace Accords. However, the country is still recovering from the impact of the war in the areas of food security and malnutrition, and in social and economic development in general. Unemployment rates are high and inequality between the Ladino and indigenous populations remains a significant problem in Guatemala, especially in relation to landownership, income, and education.

According to the government of Guatemala, one-third of the population is unable to meet their daily food needs. Food security is a bigger problem in rural areas than urban areas and among indigenous populations than others. The government of Guatemala has implemented and supported many programs to address the problem of food insecurity; however, many households continue to be food insecure.

Historically, Guatemala has had some of the highest rates of poverty in Latin America. A recent report published by the World Bank (World Bank 2009a) has indicated that Guatemala has been able to reduce the prevalence of poverty from 56 percent to 50 percent between 2000 and 2006. However, the prevalence of extreme poverty did not improve during the same period, which they believe is largely due to an increase in food prices relative to general prices. Extreme poverty is higher among indigenous populations and has not changed since 2000. In general, socioeconomic indicators have shown positive changes between 2000 and 2006 with increases in primary and secondary school enrollment and a decrease in infant and child mortality rates. Overall, the World Bank report concludes that while Guatemala is still at the low end of the distribution for poverty and socioeconomic indicators, the changes in these indicators have been better than for many poor countries between 2000 and 2006.

Figure 6.1: Map of Guatemala

6.1.2. Alta Verapaz

The PM2A program in Guatemala will be implemented in the department of Alta Verapaz. Alta Verapaz is one of the most food-insecure areas of Guatemala and has some of the highest rates of stunting and infant and maternal mortality in the country. The majority ethnic group in this area is Q'eqchi and difficulties in communications with health professionals who speak Spanish has been cited as one reason for poor utilization of health services in this area.

6.1.3. Child Growth

There are no recent nationally representative data on child nutritional status in Guatemala. The most recent data are from the Demographic and Health Survey (Encuesta Nacional de Salud Materno Infantil [ENSMI]) carried out in 2002. We used the data to estimate growth curves for height-for-age (HAZ), weight-for-height (WHZ), and weight-for-age Z-scores (WAZ) for children 0-60 months of age (Figures 6.2, 6.4, 6.6, and 6.8). The figures were then reproduced for the department of Alta Verapaz in order to demonstrate the severity of child undernutrition in this area of Guatemala (Figures 6.3, 6.5, 6.7, and 6.9). Z-scores were calculated using the new World Health Organization (WHO) reference (WHO Multicentre Growth Reference Group 2006).

The growth patterns in Guatemala follow the general pattern found in many developing countries in which growth faltering typically starts in the first few months of life (even in populations where birth weight is largely normal) and intensifies gradually throughout the first two years to reach a plateau at the ages of two to three years (Ruel 2001; Shrimpton et al. 2001) (Figure 6.2). Figure 6.3 demonstrates that in Alta Verapaz, this same pattern of growth faltering is seen; however, compared to Guatemala as a whole, the faltering is more severe in HAZ, with children 18-24 months of age having an average HAZ of -3.0, compared to the national average of approximately -2 Z-scores for this age group.

The prevalence of stunting among children under 5 in Guatemala is estimated at 49 percent, the highest in Latin America and among the highest worldwide (WFP 2009a). It is not clear where this estimate comes from, as the most recent nationally representative dataset is from the DHS in 2002, which shows a prevalence of 55 percent. The highest prevalence of stunting is found among children 12-60 months of age, where it ranges between 52 and 63 percent (Figure 6.4). In Alta Verapaz, the prevalence of stunting is even higher with 62 to 83 percent of the children 12-60 months of age being stunted (Figure 6.5). The prevalence of underweight children is much lower, ranging between 10 and 25 percent, depending on the age group. Similar to the findings for stunting, a large increase in the prevalence of underweight children is observed after 12 months of age (Figure 6.8). In Alta Verapaz, the prevalence of underweight children peaks among children 18 to 24 months of age and then slowly declines with another peak at 48-54 months of age (Figure 6.9).

In this population, as in all of Latin America, wasting is uncommon (Figures 6.6 and 6.7), with a prevalence lower than 5 percent at all age groups. Mean WHZ remains above 0 throughout infancy and childhood, reaching approximately +1 Z-score among children 54-60 months of age in Alta Verapaz (Figure 6.3).

Figure 6.2: Height-for-age, weight-for-height, and weight-for-age Z-scores, by child age in Guatemala

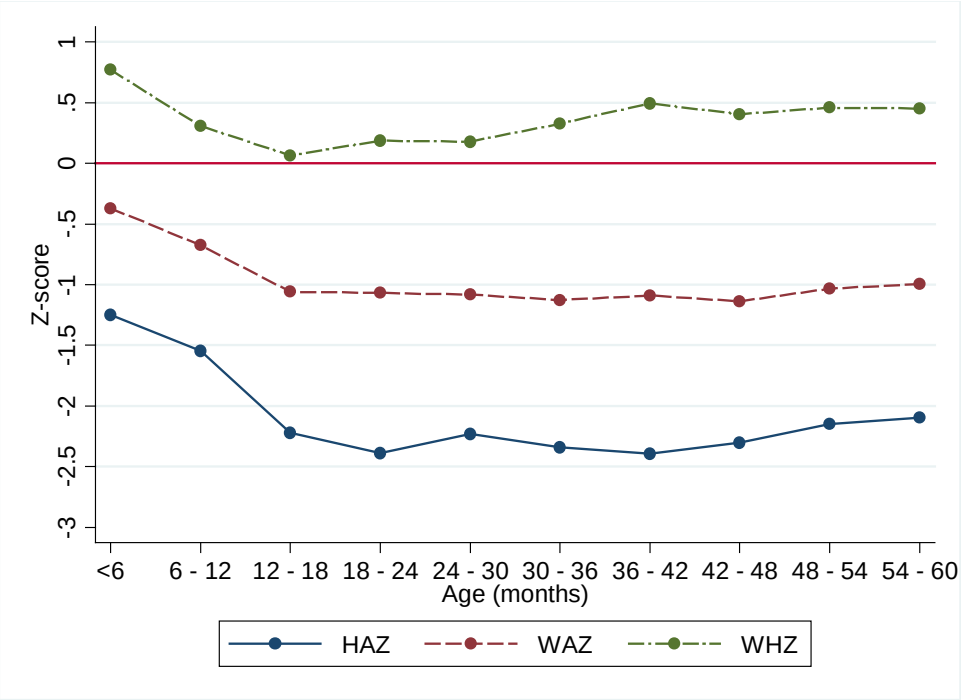


Figure 6.3: Height-for-age, weight-for-height, and weight-for-age Z-scores, by child age in Alta Verapaz

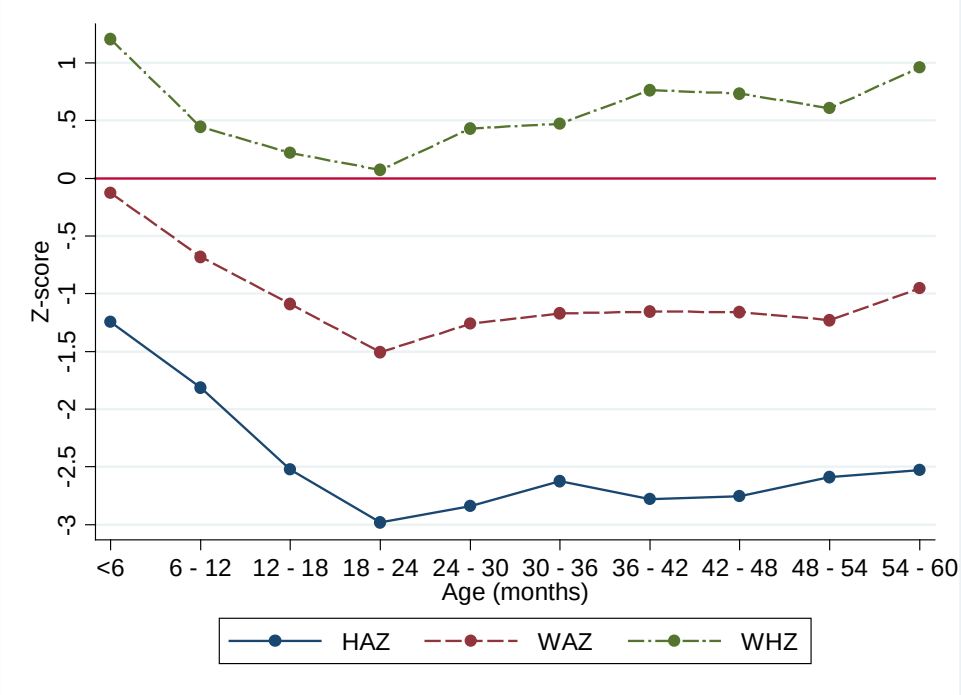


Figure 6.4: Prevalence of stunting, by child age, Guatemala

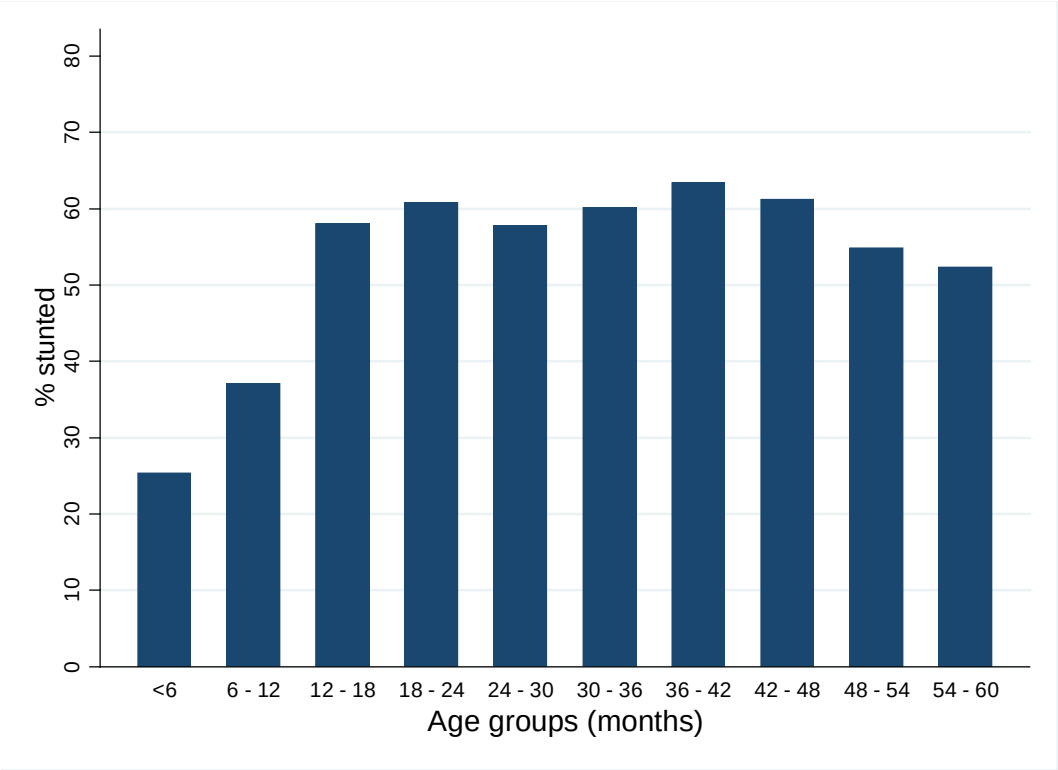


Figure 6.5: Prevalence of stunting, by child age, Alta Verapaz

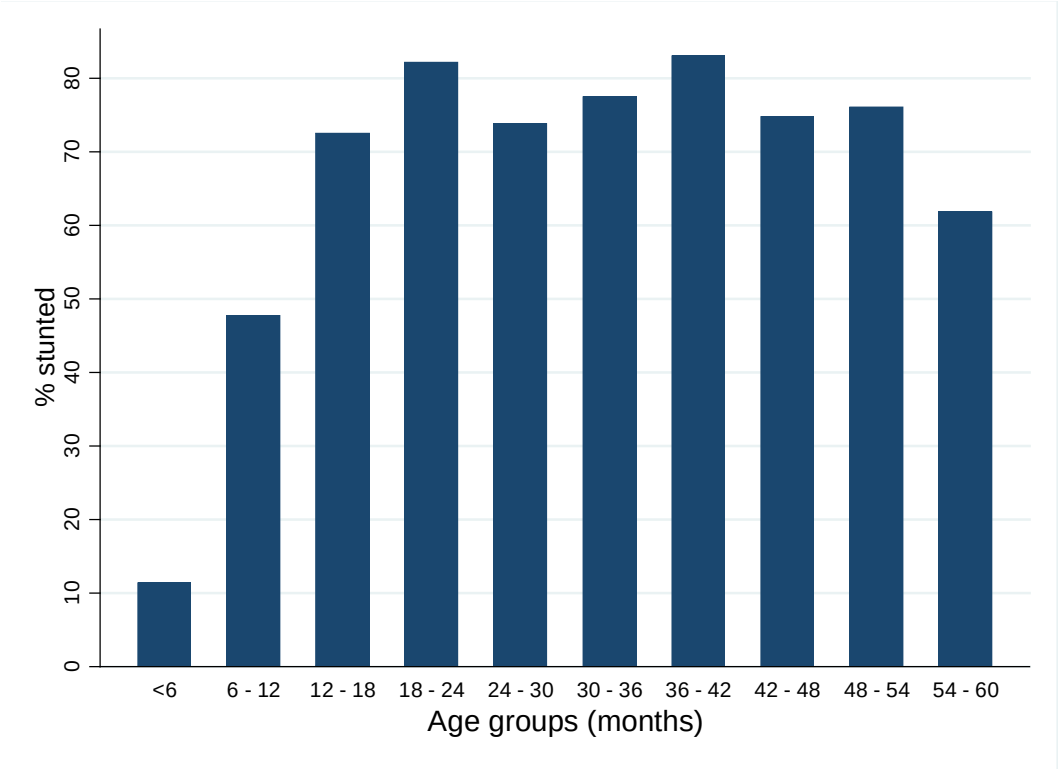


Figure 6.6: Prevalence of wasting, by child age, Guatemala

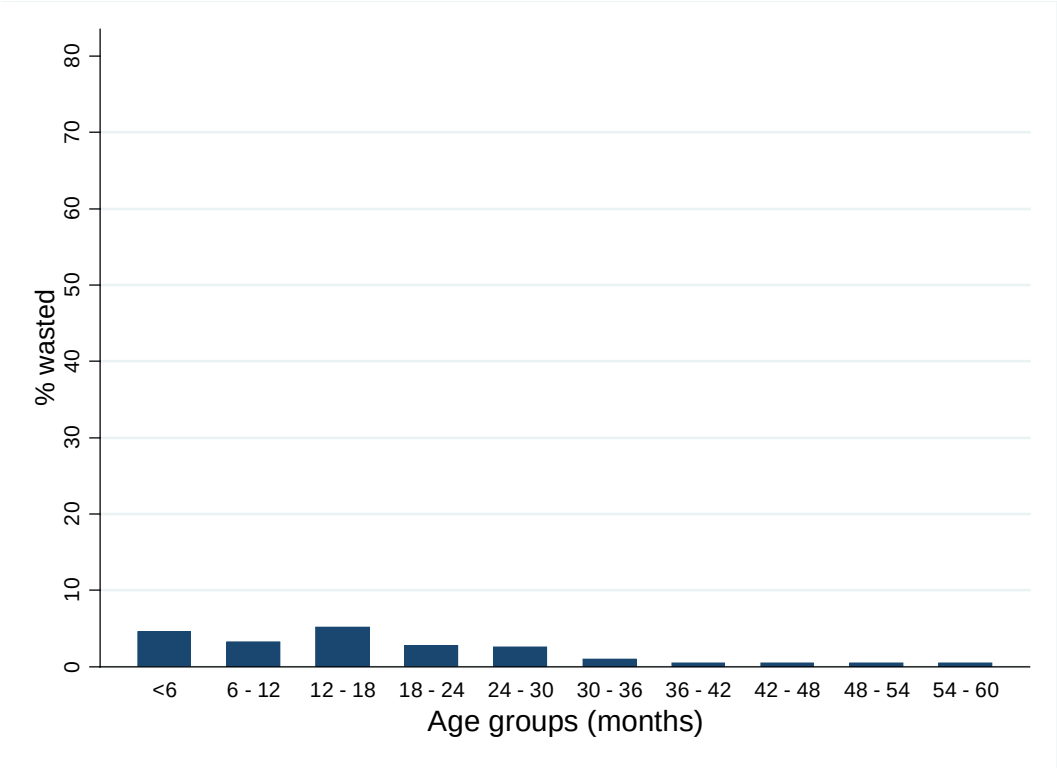


Figure 6.7: Prevalence of wasting, by child age, Alta Verapaz

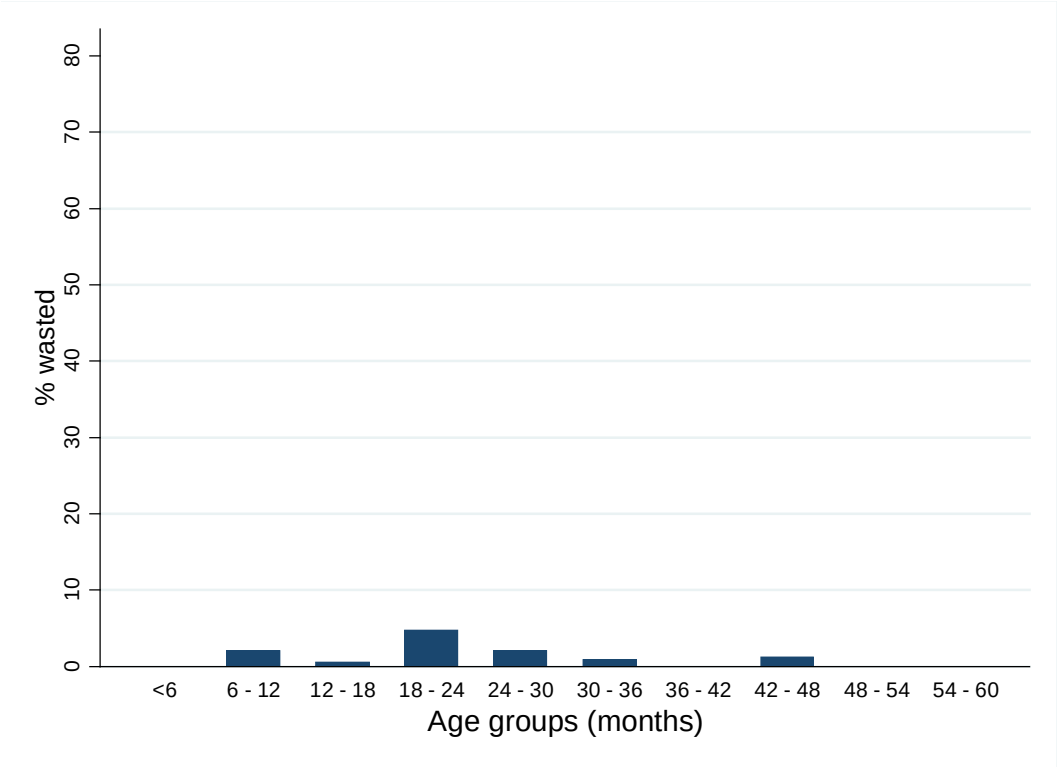


Figure 6.8: Prevalence of underweight children, by age, Guatemala

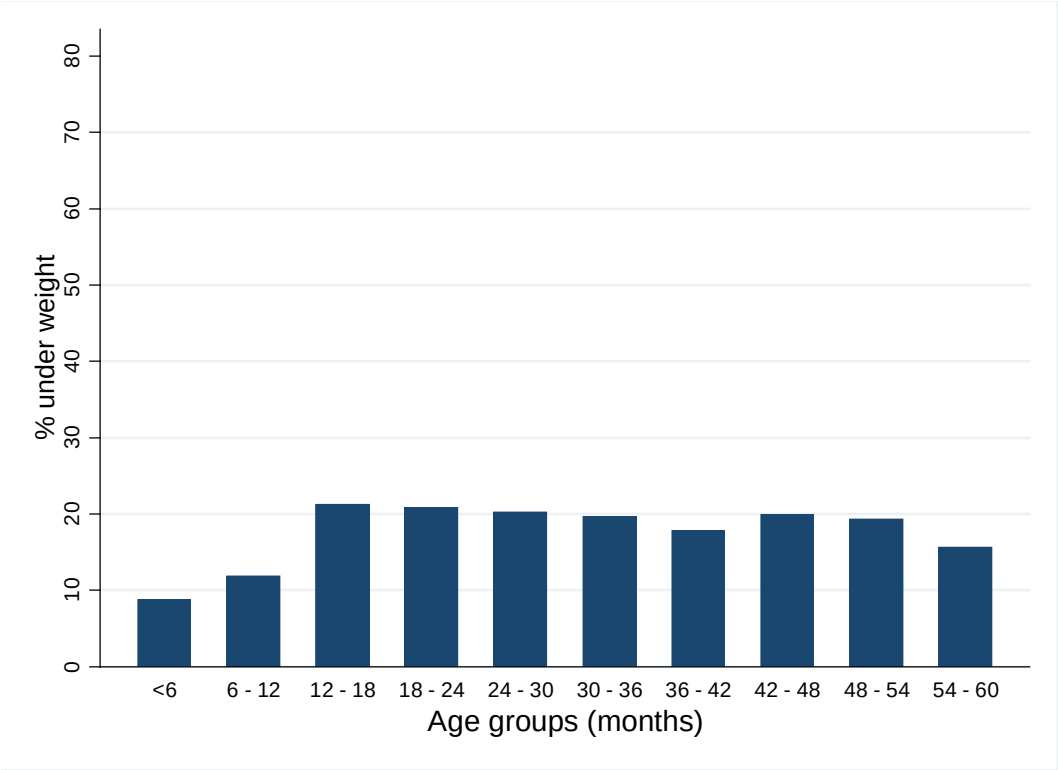
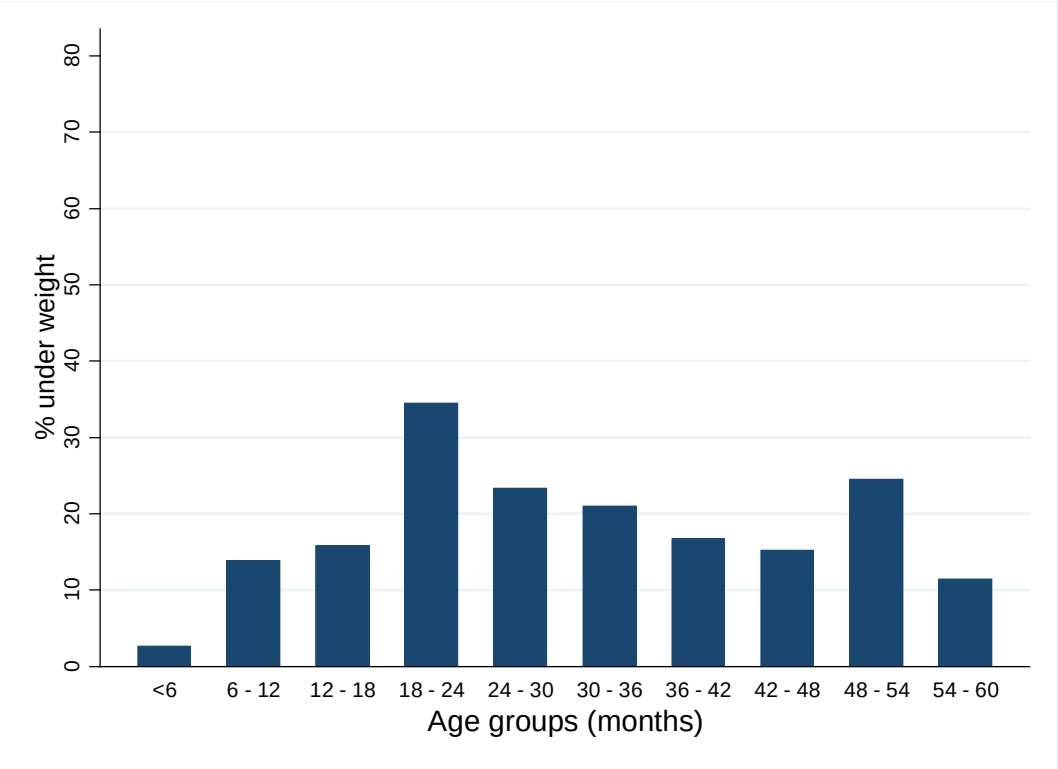


Figure 6.9: Prevalence of underweight children, by age, Alta Verapaz



6.2. Program Description

In Guatemala, the PM2A program will be implemented by Mercy Corps (MC). The program has been called *Programa Communitario Materno Infantil de Diversificacion Alimentaria* (*PROCOMIDA*) (Maternal and Child Food Diversification Community Program). *PROCOMIDA*'s main program components are summarized in Section 6.2.1, followed by the program's eligibility criteria in Section 6.2.2.

6.2.1. Program Components

PROCOMIDA 's activities focus on three interrelated components: the distribution of food rations—both family rations to increase household food security and individual rations to increase the consumption of a micronutrient-fortified food (corn-soy blend [CSB]) by pregnant and lactating women and children 6-24 months of age; the required participation in a behavior change communication strategy that focuses on improving key health and nutrition-related behaviors; and the required use of preventive health services for mothers and children. In addition, as part of the research, a lipid-based nutrient supplement or a micronutrient powder will be provided to some groups of mothers and children.

6.2.1.1. Food rations

The program will provide a family ration and an individual ration for the targeted household member (i.e., pregnant or lactating women or a child 6-24 months of age) each month. The family ration will include rice, beans, and oil; assuming an average household size of 6.3, the family ration will provide an average of 272 kcal per capita per day. Corn-soy blend (CSB) will be provided for the individual ration targeted to either the mother or the child of the participating family. The CSB is intended to be used strictly by the targeted individual, and if so, will provide an average of 494 kcal per day (Table 6.1). Rice and beans were chosen for the family ration because they are two of the primary staple foods in Guatemala; it is expected that provision of these food items will help prevent the sharing of the CSB to other household members. Families are expected to begin the program when a mother first knows she is pregnant and then to continue the program until the child reaches 24 months of age—therefore the likely duration of program participation will be about 30 months for a household (average of 6 months during pregnancy and 6 months during lactation and then 18 months while the child is between 6 and 24 months of age). Households will receive one individual ration per qualified beneficiary, but only one family ration per household, regardless of the number of qualified beneficiaries.

Food rations will be pre-packaged at a central warehouse and then delivered to three subregional warehouses. From these warehouses the rations will be delivered quarterly to about 80 communities. Within these 80 communities, food rations will be distributed monthly by the Community Health Committees (under the supervision and support of Mercy Corps) to the beneficiaries at the local Convergence Center (see below for more information on Community Health Committees and Convergence Centers). The ration distributions will take place, once, twice, or three times per month at each Convergence Center, depending on the size of the population to be served at that Convergence Center.

Table 6.1: Monthly ration size of *PROCOMIDA*

Target group	CSB	Rice	Pinto beans	Vegetable oil	Energy/ month[a]	Energy/ Day[b]	Energy/ day/capita[c]
			(kg)			(kcal)	
Pregnant/lactating women or child aged 6-24 months	4.0				15,028	494	—[d]
Family		6.0	4.0	1.85	52,134	1,714	**272**
Total ration	**4.0**	**6.0**	**4.0**	**1.85**	67,162	2,208	—[d]

[a] Energy per 100 g: 375.5 kcal (CSB), 365 kcal (rice, white, long-grain, regular, raw, unenriched), 347 kcal (pinto beans, mature seeds, raw), and 884 kcal (vegetable oil). Obtained from North American Millers' Association (CSB), USDA National Nutrient Database for Standard Reference, Release 25 (pinto beans and rice) and USAID (vegetable oil).

[b] Energy per day, using 30.42 days/month.

[c] Per capita energy is based on the assumption of 6.3 average family size (average household size in the enrollment survey, see Table 4.1 of the enrollment report)

[d] Note that the individual ration is not meant to be shared, so we do not include it in the computation of total energy/capita/day. If it was shared, it would provide an additional 78 kcal/day/capita, and the total food ration would therefore provide 350 kcal/day/capita.

6.2.1.2. Behavior change communication (BCC) strategy

The primary venue for the BCC strategy will be the Mothers' Groups. Secondary venues will also be used to reinforce the messages.

Mothers groups: Groups are usually formed according to location; the *PROCOMIDA* program will have to re-organize the groups to form small groups that include mothers of the same physiological status (pregnant or lactating mothers) and children in the same age range (e.g., 6-12; 12-18; 18-24). The groups will meet monthly for the program's BCC sessions. In addition, in communities with a sufficient number of children with SAM, Mothers' Groups will be formed for the mothers of these children. Currently, the health guardians (see description in section below) hold weekly meetings with their groups of households (~20).

Other delivery mechanisms: In addition to the mother's groups, *PROCOMIDA* plans to utilize various mechanisms for delivering the BCC messages developed for the program, including household visits, cooking demonstrations, messages delivered at the food distribution points, radio spots, and posters.

Contents of the BCC strategy: Mercy Corps is planning to focus primarily on the Essential Nutrition Actions (ENA) and will use messages developed by the Ministry of Health (MoH) as part of "Integrated Care of Prevalent Childhood Illnesses and Integrated Health Care for Women and Children at the Community Level" (AIEPI-AINM-C) as well as messages about access to health services and food security. Some examples of the topics that will be discussed in the mothers' group meetings and reinforced through the other channels include the following:

- ***Pregnant women's groups***: prenatal care, danger signs in pregnancy, safe delivery and the importance of breastfeeding.
- ***Lactating women's groups***: methods of breastfeeding, when and how to introduce complementary feeding, appropriate postpartum care.

- ***Mothers of children 6-24 months***: complementary feeding, ongoing benefits of breastfeeding, household hygiene, signs of child malnutrition.
- ***Mothers of children with SAM***: proper care for malnourished children; prevention of future malnutrition.

6.2.1.3. Use of health and nutrition services

In order to receive food rations, beneficiaries will be required to attend the appropriate pre- and postnatal health visits as well as monthly preventive health visits for children 6-24 months of age under the "Integrated Care of Prevalent Childhood Illnesses and Integrated Health Care for Women and Children at the Community Level" (AIEPI-AINM-C) program provided by the MoH under the *Sistema Integral de Atención en Salud* (SIAS) and implemented by local PVOs. In addition to promoting the use of the MoH preventive health services, *PROCOMIDA* will identify and refer children with SAM to the appropriate health services and will work with the MoH SIAS-implementing PVOs and Community Health Committees (CHCs) to strengthen the capacity of these health service providers, thereby improving the quality of the services provided in the *PROCOMIDA* program areas.

AIEPI-AINM-C: This program is implemented by local PVOs under the MOH's SIAS and covers about 60-70 percent of the population in Guatemala. The services are provided monthly at local Convergence Centers (CCs) by the Equipo *Básico de Salud* (EBS), which includes a doctor, nurse, nutrition educator (in most cases), and an Institutional Facilitator. This program provides standard care for pregnant and lactating women and monthly growth monitoring and promotion (GMP) for children. In addition, appropriate vaccines and micronutrient supplements are provided through this program.

In addition, at the community level, there are community facilitators, health guardians, and traditional birth attendants who work directly with the households. The health guardians and traditional birth attendants (TBA) are the primary health staff available at the community level on a regular basis. The health guardians meet weekly with their household groups (~20) to provide them with basic messages about hygiene and sanitation and other health and nutrition related topics. The TBAs provide support for mothers during pregnancy and lactation. The community health facilitator is responsible for the health guardians and TBAs in their communities and reports to the institutional facilitator at the CC.

Community Health Committees (CHC): In addition to the positions supported by the SIAS, Mercy Corps has formed CHCs, which are associated with the CCs. These CHCs support the SIAS by supporting the SIAS staff, monitoring and maintaining the quality of the services at the CCs, and working with the community on a number of issues, including managing the community funds for emergency transportation for health issues and creating community action plans that assess health and nutrition problems in the community and make plans as to how to address them. In addition, if problems occur at the CCs or within the community, this committee can address these issues with the implementing PVO or the MoH. This committee will also be responsible for distributing the food rations for the *PROCOMIDA* program. If this committee does not currently exist in some of the program areas, one will be created. It is expected that by the second year of the program, all program areas will have a functioning CHC.

Detection and referral of SAM: Mercy Corps will work with health providers at all levels to ensure that health providers are adequately trained and knowledgeable to identify SAM and to refer those with medical complications for treatment at Nutrition Therapeutic Centers (NTC).

Capacity strengthening activities: Mercy Corps plans to strengthen the capacity of the health services in the program areas through multiple channels. First, they will provide training to health staff at the level of the municipality by training MoH employees at the municipal health centers (~7) and health posts (~14). In addition they will provide training to the local SIAS-implementing PVOs (~7). They will also provide these PVOs with sub-grants to hire additional staff to help meet the demands of the *PROCOMIDA* program. Mercy Corps also plans to hire bilingual (Q'eqchi and Spanish) women to help facilitate communication between health-care providers and beneficiaries at the CCs.

Visits to health centers by community members: Mercy Corps will also provide orientation visits to various health facilities to the community members served by the *PROCOMIDA* program. It is believed that many people in these areas are fearful of attending government health facilities and these visits are designed to make people more familiar and comfortable with going to the facilities and accessing the available services.

Advocacy: Mercy Corps plans to work with the SIAS-implementing PVOs and MoH health-post staff to prioritize, plan, and advocate for community health priorities with key municipal, departmental, and national actors. The goal of this work will be to increase the capacity of these health staff to advocate for access to resources to improve MCHN and food security.

6.2.2. Program Eligibility Criteria

All pregnant and lactating women and children 6-24 months of age are eligible to participate in the program. Any child 5 years old or younger who is identified as having SAM (mid-upper-arm circumference < 115 mm) or weight-for-height Z-score < -3 and/or bilateral pitting oedema) will be referred to the hospital. Households will be eligible to receive one individual ration and one family ration regardless of the number of qualified beneficiaries in the household. In order to receive their food rations, households will be required to attend the appropriate preventive health visits (pre- and postnatal visits for pregnant and lactating women and monthly visits for children 6-24 months of age), and to attend monthly "Mothers' Clubs" to participate in the BCC small-group sessions held in the community.

6.3. Objectives

6.3.1. Overall objectives

The Guatemala study will address two of the broad objectives of the overall PM2A research program:

- Objective 1: Assess the impact and cost-effectiveness of PM2A (*PROCOMIDA* program) on child nutritional status.
- Objective 2: Assess the differential and absolute impact of varying the food ration composition and size of PM2A. More specifically, assess the differential effect of

modifying the family food ration sizes; assess the impact of substituting the individual food ration with a lipid-based nutrient supplement (LNS) or micronutrient Sprinkles.

6.3.2. Specific Objectives

This study has 11 specific objectives (child nutritional status is the impact measure for all of them), which correspond to objectives 1 (a-b) and 2 (a-i) of Table 3.1:

Objective 1. Assess the impact and cost-effectiveness of PM2A on child nutritional status

1a. Evaluate the impact of *PROCOMIDA* compared to a control group.

1b. Measure the cost-effectiveness of PROCOMIDA.

Objective 2. Determine the optimal size and composition of food rations in PM2A

2a. Evaluate the impact of *PROCOMIDA* **with a reduced family ration,** compared to a control group.

2b. Compare the impact of *PROCOMIDA* **with a reduced family ration** with *PROCOMIDA.*

2c. Evaluate the impact of *PROCOMIDA* **without a family ration,** compared to a control group.

2d. Compare the impact of *PROCOMIDA* **without a family ration** with *PROCOMIDA.*

2e. Evaluate the impact of *PROCOMIDA* **with a lipid based nutrient supplement (LNS*) as the individual ration** (instead of CSB*)*, compared to a control group.

2f. Compare the impact of *PROCOMIDA* **with LNS as the individual ration** (instead of CSB) with *PROCOMIDA.*

2g. Evaluate the impact of *PROCOMIDA* **with a multiple micronutrient (MN) Sprinkles supplement as the individual ration** (instead of CSB), compared to a control group.

2h. Compare the impact of *PROCOMIDA* **with MN Sprinkles as the individual ration** (instead of CSB) with *PROCOMIDA.*

2i. Compare the impact of *PROCOMIDA* **with LNS as the individual ration** with *PROCOMIDA* **with MN Sprinkles as the individual ration**.

Children's nutritional status will be assessed by attained growth (mean WAZ, HAZ, WHZ) and the prevalence of stunting, wasting, and underweight.

6.3.3. Additional Objectives

1. Assist the *PROCOMIDA* team in the design and implementation of a fully developed BCC intervention through the use of formative research.
2. Assist the *PROCOMIDA* team in assessing the current functioning of the preventive health services and assess whether or not there are things that can be done to improve the provision of essential preventive services at the Convergence Centers participating in *PROCOMIDA.* This will also be done through the use of formative research.

3. Use operations research methods to assess:
    - The implementation of the program to identify constraints and potential solutions to improving program operations;
    - The effectiveness of delivery of the various components of the program (i.e., food distribution, BCC, preventive health services, and LNS or MN sprinkles as applicable);
    - The quality of the different services provided;
    - The perceptions of different stakeholders about the program with an emphasis on their perceptions regarding its effectiveness, the quality of the services provided and their roles and responsibilities within the program structure; and
    - The institutional demands for successful implementation.
4. Document, through a mix of quantitative and qualitative approaches, the intrahousehold utilization and consumption of the food commodities, particularly consumption by the target individual (the mother during pregnancy and lactation and the child from 6-24 months of age).
5. Evaluate the impact of the interventions on other household, maternal, and child outcomes:
    a. Household food security (FANTA's Household Hunger Scale)
    b. Household food and nonfood consumption and expenditure
    c. Maternal infant and young child feeding and health seeking practices
    d. Maternal hemoglobin (Hb)
    e. Children's cognitive and motor development
    f. Children's morbidity symptoms
    g. Children's anemia

6.4. Design of the Impact Evaluation

6.4.1. Overall Design and Timing

This study will use a longitudinal study to answer the research questions related to the study objectives described in Section 6.3. The study will use a cluster randomized controlled cohort (i.e., longitudinal) design. Mothers will be followed during pregnancy and their child will be followed from birth until 24 months of age.

Even though a longitudinal study is more complex than repeated cross-sections, it provides a number of clear advantages. These include the direct measurement of how and when changes occur, the ability to collect information on the temporal sequence of events as well as on potentially confounding variables, the ability to separate temporal and individual variability, the estimation of dynamic models, and the control for selection bias (Frongillo and Rowe 1999). Additionally, the data in a longitudinal study are collected closer to the actual times at which

specific events or behaviors occur, reducing measurement error and recall bias. Infant and young child feeding practices, for instance, will be collected repeatedly, which will decrease the recall periods for the caregivers. The longitudinal information will also allow us to track feeding and caregiving practices as well as program utilization over time and to assess their cumulative impact on child growth. In summary, a longitudinal study embedded in a randomized controlled design is the strongest possible approach to establish causality.

For the longitudinal study, clusters of households will be assigned to one of six study arms: a control group, and five groups receiving different combinations of family and individual rations (and/or micronutrient supplements) in addition to BCC and health service (see Section 6.4.2 for details). The control group will not receive any rations, micronutrient supplements, or BCC, but will have access to the existing preventive health services provided under the MoH SIAS.[3]

Randomization will be done at the level of the Convergence Centers (CC). One CC serves, on average, 900 to 1,000 people living in two to three communities. For the research study, a total of 120 CCs will be randomly allocated to one of six study groups (20 CCs per group).

In order to correctly estimate the impact of *PROCOMIDA*, it is important that the enrollment of the cohort does not start before the program is fully operating, i.e., with all its components (food rations, BCC, and health care) in place. Another consideration is that we want to evaluate the impact of the full treatment, i.e., from pregnancy until the child reaches 24 months of age. We will therefore enroll pregnant mothers in the evaluation cohort study and follow them and their child until he/she reaches 24 months of age. We assume that mothers will enroll into the program at around the fourth month of pregnancy.

Community health workers (health guardians) who know the families in their area will be asked by the survey field team to identify pregnant women in the CCs selected for the evaluation study on a regular basis. All pregnant women who are willing to enroll in the evaluation study (based on informed consent) will automatically be recruited. This process will be independent from their enrollment in the *PROCOMIDA* program.[4] It is important to separate enrollment in the evaluation study from enrollment in the *PROCOMIDA* program because the evaluation aims at evaluating the population-level impact of the program (i.e., intent-to-treat effect of the intervention packages) rather than the impact on beneficiaries only (i.e., treatment-on-the-treated).

At the time of enrollment in the evaluation cohort, a household survey will be conducted to collect information on household demographic and socioeconomic characteristics and on maternal characteristics at baseline and will be repeated when the child exits the program at 24 months of age (end-line). Maternal depression, assistance at prenatal visits, and hemoglobin at 30 weeks of gestation will also be measured during pregnancy and postpartum. After delivery, the child's length and weight will be measured at the following ages: at 1, 4, 6, 9, 12, 18, and 24 months. Since growth faltering occurs most rapidly during the first year of life, we will increase

[3] We cannot exclude the possibility that other programs, including nutrition and health benefits, are (made) available in the region. This may be lead to potential contamination of the control group. The randomization, however, will distribute this risk equally among the study arms. We will also keep track of exposure to other programs/interventions (and changes over time) in all study groups.

[4] Children who enroll in the program after birth will not be enrolled in the evaluation sample.

the frequency of measurement during the first year, compared to the second year. Data will also be collected on several other child-related outcomes at these same time points: child morbidity symptoms in the two weeks prior to the measurement; on infant and young child feeding (IYCF) practices in the previous 24 hours for some indicators and since the last measurement for others; on preventive and curative health-care seeking behaviors since the previous measurement; and on selected child development outcomes.

6.4.2. Study Groups and Research Questions

The comparison groups that will be included in this study are presented in Table 6.2. Note that all groups (except the control group F) will receive the *PROCOMIDA* BCC and all beneficiaries will be required to attend the health services according to the program's schedule of visits for pregnant and lactating women and for 6-24-month-old children. The study will include the following comparison groups:

- Group A: Full family ration (rice, beans and oil, Table 6.3), individual ration (Corn soy blend,CSB, Table 6.4), BCC and required health visits.
- Group B: Reduced family ration (rice, beans, and oil, Table 6.3), individual ration (CSB, Table 6.4), BCC, and required health visits.
- Group C: No family ration, individual ration (CSB, Table 6.4), BCC, and required health visits.
- Group D: Full family ration (rice, beans, and oil, Table 6.3), lipid-based nutrient supplement (LNS, Table 6.4) as the individual ration, BCC, and required health visits.
- Group E: Full family ration (rice, beans, and oil, Table 6.3), micronutrient powder (MNP, Table 6.4) supplement as the individual ration, BCC, and required health visits
- Group F: Control group: this group does not receive *PROCOMIDA* (i.e. does not receive family or individual rations, or BCC messages) and is not required to attend health visits. Families in the control group, however, have access to the standard MoH health services.

The full nutrient composition of the LNS and MNP supplements is shown in Appendix B.

Table 6.2: Study groups[a]

		Family food ration		
		Full	**Reduced**	**None**
Individual ration	**CSB**	A	B	C
	LNS	D		
	Sprinkles	E		
	None			F

[a] Note that all groups receive *PROCOMIDA* BCC + health services except group F (control group). Group F, however will have access to the standard MOH health services.

Table 6.3: Ration sizes: Full monthly family ration and reduced family ration

	Full family ration		Reduced family ration	
Foods	**Weight**	**Energy**	**Weight**	**Energy**
	(kg)	(kcal)	(kg)	(kcal)
Rice	6.00	21,900	3.00	10,950
Pinto beans	4.00	13,880	3.00	10,410
Vegetable oil	1.85	16,354	0.925	8,177
Total		**52,134**		**29,537**
Total kcal/capita/day[a]		**272**		**154**

[a] Total kcal/capita/day is derived using an average household size of 6.3 members (average household size in the enrollment survey, see Table 4.1 of the enrollment report) and 30.42 days/month.

Table 6.4: Monthly individual ration size

	Individual Ration							
Target group	**CSB (Groups A, B, and C)**		**LNS [a] (Group D)**			**MNP [a] (Group E)**		
	Kg/month	*kcal/day*	*Sachets/ month*	*g/day*	*kcal/day*	*Sachets/ month*	*g/day*	*kcal/day*
Pregnant/lactating women	4.0	494	30	20	118	60	4	-
Child aged 6-23 months	4.0	494	60	20	118	60	4	-

[a] The full nutrient composition of the LNS and MNP supplements is shown in Appendix B.

The proposed comparison groups and how they relate to the specific research questions are shown in Table 6.5.

Table 6.5: Group comparisons and associated research questions (all impacts are on child nutritional status (NS)

Objective	Intervention group	Comparison group	Research question
1a	*PROCOMIDA* (A)	Control (F)	What is the impact of *PROCOMIDA* on child NS?
1b	*PROCOMIDA* (a)	Control (F)	What is the cost-effectiveness of *PROCOMIDA*?
2a	*PROCOMIDA* with a reduced family ration (B)	Control (F)	Does *PROCOMIDA with a reduced family ration* improve child NS?
2b	" " (B)	*PROCOMIDA* (A)	Does *PROCOMIDA with a reduced family ration* have the same impact on child NS as *PROCOMIDA?*
2c	*PROCOMIDA* without a family ration (C)	Control (F)	Does *PROCOMIDA without a family ration* improve child NS?
2d	" " (C)	*PROCOMIDA* (A)	Does *PROCOMIDA without a family ration* have the same impact on child NS as *PROCOMIDA?*
2e	*PROCOMIDA* with LNS (instead of CSB for individual ration) (D)	Control (F)	What is the impact of the *PROCOMIDA* program with *LNS instead of CSB as individual ration* on child NS?

Objective	Intervention group	Comparison group	Research question
2f	" " (D)	*PROCOMIDA* (A)	What is the differential effect of *LNS instead of CSB as individual ration* on child NS?
2g	*PROCOMIDA* with MN Sprinkles (instead of CSB for individual ration) (E)	Control (F)	What is the impact of the *PROCOMIDA* program with *MN Sprinkles instead of CSB as individual ration* on child NS?
2h	" " (E)	*PROCOMIDA* (A)	What is the differential effect of *MN Sprinkles instead of CSB as individual ration* on child nutritional status?
2i	" " (E)	*PROCOMIDA* with LNS (instead of CSB for individual ration) (D)	What is the differential effect of PROCOMIDA with LNS compared to PROCOMIDA with Sprinkles, as individual rations on child NS?

6.4.3. Study Outcomes

The main outcome of the impact evaluation of the *PROCOMIDA* program is child nutritional status. To evaluate child nutritional status we will measure child length or height and weight and calculate 2006 WHO anthropometric Z-scores. We will estimate the mean HAZ, WAZ, and WHZ, and the distribution of these indicators to determine the prevalence of childhood stunting, underweight, and wasting. Other outcomes, which will be measured at the same time as child anthropometry, include child hemoglobin, reported child morbidity symptoms in the two weeks prior to the measurement, infant and young child feeding practices using the new set of indicators proposed by WHO (2008), preventive and curative health seeking behaviors, and child development outcomes.

Household food security (using the Household Hunger Scale [HHS] developed by FANTA) and household consumption/expenditure will be measured twice, at the time of enrollment and when the child exits the program at the 24 months of age.

6.4.4. Sample Size

The sample size calculations for the longitudinal cohort study are based on the use of double difference estimation. We adjusted the sample size for the lack of independence between children living in the same cluster. Failure to take the intra-cluster correlation into account would lead to an overestimation of the statistical power.

A three-step approach was used to determine the study sample size:

- Step 1: Determine the required sample size to answer research questions 1, 2, 4, 6, and 8. The *a priori* hypothesis underlying these research questions is that the intervention will have a *positive* impact on child growth, compared to the control group.
- Step 2: Determine the required sample size to answer research questions 3, 5, 7, 9, and 10. There is no *a priori* hypothesis regarding the direction of effects (i.e., positive or negative differences between groups) underlying these research questions. The key challenge is thus to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the cost of the study) manageable.

- Step 3: Determine the sample size required to assess the impact on the other outcomes of interest[5] (food security, IYCF practices, and child development outcomes).

Sample size parameters for child growth—The parameters used for the sample size calculation are given below. For a more detailed discussion on the underlying assumptions, see Appendix C.

- Type 1 error (α): 0.05
    - One-sided for research questions 1, 2, 4, 6, and 8;
    - Two-sided for questions 3, 5, 7, 9, and 10.
- Power (1-β): 0.90.
- Selection of minimal detectable difference:
    - **Impact of different program models compared to a control group:**
        a) Research questions 1, 6, and 8: For these comparisons, we used the estimated absolute effect of the preventive model in Haiti (Donegan et al. 2009) of 0.339 for HAZ. The mean HAZ and the prevalence of stunting in Alta Verapaz are expected to be significantly higher than in the study area in Haiti. As a consequence, the potential to benefit is likely to be larger.
        b) Research question 2: Impact of PROCOMIDA with a reduced family ration, compared to a control group. The reduced family ration provides approximately half of the calories of the full family ration. The estimated effect size is therefore set to 0.325 HAZ, between the effect found in Haiti with a large family ration (0.339 HAZ) and the effect found in a study in Peru that did not include a family ration (0.31) (see next paragraph).
        c) Research question 4: Impact of PROCOMIDA without the family ration, compared to a control group. For this comparison, we used an estimated difference in HAZ of 0.31, based on the results of a nutrition education project in Peru (Waters et al. 2006) that did not include any food distribution (see Appendix C for more information).
    - **Differential impact of a reduced vs. full family food ration** (research question 3)**: Comparison of *PROCOMIDA* with a reduced family ration with standard *PROCOMIDA***. Given the limited evidence in the literature on what to expect from this comparison (and the small difference in effect size found between Haiti [with food] and Peru [without food]), the expected difference should theoretically be set to 0, but this would require an infinitely large sample size. The key challenge is thus to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the feasibility and cost of the study) manageable. Given the level of resources available for the study, we estimate that the

[5] Sample size calculations were not conducted for child morbidity, health seeking behaviors and child anemia. Evidence shows that studies powered to detect meaningful impacts on child growth are sufficiently powered to detect differences in anemia as well.

sample size should not be greater than 600 children per arm. With 600 children per arm, the detectable difference is estimated to be 0.263 Z-scores.

- **Impact of the family food ration** (research question 5)**: Comparison of *PROCOMIDA* without family ration with standard *PROCOMIDA***. As for research question 3, the sample size was set to 600 children per arm, allowing us to detect a difference of 0.263 Z-scores.
- **Differential impacts of alternative types of individual rations** (research questions 7, 9 and 10)**:** C**omparison of LNS, Sprinkles, and CSB**. There is no evidence in the literature providing information on what to expect from these comparisons. As for questions 3 and 5, the sample size was set to 600 children per arm, providing the power to detect a difference of 0.263 Z-scores.

- Intracluster correlation: 0.007
- Number of clusters per treatment: 20
- Data loss: 15 percent

The estimated required sample sizes for HAZ are shown in Table 6.6.

Minimal detectable differences for other outcomes—In order to calculate the necessary sample size to detect meaningful effects for IYCF practices, child development outcomes, food security and household expenditure, we used impact estimates from the Haiti study and from the literature. With the available evidence we calculated sample sizes to answer research questions 1, 6, and 8 for anemia. For infant and young child feeding practices, child development, household food security, and total household expenditure, we calculated the necessary sample size for research question 1 only (i.e., *PROCOMIDA* compared to control).

No information was available on the ICC of these outcomes. It was set at 0.007 for feeding and development, which is the ICC for growth in this population. Given the potentially important effect of local (i.e., cluster specific) food production conditions and market prices on food security, the ICC for this outcome was set higher (0.013, corresponding to a *Deff* of about 2). Since the correlation between baseline and end-line measurements for all these outcomes was also unknown, sample size calculations were based on comparisons at end-line. One-sided hypotheses were used for all calculations. More detailed explanations for each of the outcomes are provided below.

Minimal detectable difference for anemia (0-24 months)—The impact of fortified complementary foods on anemia was evaluated in three intervention studies conducted in Mexico, Ecuador, and Peru, and reviewed by Dewey and Adu-Afarwuah (2008). The (intended) daily iron dose was 10, 6.5, and 9 mg/day, respectively. Assuming the target child consumes the full CSB ration (66 g/day from 6 to 12 months and 132 g/day from 12 to 24 months), the daily iron dose in *PROCOMIDA* is 11.6 and 23.0 mg/day from 6 to 12 and from 12 to 24 months, respectively. Anemia was reduced by 11 percentage points (ppt) in Mexico, 16 ppt in Ecuador, and 13 ppt in Peru (increases in Hb were 3g/l and 5g/l in Ecuador and Peru, respectively; no information on changes in Hb is available for Peru). We set the expected impact of *PROCOMIDA* at a conservative 11 ppt.

The effect of LNS on Hb concentration and anemia has been tested in two efficacy trials. Kuusipalo and colleagues (2006) compared the effect of soy- and milk-based fortified spreads in 6-to-17-month-old underweight Malawian children. Children received one of four different doses for 12 weeks. Hb in children receiving 50 g/day of the milk-based spread (providing 5.5 mg of iron per day) increased by 17 g/l. No significant effect was found in the other groups. The impact on the prevalence of anemia was not reported by the authors (Kuusipalo et al. 2006). Adu-Afarwuah et al. (2007) studied the effect of daily supplementation with MN Sprinkles (12.5 mg of iron/day), crushable Nutritabs (9 mg/day), and fat-based Nutributter (9 mg/day) on child anemia. The children were 6 months at baseline and received the supplements for 6 months. Iron deficiency anemia was not different between treatment groups at 12 months; the pooled prevalence, however, was significantly lower in the treatment groups (10 percent) than in a group of randomly selected comparison children (31 percent) (Adu-Afarwuah et al. 2007). Only one study has been published on the effectiveness of Sprinkles in reducing anemia. In Haiti, the impact of a two-month treatment of Sprinkles (providing 12.5 mg of daily iron) among children 9 to 24 months of age was evaluated. Children in the treatment and the control group also received fortified wheat-soy blend. The intervention lowered anemia by 32 ppt (Menon et al. 2007a).

The baseline prevalence of anemia in children 6 to 12 months and 12 to 24 months in Guatemala is estimated to be 65.3 percent and 55.6 percent, respectively (http://who.int/vmnis/anaemia/data/database/countries/gtm_ida.pdf). An average of 60.3 percent was used for the sample size calculations. The expected effect of LNS and Sprinkles is set to 30 ppt, i.e., we expect both interventions to reduce the prevalence by half.

Table 6.6: Sample size to measure impact on child and household outcomes

Study outcome	Detectable difference (SD)	Treatment group: Control	*PROCOMIDA* (A)	*PROCOMIDA* with a reduced family ration (B)	*PROCOMIDA* without family ration (C)	*PROCOMIDA* with LNS instead of food ration (D)	*PROCOMIDA* with Sprinkles instead of food ration (E)
Child HAZ							
Research question 1	0.339 (1.15)	270	270				
Research question 2	0.325 (1.15)	295		295			
Research question 3	0.263 (1.15)		600	600			
Research question 4	0.310 (1.15)	329			329		
Research question 5	0.263 (1.15)		600		600		
Research question 6	0.339 (1.15)	270				270	
Research question 7	0.263 (1.15)		600			600	
Research question 8	0.339 (1.15)	270					270
Research question 9	0.263 (1.15)		600				600
Research question 10	0.263 (1.15)					600	600
Child anemia							
Research question 1	11 ppt	598	598	+[a]	+		
Research question 6	30 ppt	61				61	
Research question 8	30 ppt	61					61
Child feeding (Donegan et al. 2009)							
% breastfeeding to 12 months	8.9 ppt (-)	217[b]	217[b]	+	+	+	+
% breastfeeding to 24 months	25.2 ppt (-)	80	80	+	+	+	+
Child development							
Mental (Pollitt et al. 2002)	1.46 (1.195)	14	14	+	+	+	+
Motor (Faber et al. 2005)	1.1 (3.85)	262	262	+	+	+	+
Food security							
Household experiences	0.5 (2.35)	573	573	+	+	+	+
Months of inadequate household food provisioning	0.8 (2.8)	273	273	+	+	+	+
Severity of food inadequacy	1.3 (5.35)	412	412	+	+	+	+
Household expenditure							
Total household expenditure	15.5%	435	435	+	+	+	+
Minimal sample size required	**-**	**598**	**600**	**600**	**600**	**600**	**600**

[a] "+" marks that the outcome will be measured in this age group but is not related to a primary research question.

[b] This number is higher if the prevalence of breastfeeding is lower. When the prevalence in both groups is 15ppt lower (i.e., 81.8 percent and 0.73 percent in treatment and control, respectively), the required sample size is 546. It is unlikely, however, that the prevalence would be this low.

IYCF practices—Donegan and colleagues estimated the impact of the preventive model in Haiti on breastfeeding using a matched control group (Donegan et al. 2009). At the age of 12 months, 96.8 percent of children in the treatment group were being breastfed as compared to 88 percent in the matched control group (impact: 8.9 ppt). The difference at 24 months was even larger, with 45.7 percent and 20.6 percent of children being breastfed in the treatment and control groups, respectively (impact: 25.2 ppt). We use these magnitudes of effects to assess sample size requirements for these outcomes.

Child development outcomes—There is a dearth of evidence regarding the impact of food supplementation and BCC interventions on child development outcomes. In Indonesia, mental development in a group of 18 month olds (mean HAZ -2.3) was evaluated using the Bayley mental scale repeatedly over a 12-month period. Children were given a micronutrient supplement either with a high energy supplement or with skim milk. The Bayley mental development score was significantly higher in the group receiving the high energy supplement (6.13) than in children receiving the micronutrient supplement and skim milk only (4.67) (Pollitt et al. 2002). A study in South Africa compared motor development of 15-month-old children who received a fortified porridge for 6 months to children in the control group. The mean score in the treated children (15.5) was significantly higher than in the control children (14.4). The prevalence of stunting was 11 percent (Faber et al. 2005). For our sample size calculations, we used a difference of 1.46 for mental score and a difference of 1.1 for motor development.

Household food security—To estimate the sample size for household food security, we used estimates from the Haiti study that assessed differences in household food security between participants and nonparticipants. The Haiti study measured food security using three different scales: (1) household experiences related to food insecurity (which used a scale constructed by summing the total number of food-insecurity experiences [out of a possible 11] in the past 30 days); (2) months of inadequate household food provisioning (the number of months of any food inadequacy in the household); (3) severity of food inadequacy (created by adding up responses on a three-point scale for food insecurity in each of the past 12 months). Although the impact was not measured against a control group, the comparisons between participants and nonparticipants in the preventive communities gives us some idea of what we might expect in terms of differences between the households receiving *PROCOMIDA* and the control households. We therefore use these sizes of differences for our sample size calculations for the three indicators used in Haiti (see Table 6.5).

Household expenditure—Household expenditure was not measured in Haiti. The evaluation of the *Programa de Apoyo Alimentario*, a cash and in-kind transfer program in rural areas in southern Mexico, studied this outcome. The in-kind transfer group received a food basket covering approximately 20 percent of caloric needs. Total household expenditure increased by 15.5 percent from 1906 to 2203 pesos per month (Jef Leroy, unpublished results). The family and individual ration in Guatemala will provide approximately 26.6 percent of the household's energy requirements. We set the expected impact on household expenditure to 15.5 percent.

Table 6.5 summarizes the minimal detectable differences and the corresponding required sample sizes for child anemia, breastfeeding, child development, household food security, and household expenditure by treatment group. The table further shows the outcomes that will be measured in each study arm even though they are not directly linked to a research question. Outcomes for which sample size calculations were mot made, but that will still be collected, are marked with a "+" in the table.

In summary—We will recruit 600 pregnant women in each study arm for the longitudinal evaluation study. This provides sufficient statistical power to detect a minimum difference between treatment groups receiving the full family ration (A, D, and E) and the control group of 0.339 HAZ (research questions 1, 6, and 8); to detect a minimum difference between the control group and *PROCOMIDA* with a reduced family ration (group B) and without a family ration (group C) of 0.325 and 0.310 HAZ, respectively (research questions 2 and 4); to detect a minimum difference of 0.263 HAZ between the groups receiving a full, a reduced, or no family ration (research questions 3 and 5); to detect a minimum difference between treatment groups receiving CSB, Sprinkles, or LNS of 0.263 HAZ (research questions 7, 9, and 10); to detect an impact on anemia as found in previous effectiveness studies with LNS or micronutrient sprinkles; to find the same magnitude of impact on breastfeeding as that found in Haiti; to find the same size of impact on child development as documented in previous studies; to detect the same impact on household food security as was found in Haiti; and to detect the size of impact on household expenditure that was found in a Mexican food transfer program. As a final note, additional statistical power for all outcomes will be gained from pairing clusters before randomization and from controlling for relevant covariates (such as child age, sex, and household characteristics) in the analyses.

6.4.5. Selection and Randomization of Study Clusters

The 120 convergence centers for the longitudinal survey were selected from the overall pool of 216 CCs where MC initially decided to implement the *PROCOMIDA* program. MC presented IFPRI with information on a small number of CC characteristics such as the number of communities served, the NGO serving the CC, the municipality where the CC was located, and the total population size and number of families in each community. CCs with missing information (n=7) or extremely large CCs i.e. serving more than 6 communities or with a population of more than 2500 people (n=8) were excluded. With the relatively small pool of CCs to draw the sample from, the number of characteristics that could be used to stratify the sample was limited. It is important to note, however, that the high proportion of CCs selected into the sample (approximately 60%), automatically guarantees a reasonable degree of sample representativity.

It was decided to first stratify on the number of communities served by the CC, which had been identified in the formative research as a potentially important determinant of the outcomes of interest. CCs were assigned to three different strata based on the number of communities served by the CC: 1) one community (n=82), 2) two communities (n=57), and 3) three or more communities (n=62).

The number of CCs to be drawn from each stratum (which had to be multiples of 6, given the 6 study arms) was proportional to the stratum's population size: 48 CCs from the first stratum (stratum representing 38.5 % of the total population), 30 CCs from the second stratum (36.5% of the total population), and 42 from the third stratum (35.0% of the total population).

CC selection within each stratum was proportional to population size. Because of the small number of CCs in each stratum, a "classic" probability proportional to size (pps) selection could not be implemented. It was thus approximated by dividing each stratum in substrata based on population size (11 substrata for stratum 1 and 8 substrata in stratum 2 and 3), and randomly selecting CCs from all of the larger substrata and from every other substratum and the lower end of the population distribution. The 6 selected CCs in each substratum were then randomly assigned to one of the six research arms.

6.4.6. Data Collection

Data will be collected at the community, household, and child level. A comprehensive household questionnaire will be applied when the pregnant women are enrolled in the study cohort and when the child is 24 months of age. Data on child morbidity, infant and young child feeding (IYCF) and health seeking practices, and child development will be collected at the time of the repeated anthropometric measurements for each child. More details on what data will be collected in each of the surveys are provided below.

Community questionnaire (at enrollment and when the child is 24 months of age) [6]

- Availability of services (clinic, school, electricity, water, sewage, garbage, TBAs, healers, stores, markets, etc.)
- Food availability and prices

Household questionnaire (at enrollment and when the child is 24 months of age)

- Household identification
  Municipality, health sector, community, address and contact information to facilitate finding the household in the follow-up surveys
- Household composition, occupation, and education
  Name, sex, age, birth date (for < 5 years, with source of information for children < 5), relation to head, education, literacy, employment (including time use: e.g., time to and from work and time at work)
- Housing quality, hygiene, and sanitation
  Floor, roof, walls, water, electricity, sanitation, rooms, kitchen
  Cleanliness spotcheck
- Assets

[6] Given the 10-month duration of the baseline and follow-up measurement, we may need repeated market surveys in the 10-month window to capture any fluctuation in prices.

Major household assets (including all assets related to hygiene and sanitation and food preservation, such as a refrigerator)
Availability of toys, books, etc.—important for child development outcomes—will be used as a covariate in the analyses (module drawn for the MICS, UNICEF)

- Food security
  Household Hunger Scale (FANTA)
- Household food expenditure
  Amount and value of food consumed, purchased, consumed from own production, given away and/or received in the past 7 days. [7]
- Household nonfood expenditure
  The consumption of nonfood items, including expenditures on household consumables (soap, candles, etc.), electricity, fuel, health, education, transportation, housing, clothing, tobacco, alcohol, and larger items such as a television, a bike, a car. The recall period will depend on the specific item (the past month, 6 months or year).
- Social and development programs
  Household participation in social and development programs provided by the government, PVOs, or international agencies, and the benefits they receive from these programs.
- *PROCOMIDA* program (participation and utilization)
  Household participation in *PROCOMIDA*, experiences related to program participation; the number of times the mother received food and BCC and the number of health check-ups the mother and child attended.
- Mother
  Anthropometry, including mid-upper arm circumference (MUAC)
  Autonomy, knowledge on childcare (i.e., knowledge of feeding practices, prevention of illness, danger signs, what do when the child is ill, danger signs, etc.)
- Children (siblings of unborn child) (to evaluate balance between the groups at enrollment)
  Anthropometry
  Morbidity in the past 2 weeks

Repeated child measurements (at 1, 4, 6, 9, 12, 18, and 24 months)

The multiple measurements that will be taken on repeated visits to the households are summarized in Table 6.7.

[7] A 7-day recall is standard for measuring household food consumption. A one-day recall may also be used for some foods that are known to be consumed on a daily basis (e.g., maize in Guatemala). The recall period for nonfood expenditure depends on the specific item (see household nonfood expenditure).

Table 6.7: Indicators measured in repeated visits (at 1, 4, 6, 9, 12, 18, and 24 months of age, unless specified otherwise)

Outcome	Measure	Indicator
Mother		
Anemia (at 6 and 12 mo postpartum)	Hemoglobin concentration	Mean Hb and prevalence of anemia
Weight	Weight gain	Weight gain and body mass index (BMI)
Prenatal and postnatal visits attended[a]	Beneficiary cards and Maternal recall	Number of visits/number of visits recommended
Maternal depression[a]	Depression scale	% of mothers with signs of depression
Child nutritional and health status		
Anthropometry	Length or height and weight	HAZ, WAZ, WHZ, prevalence of stunting, underweight and wasting
Anemia (at 6, 12, 18, and 24 mo of age)	Hemoglobin concentration	Mean Hb and prevalence of anemia
Morbidity symptoms	Parent recall (2 weeks)	% of children with fever, diarrhea and respiratory infections
IYCF and health care seeking practices		
IYCF practices	Parent recall (24 hours and since last visit)	IYCF indicators recommended by WHO (2007)
Preventive health care utilization	Beneficiary cards and parent recall (since last visit)	% of preventive health visits attended, immunizations received, MN Sprinkles received
Curative health care utilization	Parent recall (2 weeks)	% seeking adequate and timely care for childhood illness
Child development		
Motor development	Parent report scale	Summary score from parental report scale
Cognitive development	Parent report scale	Summary score from parent report scale

[a] These outcomes may not need to be collected at every time point.

6.4.7. Data analysis

In the sections below we describe how the data will be analyzed.

Program impact and group comparisons—The impact of the intervention will be estimated using a double difference approach. The equation is as follows:

$$program\ impact = (Y_{t1\_a1} - Y_{t2\_a2}) - (Y_{t24\_a1} - Y_{t24\_a2}), \quad (6.1)$$

with Y the outcome of interest and subscripts $t1$ *and* $t24$ *representing* the measurements at 1 and 24 months and $a1$ and $a2$ two different study arms (could be treatment and control or any other two treatment arms).

We will also use multivariate regression to condition the estimated impact on a set of individual, household, and community characteristics in order to reduce residual variation and improve statistical power.

Since treatment in *PROCOMIDA* starts in pregnancy, the child may have benefited from the intervention by the time of the first measurement at 1 month of age. To the extent that this has a positive impact on child anthropometry, our impact estimation strategy will lead to an underestimation of the program's full impact.[8] In fact, equation (6.1) will estimate the added impact of receiving the program between month 1 and 24 months, after having received the program from enrollment in pregnancy up to 1 month of age.

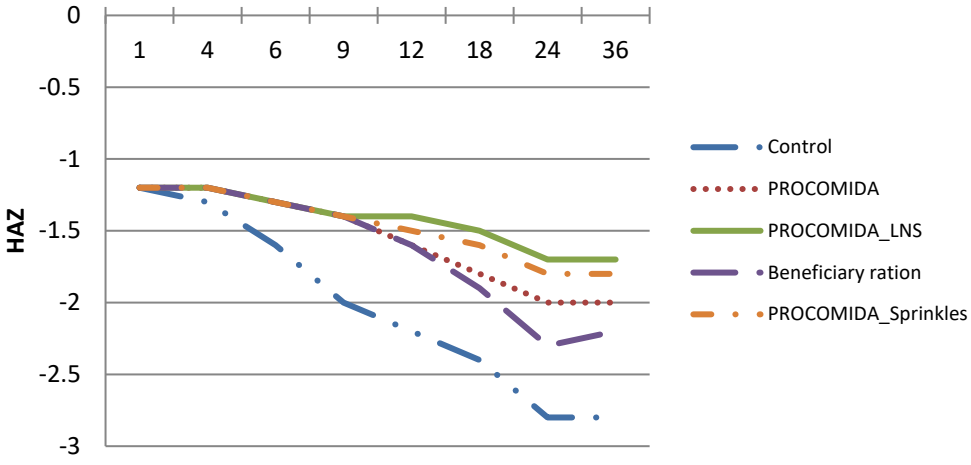
If the groups are balanced at baseline, the program's full impact can be correctly estimated by estimating the simple difference in means at 24 months. To evaluate group balance at enrollment, height and weight data of the unborn child's siblings will be collected. If the groups are not balanced, adjustments will need to be made. A more detailed discussion is provided in Appendix D.

Developmental curve approach—In these models, changes over time in the outcomes of interest are modeled as a function of time and a series of covariates (Frongillo and Rowe 1999). These covariates will include the treatment arms. Other relevant variables could be added, such as the age and sex of the child. The result of these models can be thought of as a graph showing the outcome (Y-axis) as a function of time or child age (X-axis). Different treatment specific lines could be estimated and drawn.

A clear-cut application of this approach is the modeling of growth curves. These models could give us important insights into the potential of the different packages of interventions to prevent growth faltering and further provide information on the timing of the effects of these packages of interventions. For example, from the hypothetical graph below (Figure 6.10), it appears that the package that includes LNS is the best at preventing growth faltering but may be a more important intervention for children 9-24 months of age rather than for pregnant and lactating women. And the package with an individual ration only appears to be doing equally well as *PROCOMIDA* in terms of preventing growth faltering up until the child is 12 months of age; as the child gets older, however, the family rations may contribute more to preventing growth faltering than the individual ration alone.

[8] Note that this will also affect comparisons between treatment groups. The discussion here (and Appendix D) focuses on the comparison of *PROCOMIDA* with control.

Figure 6.10: Hypothetical growth curves



Dynamic approach—The rich nature of the longitudinal data will be fully exploited in a series of dynamic models. In these models, the outcome of interest is modeled as a function of the lagged (i.e., earlier in time) response and covariates (Frongillo and Rowe 1999). A possible model, only taking into account three time points, could be

$$Y_t = \beta_0 + \beta_1.X_1 + \beta_2.X_2 + \beta_3.Y_{t-1} + \beta_4.Y_{t-2}. \quad (6.2)$$

Estimating the dynamic models will shed light on the contribution of the different components of the program and their timing to child growth, health, and development outcomes. It will also show how the child's nutritional status at one point in time is affected by the child's status at previous time points. Additionally, we can estimate dose response relationships between the different outcomes and the attendance at the BCC sessions, utilization of preventive/curative care and ration/supplement utilization. This will provide valuable insights in the quantity of those inputs needed and their timing for improved outcomes.

Dynamic models can also be used to estimate the determinants of program participation. Community, program, and household factors at previous time points may explain why or why not caregivers in this group are or are not attending the BCC sessions, picking up their food rations and attending health care.

Additional notes on the longitudinal analyses—All models will adequately control for clustering, i.e., the potential lack of independence between observations living in the same clusters. Not doing so would lead to an underestimation of standard errors and consequently to overestimation of statistical significance. The models will also control for repeated measures.

6.5. Formative Research

The formative research for Guatemala will be conducted as a collaborative effort by Mercy Corps and IFPRI. IFPRI will be primarily responsible for conducting the formative research related to nutrition and the use of the MN supplements. Mercy Corps will complement IFPRI's

activities by conducting complementary formative research on other important topics, especially those related to preventive and curative health services and general topics related to health and hygiene and the SIAS.

For the formative research related to child nutrition and feeding practices, IFPRI will explore working with the PROPAN method. We will work with local experts to adopt the method as necessary and to conduct the formative research. Since PROPAN specifically focuses on infant and young child feeding, the IFPRI team will develop additional methods to assess the other topics that will be addressed in the formative research, including maternal nutrition, what people know about health and nutrition, and how and where people get this information.

Some of the overarching issues that will be included in the formative research include men's (and other family members such as grandmothers) involvement in infant and young child feeding (including breastfeeding) and their involvement in other aspects of infant and young childcare as well as issues related to communication and decision-making within the household. The primary topics that will be addressed through the formative research are shown in Table D.1 in Appendix E.

The formative research both for the developing the BCC strategy and for strengthening the preventive health services will also serve as a foundation for developing the data collection instruments for the impact evaluation and the operations research. The qualitative research to aid in the development of the baseline survey and for the development of the different components of the intervention is planned to take place between from November 2009 to March 2010.

6.6. Operations Research

Once the program is implemented, operations research will be used to assess the quality of implementation and of service delivery, and to identify operational and utilization constraints. The basis for developing the operations research will be the detailed program theory framework underlying the *PROCOMIDA* program. This framework will be developed in coordination with Mercy Corps and other key stakeholders and will be used to identify the program's key inputs, outputs, and expected outcomes. The key steps along the program theory pathway will be evaluated during the operations research with a focus on program operations and service delivery and utilization (i.e., inputs through outcomes).

Using a combination of quantitative and qualitative assessments to collect information about all of the essential steps will improve understanding of how the program is working or not working (i.e., whether or not there are any bottlenecks in operations, service delivery, or utilization). This information will then be used to design corrective measures for poorly functioning or underused program components to ensure that the *PROCOMIDA* program is able to attain optimal impacts. In addition, documenting and understanding these aspects will allow a better understanding of program impacts and will improve the ability to attribute impact to the program. Due to the longitudinal design of the study in Guatemala, the operations research conducted here may be especially informative in helping us to better understand the factors related to growth faltering or

those that are especially protective in preventing growth faltering. In this study we will conduct two rounds of operations research in Year 2 and Year 3 of the program.

As described earlier, some of the key components that need to be in place for the success of *PROCOMIDA* to improve child growth are the availability of food rations and preventive health and nutrition inputs and services, the appropriate training of staff and their use of optimal BCC techniques, the availability and effective delivery of age-appropriate messages for infant and young child feeding, the identification of adequate venues for the BCC messages, and communications materials for interacting with caregivers. In addition, for optimal impact, caregivers need to understand and utilize the program services and adopt the key behaviors promoted by the BCC strategy. The operations research aimed at identifying constraints or bottlenecks to optimal program implementation, operations, and utilization will measure these key success factors. Table 6.8 summarizes the main steps used in program theory (inputs, process, outputs, and outcomes) and provides examples of the types of data collection methods that we will use to measure each of the steps of the hypothesized impact pathway. This preliminary table will need to be refined once the program theory framework for *PROCOMIDA* is developed with Mercy Corps and will need to be further refined to account for differences in the treatment arms of the study.

6.7. Ethics Review

The research protocol and all data collection instruments will be submitted to IFPRI's Institutional Review Board prior to conducting the fieldwork. Approval will also be sought from Guatemala's Ministry of Health.

Informed consent will be sought from all respondents. It will be made clear to all respondents that participation is voluntary and that not participating in or withdrawing from the study will not affect the benefits they receive from *PROCOMIDA* or any other program or project.

Table 6.8: Basic program theory steps for *PROCOMIDA*

Step in program theory	Examples of potential data collection methods
Inputs	
Food supplement for pregnant and lactating women and 6-24 month old children	Ration availability check, observations of food distribution points
Trained staff for food distribution, preventive health services and BCC	Review of training protocols, observations of training, assessment of staff skills and knowledge
Equipment and space	Facility assessments and equipment checks, review of BCC materials
Process	
Health promoters and assistants effectively communicate with caregivers about the importance of utilizing the program services	Focus group discussions with health workers and caregivers, exit interviews with caregivers, observations of mothers' clubs/other education sessions
Health promoters and assistants provide a good learning environment for BCC sessions	Observations of mothers' clubs/other educational sessions, interviews with caregivers and health workers, group discussions on constraints faced by health workers
Caregivers collect supplement from distribution point	Distribution check, re-weighing of rations received, quality check of commodities
Caregivers attend BCC sessions	Attendance monitoring, focus group discussions and interviews with caregivers and staff to identify barriers and facilitators to attending BCC sessions
Caregivers utilize preventive health services	Attendance monitoring, focus group discussions and interviews with caregivers and staff to identify barriers and facilitators to utilizing services
Outputs	
High quality BCC program operating and being utilized as planned; quality health services available	Observations, focus group discussions with caregivers and health workers, surveys of program use and exposure
Caregivers understand and utilize the BCC messages	Exit interviews, focus group discussions, surveys of program use, exposure, and adoption of program recommendations
Outcomes	
Children regularly consume rations and other recommended foods, and are fed appropriately for their age.	Interviews with caregivers on use of rations, magnitude of sharing of different commodities (and reasons for sharing), adoption of recommended infant and young child feeding practices, constraints to adoption of optimal practices, etc.
Children receive appropriate preventive health services	Observations of health facilities, tracking using child card which records services received, interviews with caregivers through surveys

7. Burundi

7.1. Country Specifics and Patterns of Child Growth

7.1.1. Burundi

Burundi is a small landlocked country in Central Africa, east of the Democratic Republic of Congo (Figure 7.1). It has an equatorial climate with two wet seasons (February to May and September to November). More than 90 percent of the population depends on subsistence agriculture. Coffee and tea exports account for 90 percent of foreign exchange earnings. Per capita GDP is US$400 and 68 percent of the population is below the poverty line. The population growth rate is 3.28 percent, leading to an estimated doubling of the population in 21 years (CIA 2009b).

Burundi suffered from a war between 1993 and 2005. The country's first democratically elected president was assassinated in October 1993, triggering widespread ethnic violence between Hutu (the ethnic majority in the country) and Tutsi factions. More than 200,000 Burundians died during the 12-year conflict that followed. Hundreds of thousands of Burundians were internally displaced or became refugees in neighboring countries. A power-sharing agreement between the Tutsi-dominated government and the Hutu rebels in 2003 paved the way for a transition process. This led to an integrated defense force, a new constitution in 2005, and an elected majority Hutu government in 2005 (CIA 2009b).

Only a small fraction of the population (19 percent) is food secure. Food production has stagnated at pre-1993 levels. Combined with the high population growth rate, per capita agricultural production has declined by a staggering 24 percent since the beginning of the war. Per capita production is 1,400 kcal per day and even during harvest season, 60 percent of household income is spent on food. Burundi has been identified by the World Food Programme (WFP) and the Food and Agriculture Organization of the United Nations (FAO) as a "red zone" country, i.e., a country likely to be most affected by increasing food prices (WFP 2009b).

In September 2006, the Government of Burundi approved the first Poverty Reduction Strategy Paper. The paper has four strategic priorities: (1) improve governance and security; (2) promote sustainable and equitable economic growth, (3) develop human capital, and (4) prevent and control HIV.

A large number of multilateral and bilateral donors and PVOs are active in Burundi. The World Bank has provided US$309 million (mid-2008 to mid-2012) to promote sustainable and broad-based economic growth, to improve access to social services and consolidate social stability and to improve governance. The World Bank is also supporting a number of different initiatives, including projects to improve health care, education, agriculture, and water supply, among others (World Bank 2009b).

The WFP provides food to over 700,000 people in the food-insecure north and northeastern areas every month, targeting the most vulnerable households. WFP further assists refugees, asylum

seekers, and returnees, and has set up a food-for-work program and a school feeding program. Finally, WFP also provides food assistance to therapeutic and supplementary feeding centers and food rations to HIV/Aids patients on antiretroviral drugs (WFP 2009b).

Figure 7.1: Burundi

Map No. 3753 Rev. 6 UNITED NATIONS
September 2004

Department of Peacekeeping Operations
Cartographic Section

The United Nations Children's Fund (UNICEF) has been actively supporting the immunization and deworming of children and pregnant women, the prevention of malaria through the distribution of insecticide-treated nets, the therapeutic treatment of malnourished children, the training of doctors in emergency obstetric care, and improving access to potable water. It has further supported government education efforts through the training of school heads and teachers and the construction of schools and toilet facilities in schools. UNICEF has also helped with the reintegration of refugees and displaced persons (UNICEF 2009). Other multilateral donors active in Burundi include the United Nations Development Program and the European Community (USAID 2009b).

The United States and Belgium are Burundi's major bilateral donors. USAID currently funds a Multi-Year Assistance Program (MYAP) in Kirundo and Muyinga, two provinces in northeastern Burundi. The MYAP is implemented by Catholic Relief Services (CRS) and is based on the recuperative model. Other important bilateral donors include France and Britain (jointly funding HIV/AIDS activities with USAID), Austria (active in water, sanitation, and human rights), Germany (debt relief, conflict mitigation and prevention, democracy, and health), and Italy (emergency assistance, HIV/AIDS, water and sanitation) (USAID 2009b).

7.1.2. Cankuzo and Ruyigi

The PM2A project will be implemented in the provinces of Cankuzo and Ruyigi. In these eastern provinces (Figure 7.1), food insecurity is a major problem for the largely rural population. An additional problem that these provinces have faced is the reintegration of returning refugees from Tanzania. The land of many of these refugees has been occupied by others during their absence, leaving the returnees landless.[9]

7.1.3. Patterns of Child Growth in Burundi and Cankuzo and Ruyigi

Data from the Multiple Indicator Cluster Surveys (MICS, UNICEF) for Burundi (2000)[10] were used to estimate growth curves of attained height-for-age (HAZ), weight-for-height (WHZ), and weight-for-age Z-scores (WAZ) by child age and to document the prevalence of stunting, wasting, and being underweight (Figures 7.2 to 7.5).[11] Z-scores were calculated using the new WHO growth references (WHO Multicentre Growth Reference Study Group 2006).

A number of important observations can be made. First, the curves do not follow the typical pattern found in most developing countries where mean HAZ and WAZ decline almost linearly from birth to approximately 18 months, after which they tend to stabilize at a low level (Ruel 2001). In Burundi, mean HAZ continues to decline up to the age of 30 to 36 months, after which the mean Z-score stabilizes at a very low level of -2.7 Z-scores. Second, by 6-12 months of age,

[9] The issue of returning refugees was discussed during the IFPRI/FANTA field visit in July 2009. It appears that the influx of returning refugees has slowed down considerably. It is thus unlikely that it would negatively affect the implementation of *Tubaramure* or the study proposed here.

[10] A more recent MICS survey (2005) is available on the UNICEF website. No anthropometric data were collected in this survey, however.

[11] Two points must be noted. First, even though data were collected on all children 0 to 60 months of age, no anthropometric data are available for children 0 to 6 months of age in the dataset. Second, the date of birth is not available for 10 percent of the children, height and weight data are missing for 20 percent, resulting in missing Z-scores for about 30 percent of the survey sample.

mean HAZ is already close to -2 Z-scores, which is much lower than in most populations for which data are available. Even among some of the poorest countries of Africa and South Asia, HAZ in that age range is usually between -1 and -1.5 (Ruel 2001). A third atypical pattern observed in Burundi is that the highest prevalence of linear growth retardation or stunting is found in children 36 to 48 months of age. This is in contrast to a previous analysis of Demographic and Health Surveys from 28 countries representing the three main regions of the developing world. In these analyses, the peak prevalence of stunting was systematically found at 18 months of age (Ruel 2001). Finally, the analyses show a very high overall prevalence of stunting of 64 percent.

Mean WAZ follows similar patterns as HAZ, a pattern observed in many other countries. The overall prevalence of wasting is 8 percent. The highest prevalence (12 to 13 percent) is found in children 6 to 18 months of age, after which the prevalence gradually decreases (with an intriguing spike in prevalence (8 percent) in children 48 to 54 months). In the review of growth patterns from 28 countries, the peak period of wasting was found between 9 to 12 months of age, similar to the findings for Burundi (Ruel 2001).

The key question is why the pattern of linear growth retardation is different from most other countries and why the absolute levels are so low. The most probable explanation is the 12-year war in Burundi, which ended in 2005. Another—less likely— explanation is selection bias. If the 30 percent of children for whom no growth data are available in the dataset were in general better off than the children in the sample, then the prevalence of undernutrition would be biased upward. This is unlikely, since 10 percent of the missing values are due to missing birth date information, which is more likely to occur among poorest, less educated households, which, in turn, are more likely to have undernourished children. No other data were found to corroborate the 2000 estimates from the MICS. The 2009 UNICEF Humanitarian Action Report for Burundi (http://www.unicef.org/har09), however, cites the following from a National Nutrition Survey, 2007: "Chronic malnutrition rose from 48.1 percent in 1987 to 56.8 percent in 2000 to decrease to 46 percent in 2007." We do not have access to the National Nutrition Survey data to corroborate these findings.

Even though there are uncertainties relative to the exact estimate of child undernutrition in the country, the key message here is that the prevalence of malnutrition is unacceptably high in Burundi.

We also looked at child growth in Cankuzo and Ruyigi and found the patterns to be very similar to those found for the entire country. The graphs are thus not presented.

Figure 7.2: Height-for-age, weight-for-height, and weight-for-age Z-scores, by child age, Burundi

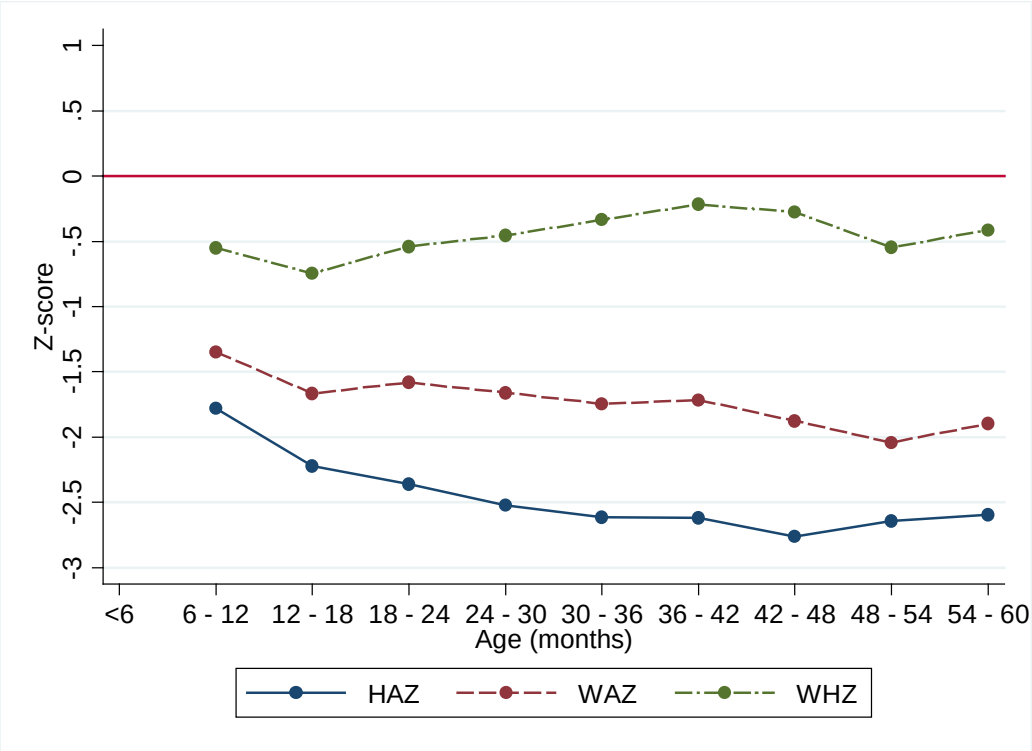


Figure 7.3: Prevalence of stunting, by age, Burundi

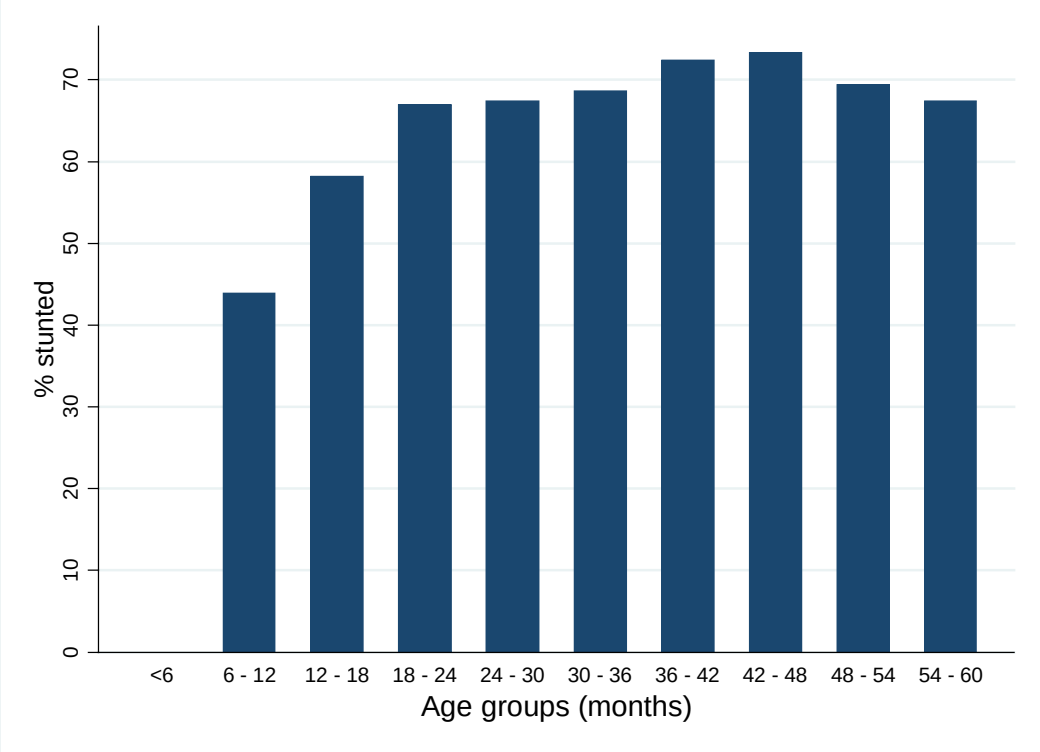


Figure 7.4: Prevalence of wasting, by age, Burundi

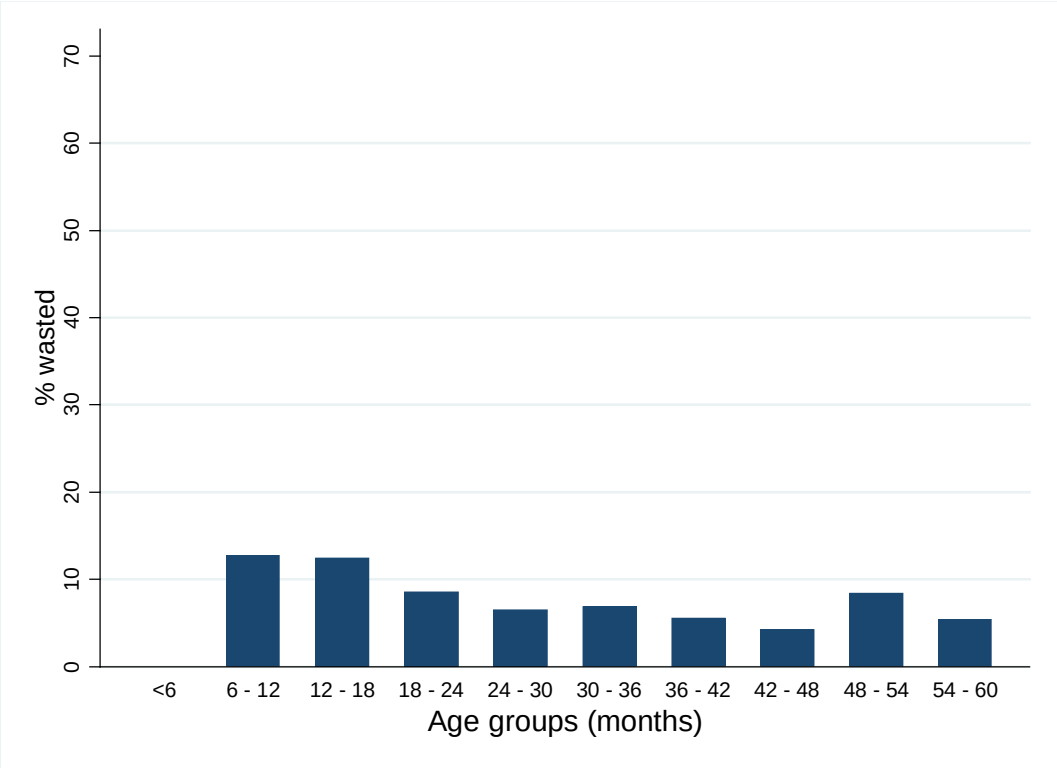
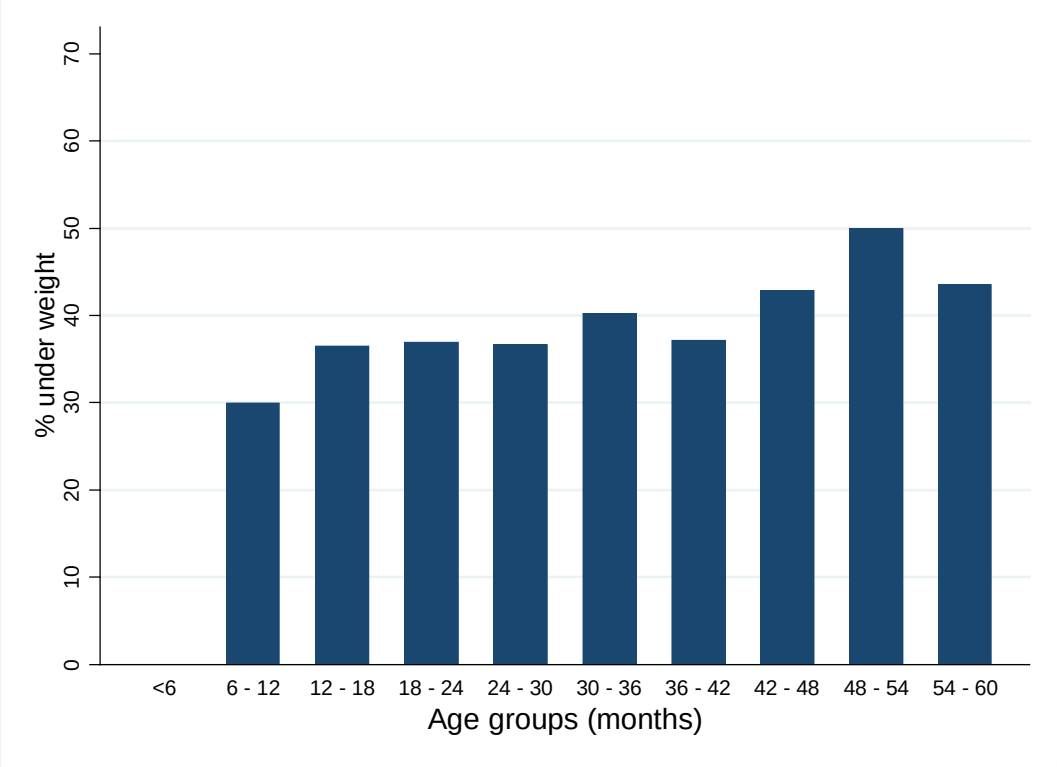


Figure 7.5: Prevalence of underweight children, by age, Burundi



7.2. Program Description

In Burundi, the program to be evaluated will be implemented by Catholic Relief Services (CRS), in consortium with Food for the Hungry (FH), International Medical Corps (IMC), and Caritas Burundi. The program has been named *Tubaramure*, a Kirundi word meaning "Let's help them grow."

Tubaramure's main components are summarized in Section 7.2.1, followed by the program's eligibility criteria in Section 7.2.2. The program's field organization is summarized in Box 7.1.

7.2.1. Program Components

The *Tubaramure* program includes the three broad areas of PM2A: the distribution of food rations, the required participation in BCC activities, and the required use of preventive and primary health care and nutrition services. Details on each of the components are provided below.

7.2.1.1. Food rations

Tubaramure will provide households with both a family- and an individual-food ration. The ration sizes are summarized in Table 7.1. By contrast with Guatemala, the same types of food (CSB and oil), are used for the family and the individual ration.

Table 7.1: Monthly ration size, *Tubaramure*

Target group	CSB	Vegetable oil	Energy/ month	Energy/ day[a]	Energy/day/ capita[b]
	(kg)	(g)	(kcal)	(kcal)	(kcal)
Pregnant/lactating women	6	600	27,846	915	158[c]
Under 2s	3	300	13,923	458	79[c]
Family ration	12	1,200	55,692	1,831	316
Total ration (pregnant/lactating women)	**18**	**1,800**	**83,538**	**2,746**	**474**
Total ration (under 2s)	**15**	**1,500**	**69,615**	**2,288**	**395**

[a] Energy per day: using 30.42 days/month.
[b] Energy per capita is calculated based on the assumption of 5.79 average household size.
[c] Note that the individual ration is not meant to be shared, but this may be difficult to achieve, as the individual and the family ration include the same foods.

Mothers will receive a specially designed *Tubaramure* ration bucket with their monthly ration, and ration cards will be distributed by the Leader Mothers (LMs) during monthly home visits, conditional on meeting the criteria in Table 7.2. The targeting and eligibility criteria will be communicated to the community through an awareness campaign.[12]

[12] Whether the LM will be in charge of reviewing mothers' eligibility to receive the food rations is still being discussed by the consortium.

Box 7.1: *Tubaramure* field organization

Tubaramure will hire its own staff and will closely collaborate with existing ministry, government, and community staff.

***Tubaramure* Project Staff**

Tubaramure Health Promoters (THP)

- Coordinate commune-level activities;
- Train Lead Mothers (LMs) in Care Groups (CGs) and Traditional Birth Attendants (TBAs) on BCC; train Community Health Workers (CHW) and Public Health Technicians (TPSs) on referrals;
- Work with Community Health Committee (CHC) to create a feedback mechanism by which the community can be informed of households' progress toward the reduction of malnutrition;
- Report to CRS head of office in each province.

Leader Mothers (LM) and Care Groups (CG)

- Selected by households (1 for every 10-15 households) based on trust, respect, leadership skills, and mothering knowledge;
- Ten LMs form a CG led and trained by a THP in techniques to promote behavior change in ENA, EHA, and early detection, and referral to pre-postnatal services, referral, and proper home management of childhood illnesses;
- Work with 10 to 15 households through home visits and group meetings.

Technical advisors

- One from each consortium partner (IMC-General health, FH-BCC, and CRS- Food Utilization);
- Responsible for designing curricula and harmonizing with MoH when relevant; implementing trainings; providing technical support to THPs to ensure targets are being met; and making adjustments to approaches or messages when barriers are identified.

Ministry/Government Staff

Health facility staff (MoH)

- Doctors at the hospital level; nurses at the health centers; mid-wives; provincial medical coordinators; public health technicians (TPS);
- Receive specific trainings; support referral processes; engaged in M&E, planning, and review; participate in surveys or other assessment activities.

Community Health Workers (CHW)

- Community-level volunteers sponsored by MOH, trained by the TPS to support basic health services at the community level. MoH protocol recommends 1 CHW for every 10-15 households;
- Carry out consultations with households; refer cases for service; participate and support Care Group; receive training and support from project.

Existing Community Staff

Traditional Birth Attendants (TBA)

- Few exist within communities, but where they do, they will be included in CG trainings.

Community Health Committees (CHC)

- Respected leaders named by community to support Community health and nutrition activities (project will determine if existing committees could serve this purpose before duplicating committees);
- Monitor progress of activities; convene monthly feedback meetings with CGs and health promoters; develop and implement community projects (i.e., communal gardens or animal production) based on local needs;
- Community proposals up to $500 will be considered by project.

Table 7.2: Criteria for receiving ration cards in *Tubaramure*

Age	Criteria
Pregnancy (at least 3 months pregnant)	• Registered for pre-natal services (demonstrated by show of health card) • Agrees to complete 4 pre-natal visits • Household agrees to practice at least 6 selected activities on the *Tubaramure* Family Poster
Lactation	• Completed 4 pre-natal visits (show card) • Registered for postnatal services (show card) • Baby has been registered for growth monitoring • Household agrees to practice (or has completed) at least 6 selected activities on the *Tubaramure* Family Poster
6 to 9 months old	• Postnatal visits completed (show card) • Child's immunization record is current (show card) • Child shows satisfactory progress in growth (MUAC) or mother demonstrates capacity to recuperate the child • Household agrees to introduce some animal products, vegetables, and fruit as part of IYCF
10 to 24 months (23rd month is final month for receiving food)	• Child's immunization record is current (show card) • Child shows satisfactory progress in growth (MUAC) or mother demonstrates capacity to recuperate the child • Household agrees to continue IYCF practices • Household agrees to practice (or has completed) at least six selected activities on the *Tubaramure* Family Poster

7.2.1.2. Behavior change and communication strategy

Care Groups (CG)—The main delivery mechanism for the BCC messages are the Care Groups. CGs are teams of approximately 10 Leader Mothers (LMs) who are selected by their neighbors. LMs receive two lessons per month from the *Tubaramure* Health Promotor (THP), with key themes including essential nutrition actions (ENAs), essential health actions (EHAs), and home-based prevention and management of illnesses. The LMs are supported by the local Community Health Committee (CHC).

The specific contents of the curriculum will be determined through a Barrier Analyses and Local Determinants of Malnutrition Study. The LMs will conduct monthly home visits to pregnant women, women of children 0 to 5 months and children 6 to 24 months, and with other family members who influence decisions and sometimes care for children in the household. They will also hold monthly group meetings with the women (a total of 10 to 15 women per LM).

Other delivery mechanisms—The project will also coordinate with other providers (THPs, CHWs, nurses). Each family will have a *Tubaramure* Family Poster to help them assess progress in preventing malnutrition. At the community level, CHCs will use a checklist to monitor changes and to make decisions on possible changes. The BCC strategy will further include serial stories, demonstrations, skits, songs, and radio broadcasts.

Contents of the BCC campaign—The messages to be delivered relate to Essential Nutrition Actions, the use of the food ration, Essential Hygiene Actions, the prevention and management of maternal and childhood illnesses, the use of pre- and postnatal care, and men's involvement.

- **Essential Nutrition Actions (ENA):** LMs will discuss ENAs during the home visits and group meetings. LMs will use the *Tubaramure* Family Posters during home visits to promote adoption of ENAs, and will follow up in the home with progress toward each action.
- **Use of the food rations:** The program will promote the proper utilization of the food ration, avoiding sharing or dilution and ensuring that children are fed frequently. LMs will promote the proper utilization of the food ration with local foods. They will also reinforce the messages on how to use the ration bucket. Additionally, recipes appropriate for pregnant and lactating women and children under 2 years of age, using local foods (including animal products), will be developed by *Tubaramure* and MoH nutrition experts in consultation with LMs. The recipes will be evaluated for food composition and pilot tested.
- **Essential Hygiene Actions (EHA):** LMs will use home visits for inspection of EHA behaviors including hand-washing stations, soap, latrines, and water, as well as sanitation conditions. LMs will work with the family to adopt appropriate practices and will periodically follow up on progress. Mothers will be helped to establish hand-washing stations, tippy taps, and covered water containers. CHCs will assist mothers in identifying ways to set up tippy taps. *Tubaramure* will identify the currently available materials on hygiene practices in Burundi and ensure that health facilities have these materials on display.
- **Prevention and management of maternal and childhood illness:** LMs will explain and promote behaviors to prevent and manage illnesses during home visits and group meetings. During the group meetings, strategies for encouraging mothers to adopt recommended practices, such as giving the child oral rehydration salts (ORS) and additional foods during and after illness, and sleeping under bed nets, will be discussed. Using the *Tubaramure* Family Poster, LMs will help family members (including husbands/fathers, extended family members, older siblings of infants) to track progress.

  Additionally, each health facility will be given the same set of messages that will be developed for the CGs in order to harmonize messages concerning home management (including dietary management) of illness.
- **Use of pre- and postnatal care**: Attending pre- and postnatal care will be promoted through the CGs. Additional topics will include maternal ENAs, including iron and iodine supplementation during pregnancy, EHAs, danger signs in the pre- and postnatal period, exclusive breastfeeding, and iron supplementation during lactation.
- **Men's involvement:** A strategy to promote men's involvement in maternal and child health and nutrition will be implemented. This strategy will be developed based on the formative research.

7.2.1.3. Use of health and nutrition services

Tubaramure will promote attending pre- and postnatal care, growth monitoring and promotion, health-care seeking for illness, and the timely detection and referral of severe acute malnutrition (SAM). It will also support the planned roll-out of the Integrated Management of Childhood Illness (IMCI) by the MoH.

Pre- and postnatal care services: *Tubaramure* will develop a training curriculum aimed at increasing the use of pre- and postnatal services. Pre- and postnatal and newborn care practices will be reinforced through the CGs. A prerequisite for receiving food rations is to comply with pre- and postnatal visits. The program will also develop a "Pre and Postnatal Poster," which can be given to facilities that are effectively delivering good quality services.

Growth monitoring and promotion: The quality of the health facility-based growth monitoring and promotion (GMP) will be improved through a training curriculum. Messages related to GMP will be included in the training of LMs, who will encourage households to attend monthly GMP. *Tubaramure* will also support the MoH in the planned roll-out of community-based GMP.

Health-care seeking for illness: The existing services that can be accessed by households to prevent or manage illnesses will be mapped so households know where and from whom to seek support. The map will include provincial- and community-level services (where to find oral rehydration salts, community health workers, insecticide treated nets, etc.). Husbands and fathers will be involved in the process so they learn about existing resources in the community to draw upon for their wives and young children's health and nutrition.

Detection and referral of SAM: UNICEF is supporting the Ministry of Health to support the scaling up of Community Management of Acute Malnutrition (CMAM). *Tubaramure* will work with UNICEF and the Ministry of Health to coordinate activities and will provide technical support (scales and measuring boards) where necessary. *Tubaramure* will also build community capacity with respect to the prevention, screening, referral, and follow-up of cases of SAM:

- Prevention: will be done through training of community health workers (CHWs) and LMs.
- Screening: will rely on MUAC for screening through door-to-door campaigns, community-wide events such as fairs or market days, and mobilizing and training LMs to be engaged in the MUAC screening with the assistance of parents; interested fathers will also be trained to help in MUAC screenings, providing an opportunity to engage them.
- Referral: will be done by developing a community-based referral plan for malnutrition.
- Follow-up: will rely on home visits to follow children after graduation with specific messages for catch-up feeding.

Implementation of IMCI: *Tubaramure* will support the MoH to train facility-level staff, public health technicians, CHWs, and LMs in Community IMCI (C-IMCI).

7.2.2. Program Eligibility Criteria

The program will enroll pregnant women and mothers of children younger than 6 months of age. Program benefits are provided up to the age of 24 months. In order to receive the program's food rations, households have to comply with certain program requirements related to attending BCC activities and preventive health-care utilization. Details are provided in Table 7.2.

7.3. Objectives

7.3.1. Overall Objectives

The Burundi study will address all three broad objectives of the overall PM2A research program:

- Objective 1: Assess the impact and cost-effectiveness of PM2A on child nutritional status.
- Objective 2: Determine the optimal size and composition of food rations in PM2A.
- Objective 3: Determine the optimal duration of exposure to PM2A.

7.3.2. Specific Objectives

The Burundi study has five specific objectives (child nutritional status is the impact measure for all of them):

1a. Evaluate the impact of *Tubaramure* compared to a control group and measure the program's cost-effectiveness.

1b. Evaluate the cost-effectiveness of *Tubaramure*.

2j. Evaluate the impact of *Tubaramure* **without food during pregnancy (both individual and family ration)**, compared to a control group.

2k. Evaluate the differential impact of *Tubaramure* **without food during pregnancy (both individual and family ration)**, compared to *Tubaramure* with individual and family food rations.

3a. Evaluate the impact of *Tubaramure* **provided only up to the age of 18 months,** compared to a control group.

3b. Evaluate the differential impact of *Tubaramure* **provided up to the age of 18 months**, compared to *Tubaramure* provided up to 24 months of age.

Child nutritional status will be evaluated by calculating the mean WAZ, HAZ, and WHZ, and the prevalence of stunting, wasting, and being underweight.

7.3.3. Additional Objectives

1. Assist the *Tubaramure* team in the design and implementation of a fully developed BCC intervention, as requested by PVO implementing partners.
2. Use operations research methods to assess
    - The implementation of the program to identify constraints and potential solutions to improving program operations;
    - The effectiveness of delivery of the various components of the program (i.e., food distribution, BCC, and preventive health services);
    - The quality of the different services provided;

- The perceptions of different stakeholders about the program with an emphasis on their perceptions regarding its effectiveness, the quality of the services provided and their roles, and responsibilities within the program structure; and
- The institutional demands for successful implementation.

3. Document, through a mix of quantitative and qualitative approaches, the intrahousehold utilization and consumption of the food commodities, particularly consumption by the target individuals (the mother during pregnancy and lactation and the child from 6-24 months of age).
4. Evaluate the impact of the interventions on other household, maternal and child outcomes:
   a. Household food security (FANTA's Household Hunger Scale)
   b. Household food and nonfood consumption/expenditure
   c. Maternal infant and young child feeding and health-seeking practices
   d. Maternal Hb
   e. Children's cognitive and motor development
   f. Children's morbidity symptoms
   g. Children's anemia

7.4. Design of the Impact Evaluation

7.4.1. Overall Design and Timing

This study will use a cluster randomized controlled design to compare communities that have been randomly assigned to one of four groups: a control group and three groups receiving a different package of interventions (see Section 7.4.2 below). A pre-post design using three cross-sectional (one pre-intervention, two after the intervention has started; see below) surveys will be used. The three intervention groups will receive different packages of interventions including different duration of the food ration, BCC, and health services. The control group will receive no additional intervention, but may use the existing preventive health services provided under the MoH.

Randomization will be done at the level of the *colline*.[13] There are a total of 276 *collines* in the two provinces which CRS plans to include in *Tubaramure*. For the research study, a total of 60 *collines* will be randomly assigned to each one of the three intervention groups or to the control group (15 *collines* per arm).

Within each of these study areas, we will draw a random sample of households with children between 0-42 months at baseline, 0-24 months at the first follow-up and 24-42 months of age during the second follow-up (see below for details on timing and age range of the surveys). Being part of the study sample will thus be independent from enrolment in the *Tubaramure* intervention. This is important as we want to estimate the intent-to-treat effect of the

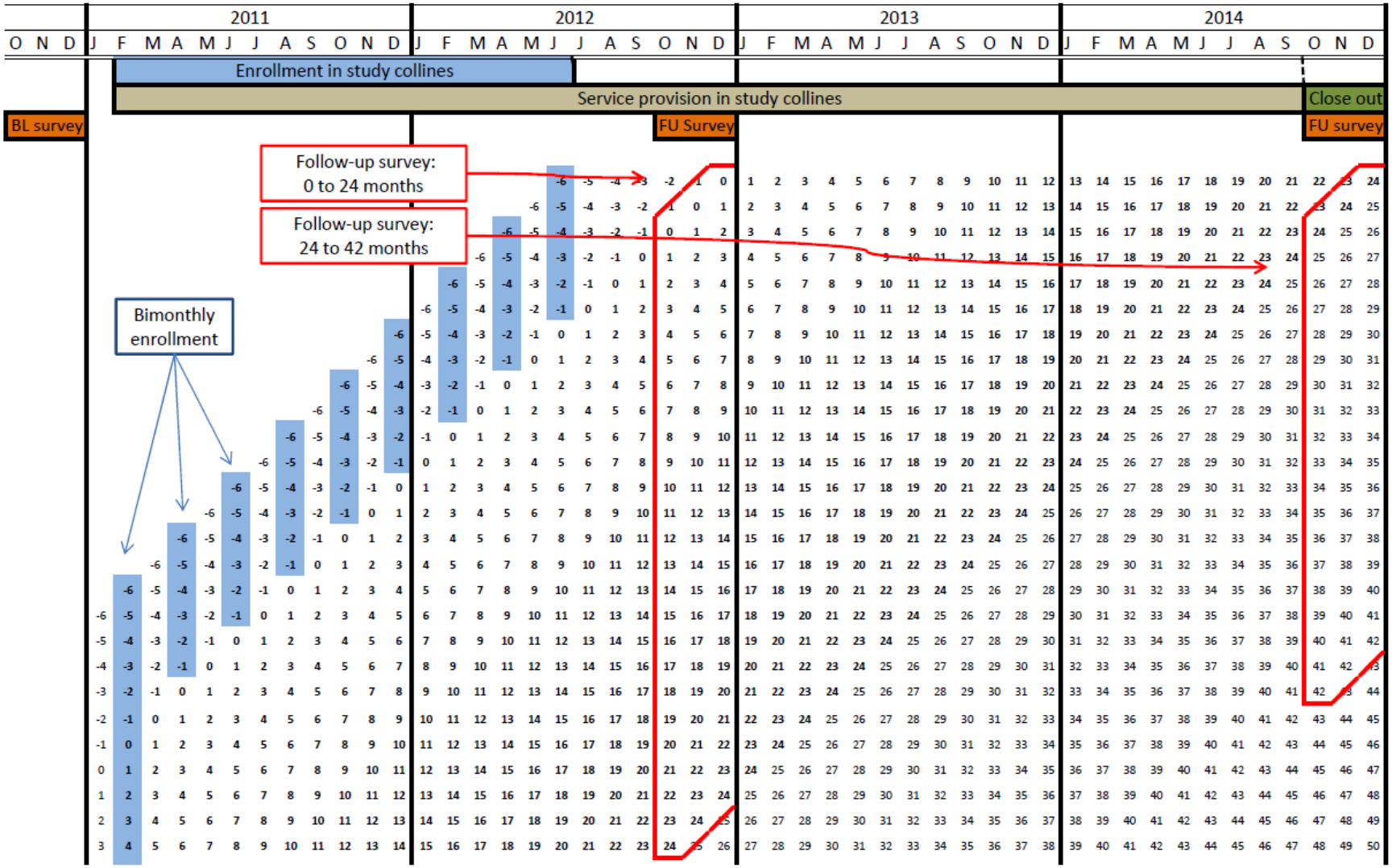
[13] A study cluster is defined as one hill (or *colline* in French). The *colline* is an official administrative unit in Burundi.

intervention rather than the treatment-on-the-treated, which would happen if we only sampled households who are *Tubaramure* beneficiaries.

We will collect community-, household-, and child-level data on all households included in the survey sample. The community questionnaire will collect data on the availability of services (clinic, school, electricity, water, sewage, garbage, TBAs, healers, stores, markets, etc.) and the price and availability of food. The household questionnaire will gather information on household demographics and socioeconomic indicators, household food security, household food and nonfood consumption and expenditure, and ownership of assets related to child stimulation (e.g., books, toys, etc.). Data on maternal characteristics will include anthropometry and infant and young child feeding practices and health care seeking behaviors. The child-level data for the target child (0-42 months of age) will include anthropometry, anemia, morbidity symptoms, and child development outcomes.

We will conduct two follow-up surveys (in addition to the baseline survey in 2010). These repeated cross-sectional surveys are carefully timed in order to measure certain indicators among specific age groups (e.g., feeding practices, child growth), as well as to evaluate as much as possible the impact of full exposure to the set of interventions throughout the first 1000 days (i.e., from early pregnancy up to the age of 24 months). Because the enrollment into the research study is on a rolling basis, the timing of these cross-section surveys is critical in order to capture the right age group of children with adequate exposure to the set of interventions. The age group of interest for the first follow-up evaluation is 0-24 months of age (to assess outcomes such as feeding practices); for the second follow-up evaluation, the age group of interest is 24-42 months of age (for outcomes including child growth, the main outcome of interest for the research). The second critical timing factor is seasonality; all surveys need to be conducted during the same time of year in order to avoid seasonality effects which could confound the results. Finally, we need to consider the timing and duration of the actual program implementation in the research *collines* (enrollment of new beneficiaries from February 2011 to June 2012 and service provision from February 2011 to September 2014) to maximize program exposure.
The baseline survey was conducted in the last quarter of 2010 before the interventions started (Table 7.3). Taking into account the factors outlined above, the first follow up (children 0 to 24 months of age) is planned for the last quarter of 2012 and the second follow up (children 24 to 42 months of age) for the last quarter of 2014.

Table 7.3: Determining the child age range and timing of the follow-up surveys[a]



[a] Numbers refer to the age in months of children in the study collines.

7.4.2. Study Groups and Research Questions

The study will compare groups of households that have been randomly assigned to one of four groups:

- Group 1—*Tubaramure 24*: this group will receive the full *Tubaramure* program. This includes BCC and food rations (individual + family) during pregnancy, lactation, and up to the age of 24 months.
- Group 2—*Tubaramure 18*: this group receives the full *Tubaramure* program, but only up to the age of 18 months.
- Group 3—*Tubaramure* NFP (no food in pregnancy)[14]: women in this group receive BCC but no food rations—either individual or family rations- during pregnancy. From birth, they receive the full *Tubaramure* program, including the individual (mother) and family food ration during the first six months of lactation and the child and family ration when the child is between 6 and 24 months of age.
- Group 4—Control: *Tubaramure* is not provided to these households.

The proposed comparison groups and how they relate to the specific research questions are shown in Table 7.4.

Table 7.4: Group comparisons and associated research questions

Objective	Study group	Compared to	Research question
1a	*Tubaramure 24*	Control	What is the impact of *Tubaramure* (compared to a control group) on child nutritional status?
1b	*Tubaramure 24*	Control	What is the cost-effectiveness of *Tubaramure?*
2j	*Tubaramure NFP*	Control	What is the impact of *Tubaramure without food rations during pregnancy* (individual + family) on child nutritional status?
2k	*Tubaramure NFP*	*Tubaramure 24*	What is the impact of *Tubaramure without food rations during pregnancy* (individual + family), compared to *Tubaramure*
3a	*Tubaramure 18*	*Control*	What is the impact of receiving *Tubaramure only up to the age of 18* months on child nutritional status?
3b	" "	*Tubaramure 24*	What is the differential impact of receiving *Tubaramure* up to the age of 18 months *vs.* receiving it up to the age of 24 months?

7.4.3. Study Outcomes

The main outcome of the study is child nutritional status. To evaluate child nutritional status, we will measure child length or height and weight and calculate anthropometric Z-scores using the 2006 WHO growth reference (WHO Multicentre Growth Reference Study Group 2006). We

[14] Mothers will receive MN Sprinkles during pregnancy instead of the fortified CSB. The main rationale is that we want to test whether providing additional energy (kcal) from food rations during pregnancy provides greater benefits for the child's nutritional status up to 24 months of age than supplementing mothers only with micronutrients (including iron and folic acid, as per current recommendations, and several other essential micronutrients).

will estimate the mean HAZ, WAZ, and WHZ, and the distribution of these indicators to determine the prevalence of childhood stunting, underweight, and wasting. Other outcomes include anemia, reported child morbidity symptoms in the two weeks prior to the measurement, infant and young child feeding practices using the new set of indicators proposed by WHO (2008), preventive and curative health seeking behaviors, and child development.

Household food security using the FANTA Household Hunger Scale and household food and nonfood consumption and expenditure will also be measured at baseline and final survey.

7.4.4. Sample Size

The sample size calculations are based on estimating program impact using the difference between study groups in the cross-sectional survey at follow-up. We adjusted the sample size for the lack of independence of children living in the same cluster. If this intra-cluster correlation is not taken into account, statistical power would be overestimated.

A three-step approach was used to determine the study sample size:

- Step 1: Determine the required sample size to answer research questions 1, 2, and 4. These research questions correspond to an *a priori* hypothesis that the intervention will have a *positive* impact on child growth.
- Step 2: Determine the required sample size to answer research questions 3 and 5. There is no *a priori* hypothesis regarding the direction of effects (i.e., positive or negative differences between the groups) underlying these research questions. The key challenge, therefore, is to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the cost of the study) under control.
- Step 3: Determine the sample size for the other outcomes[15] (anemia, IYCF practices, child development, and food security).

Sample sizes and minimal detectable differences for child growth (24-42 months)—The parameters used for the sample size calculation are given below. For more detailed information on the underlying assumptions, see Appendix F.

- Type 1 error (α): 0.05
  - One-sided for research questions 1, 2, and 4;
  - Two-sided for questions 3 and 5.
- Power (1-β): 0.90
- Selection of minimal detectable difference:
  - **Impact of different program models compared to a control group:**
    - Research question 1: For this comparison, we used the estimated absolute effect of the preventive model in Haiti (Donegan et al. 2009): a 15.8 percentage point (ppt) decrease in the prevalence in stunting (i.e., HAZ below -2 SD) or a 0.339

[15] Sample size calculations were not conducted for household food and nonfood consumption and expenditure, child morbidity, health seeking behaviors, and child anemia. Evidence shows that studies powered to detect meaningful impacts on child growth are sufficiently powered to detect differences in anemia as well.

increase in HAZ. The prevalence of stunting in Burundi is significantly higher than in the study area in Haiti. As a consequence, the potential to benefit is larger. We thus expect a minimal impact of a 15.8 ppt reduction in stunting or a 0.339 increase in HAZ.

- Research question 2: For this comparison, we used the same estimated absolute effect as for research question 1 (i.e., 0.339 Z-scores for HAZ and 15.8 ppt for the prevalence of stunting).
- Research question 4: For this comparison, we assume that shortening the child's program participation by 25 percent (i.e., from 24 months to 18 months) will reduce its impact by an equivalent percentage. We therefore estimate the absolute effect of the *Tubaramure 18* program, compared to the control group, to be 0.254 Z-scores for HAZ and 12.64 ppt for the prevalence of stunting.

- **Impact of food compared to no food during pregnancy** (research question 3): Given the limited evidence of the impact of food supplements during pregnancy on child nutritional status at 24 months of age, the expected difference should theoretically be set to 0. This, however, would require an infinitely large sample size. The key challenge is thus to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the feasibility and cost of the study) manageable. Given the level of resources available for the study, we estimate that the sample size should not be greater than 1,000 children 24 to 42 months of age per study group (or a total of 4,000 children 24 to 42 months of age total). With this sample size, the minimum detectable difference is estimated to be 0.222 Z-scores for HAZ and 7.8 ppt for the prevalence of stunting.

- **Impact of providing food between 18 and 24 months** (research question 5)**: B**ased on the assumption underlying the expected effect in research question 4 (i.e., a 25 percent reduction of the effect if giving the intervention up to 18 rather than 24 months), the expected difference in impact between *Tubaramure 18* and *Tubaramure 24* is 0.085 in HAZ and 3.16 ppt in stunting. Detecting this difference, however, would require a sample size of over 400,000 children. Given 1,000 children per arm (see previous paragraph), the detectable difference is estimated to be 0.222 Z-scores and 7.8 ppt for the prevalence of stunting.

- Intracluster correlation: 0.006 for stunting and 0.009 for HAZ.
- Number of clusters per treatment: 15.
- Data loss: 15 percent.

Sample sizes were computed using these parameters, and results are summarized in Table 7.5.

Minimal detectable differences for other outcomes—In order to calculate the necessary sample size to detect meaningful effects for child anemia, infant and young child feeding practices, child development, and household food security, we documented impacts from the Haiti study and from the literature. With the available evidence, we calculated sample sizes to answer research questions 1, 2, and 4 (i.e., comparing the three treatment groups with the control group) for anemia. For infant and young child feeding practices, child development, and household food security, we could only calculate the necessary sample size for research question 1 (i.e., *Tubaramure 24* compared to control). Unlike for child growth, which will be collected in children 24 to 42 months of age, child anemia, feeding practices, and development will be

measured in children 0 to 24 months of age. Household food security will be measured in all households of children 0 to 42 months of age.

No information was available on the ICC for any of these outcomes and, therefore, it was set at 0.006 for child anemia, and infant and young child feeding practices (the same as for the prevalence of stunting). Given the potentially important effect of local (i.e., cluster-specific) food production conditions and market prices on food security, the ICC for this outcome was set to twice that (0.012). One-sided hypotheses were used for all calculations as the research questions have clear *a priori* hypotheses, i.e., that the impact will be positive (i.e., outcome in *Tubaramure 24* will be higher or better than in the control group). More detailed explanations for each of the outcomes are provided below.

Minimal detectable difference for anemia (0-24 months)—The impact of fortified complementary foods on anemia was evaluated in three intervention studies conducted in Mexico, Ecuador, and Peru, and reviewed by Dewey and Adu-Afarwuah (2008). The (intended) daily iron dose was 10, 6.5, and 9 mg/day, respectively. Assuming the target child consumes the full CSB ration (100g/day), the daily iron dose in *Tubaramure* is 17.5 mg. Anemia was reduced by 11 ppt in Mexico, 16 ppt in Ecuador, and 13ppt in Peru (increases in Hb were 3g/l and 5g/l in Ecuador and Peru, respectively; no information on changes in Hb is available for Peru). We set the expected impact of *Tubaramure 24* and *Tubaramure NFP* at a conservative 11 ppt. The expected impact was lowered by 25 percent for *Tubaramure 18* to 8.25 ppt. The baseline prevalence of anemia in children younger than 5 years of age in Burundi is estimated to be 58.5 percent (http://www.who.int/vmnis/anaemia/data/database/countries/bdi_ida.pdf).

Minimal detectable differences for feeding, child development (0-24 months), and food security (0 to 42 months)—The study in Haiti found positive impacts on food security (Menon et al. 2007b) and several child feeding practices, including breastfeeding (Donegan 2009). Studies in Indonesia and South Africa found positive effects of energy supplementation on child development (Pollitt et al. 2002; Faber et al. 2005). More details are provided in Section 6.4.4.

Table 7.5 summarizes the minimal detectable differences and the corresponding required sample sizes for child anemia, breastfeeding, child development, and household food security by treatment group. The table further shows the outcomes that will be measured, even though they are not directly linked to a research question. For instance, anthropometric data will be collected in all children 0 to 24 months of age, even though the impact estimate (and thus the sample calculation for this outcome) is based on children 24 to 42 months old. Collecting anthropometry in the younger children is highly relevant, however, to study growth patterns. Outcomes that did not determine sample size in a specific age group but that will still be collected are marked with a "+" in the table. Details of the all measurements in children are also shown in Table 7.6.

Table 7.5: Sample size to measure impact on child and household outcomes

Study outcome	Detectable difference (SD)		Treatment group							
			Control		*Tubaramure 24*		*Tubaramure NFP*		*Tubaramure 18*	
	0-24 mo	24-42 mo	0-24 mo	24-42 mo	0-24 mo	24-42 mo	0-24 mo	24-42 mo	0-24 mo	24-42 mo
Child growth										
Research question 1										
Stunting		15.8 ppt	+	182	+	182				
HAZ		0.339 (1.28)	+	285	+	285				
Research question 2										
Stunting		15.8 ppt	+	182			+	182		
HAZ		0.339 (1.28)	+	285			+	285		
Research question 3										
Stunting		8.3 ppt	+		+	1,000	+	1,000		
HAZ		0.240 (1.28)	+		+	1,000	+	1,000		
Research question 4										
Stunting		12.64 ppt	+	284					+	284
HAZ		0.254 (1.28)	+	584					+	584
Research question 5										
Stunting		7.8 ppt	+		+	1,000			+	1,000
HAZ		0.222 (1.28)	+		+	1,000			+	1,000
Child anemia (Bhutta et al. 2008)										
T24 vs. Control	11 ppt		431	+	431	+				
TNFP vs. Control	11 ppt		431	+			431	+		
T18 vs. Control	8.25 ppt		869	+					869	+
Child feeding (Donegan et al. 2009)										
% BF to 12 mos	8.9 ppt		189[a]		189[a]		+		+	
% BF to 24 mos	25.2 ppt		69		69		+		+	
Child development										
Mental (Pollitt et al. 2002)	1.46 (1.195)	+	12	+	12	+	+	+	+	+
Motor (Faber et al. 2005)	1.1 (3.85)	+	229	+	229	+	+	+	+	+
Food security (Menon et al. 2007b)										
Household experiences	0.5 (2.35)		539		539		+		+	
Months of inadequate hh food provisioning	0.8 (2.8)		247		247		+		+	
Severity of food inadequacy	1.3 (5.35)		381		381		+		+	
Minimal sample size required (by age)	-	-	**869**	**584**	**431**	**1,000**	**431**	**1,000**	**869**	**1,000**
Minimal sample size required (per arm)			**1,453**		**1,431**		**1,431**		**1,869**	

Note: "+" indicates that the outcome will be measured in this age group but is not related to a primary research question.
[a] This number is higher if the prevalence of breastfeeding is lower. When the prevalence in both groups is 15 ppt lower (i.e., 81.8 percent and 73 percent in treatment and control, respectively), the required sample size is 561. It is unlikely, however, that the prevalence would be this low.

In summary—We will enroll 1,453 children in the control arm and 1,431 children in the *Tubaramure 24* and *NFP* arms and 1,869 children in the *Tubaramure 18* arm. This provides sufficient statistical power to detect the impact on child stunting found in the Haiti study between the treatment (*Tubaramure 24* and *Tubaramure NFP*) and the control group (research questions 1 and 2); to find differences of 0.254 Z-scores and to 12.64 ppt in stunting (research question 4); to be able to detect differences of 0.222 Z-scores and 7.8 ppt for the prevalence of stunting (research questions 3 and 5); to find an impact on anemia of 11 ppt; to detect the same impact on household food security and breastfeeding as was found in Haiti; and to find the impact on child

development found in previous studies. As a final note, additional statistical power will be gained from pairing clusters before randomization.

7.4.5. Selection and Randomization of Study Clusters

Randomization was done at the level of the *colline*.[16] There are a total of 276 *collines*[17] in the two provinces (90 in Cankuzo, 186 in Ruyigi).

The available data provide information on the population size for each *colline*, the health center(s) serving its population and the province where the *colline* is located. These data were compiled by CRS using health sector information from both provinces. The majority of *collines* (216 or 78%) are served by one health center; the remaining *collines* are split between two or three health centers.

The following guiding principles were used in the sampling and randomization protocol:

- The study arms should not be associated with population size or with province.
- *Colline*s served by more than one health center should be excluded. Since part of the intervention is received through the health system, the study *collines* need to be homogenous with respect to the health center attended by the population.
- An appropriate balance between representativeness and homogeneity should be found. This is a proof of concept study, so it is important to maximize the homogeneity of the sample across study arms. The objective of the study is not to estimate the impact in a perfectly representative sample of the beneficiary population. The "homogeneity principle", however, should not be pushed to the extreme: we do not want to estimate the impact for a sample of clusters with characteristics so rare that it affects the study's external validity.
- The study sample should include proportional representation from the two provinces. Of the total population in the program areas, 35% lives in Cankuzo, 65% in Ruyigi.

Based on these principles, the following protocol was used:

- Step 1: Excluded *collines* served by more than one health center.
- Step 2: Truncated the sample at 1% of population size, i.e. exclude all *collines* that are below percentile 1 and above percentile 99 of the population distribution. This helps with homogeneity (i.e. comparability of population size across the study groups) without compromising representativeness. Step 1 and 2 resulted in a total of 66 *colline*s in Cankuzo and 144 in Ruyigi.

[16] A study cluster is defined as one hill (or *colline* in French). The *colline* is an official administrative unit in Burundi.

[17] CRS originally proposed to cover all *collines* in both provinces. Because of the IFPRI study, they will leave the 15 control *collines* untouched.

- Step 3: Ranked the *collines* by population size in each province, and divided them into 5 strata in Cankuzo (13 or 14 *colline*s per stratum) and 10 strata in Ruyigi (14 or 15 *colline*s per stratum) along the gradient of population size. The 5/10 split is based on the relative population size of both provinces.

- Step 4: Within each stratum, 4 *collines* were randomly selected using random numbers with a fixed random number seed in Stata. The 4 *collines* in each stratum were then assigned to the 4 arms in a public event organized in the administrative center of Ruiygi on January 25, 2010. A total of 17 representatives from both provinces were present at the event. The participants were each assigned a number and 4 of the numbers were selected at random from a bag. The 4 participants whose numbers were selected were assigned to represent the *Tubaramure-24 (T24); Tubaramure-18 (T18); Tubaramure NFP (TNFP) and Control* arms of the study. For each stratum, the 4 *collines* selected were numbered and these numbers placed in a bag and the members assigned to represent each arm selected one *colline* from the bag. This process was repeated until all 60 *collines* were assigned to a study arm.

The application of this protocol resulted in the selection of a total of 60 *collines* (20 from Cankuzo and 40 from Ruyigi). The *collines* were randomly assigned to one of the four study arms (15 *collines* per arm).

7.4.6. Data Collection

Data will be collected at the community, household, and child level. Information on community-level factors that may influence the impact of the program will be collected on a yearly basis throughout the *Tubaramure* program. Baseline and final household surveys will be conducted with households of the children 0 to 42 months of age. The household survey will include household demographics and socioeconomic indicators, household food security, household food and nonfood consumption and expenditure information, and information related to child stimulation, and maternal characteristics, including anthropometry and infant and young child feeding practices and health-care seeking behaviors. The child-level data will include anthropometry, anemia, morbidity symptoms, and cognitive and motor development. More details on what data will be collected in each of the surveys are provided below.

Community Questionnaire[18] (yearly survey)

- Availability of services (clinic, school, electricity, water, sewage, garbage, TBAs, healers, stores, markets, etc.)
- Food availability and prices

Household Questionnaire (baseline and final survey)

- Household identification

  Municipality, community, and address

- Household composition, occupation, and education

[18] Household in rural Burundi live scattered on hills (*collines*). The proper definition of "community" will be assessed locally.

Name, sex, age, birth date (for < 5 years, with source of information for children < 5), relation to head, identification of polygynous unions and their children, education (current and past), literacy, employment (including time use: time to and from work and time at work)

- Housing quality, hygiene, and sanitation

  Floor, roof, walls, water, electricity, sanitation, rooms, kitchen

  Cleanliness spot-check

- Assets

  Major household assets (including all assets related to hygiene and sanitation and food preservation [such as a refrigerator])

  Availability of toys, books, etc.,—important for child development outcomes, will be used as a covariate in the analyses (module drawn for the MICS, UNICEF)

- Food security

  Household Hunger Scale (FANTA)

- Household food expenditure

  Amount and value of food consumed, purchased, consumed from own production, given away, and/or received in the past 7 days.

- Household nonfood expenditure

  The consumption of nonfood items, including expenditures on household consumables (soap, candles, etc.), electricity, fuel, health, education, transportation, housing, clothing, tobacco, alcohol, and larger items such as a television, a bike, a car. The recall period will depend on the specific item (the past month, 6 months, or year).

- Social and development programs

  Household participation in social and development programs provided by the government, PVOs, or international agencies, and the benefits they receive from these programs.

- *Tubaramure* program

  Household participation in *Tubaramure*, experiences related to program participation; the number of times the mother received food and BCC, and the number of health check-ups the mother and child attended.

- Mother

  Anthropometry

  Physiological status (to adjust for weight)

Autonomy, knowledge on childcare (i.e., knowledge of feeding practices, prevention of illness, danger signs, what do when the child is ill, danger signs, etc.), depression, domestic violence.[19]

Prenatal and postnatal visits attended

Hemoglobin

Child-level Data

The child-level measurements are summarized in Table 7.6.

Table 7.6: Measurement of child outcomes

Outcome	Age group (mo)	Measure	Indicators
Child nutritional and health status			
Anthropometry	0-23 24-42	Length/height and weight	HAZ, WAZ, WHZ, prevalence of stunting, underweight, and wasting
Anemia	0-23 24-42[a]	Hemoglobin concentration (Hb)	Mean Hb and prevalence of anemia
Morbidity	0-23 24-42	Parent recall	Percent of children with fever, diarrhea, and respiratory infections
IYCF and health-care seeking practices			
IYCF practices	0-23	Parent recall	IYCF indicators recommended by WHO 2008
Preventive health-care utilization	0-23 24-42	Beneficiary cards and parent recall	Percent of preventive health visits attended, immunizations received, micronutrient supplements received
Curative health-care utilization	0-23 24-42	Parent recall	Percent seeking adequate and timely care for childhood illness
Child development			
Stimulation	0-23 24-42	Parent report scale	MICS instrument
Motor development	0-23 24-42	Parent report scale	Summary score from parental report scale
Language development	0-23 24-42	Parent report scale	Summary score from parent report scale

[a] Hemoglobin concentration will be measured in these children, even though they have not been exposed recently to the program. Measuring Hb levels in these children, however, will allow us to evaluate to what extent program participation early on in life had lasting effects.

7.4.7. Data Analysis

The primary outcomes that will be evaluated in this study are the differences in mean HAZ, WAZ, and WHZ, and differences in the prevalence of stunting, underweight, and wasting between treatment groups. The differences between the program communities in the mean HAZ, WAZ, and WHZ will be tested using pair-wise comparisons at the cluster level (15 clusters per group) (and paired t-tests for statistical significance). Additional analyses will be conducted to examine the differences in children's anthropometry between the treatment groups using random effects regression modeling with child-level data and adjusting for clustering and further

[19] The measurement of depression and domestic violence are sensitive.

adjusting for child age and gender and maternal height and schooling. Differences in the prevalence of undernutrition will be tested using random effects logit approaches and will adjust for clustering, child age, gender, and other relevant covariates.

In addition to these primary analyses to examine the impact of the program on children's nutritional status, we will also examine participation patterns and factors associated with participation to better interpret the impact evaluation results. It is possible that program participation will vary according to the assigned treatment group and, therefore, it is important to examine these variations in combination with the impact evaluation to better understand the results from these analyses.

7.5. Formative Research for the Development of BCC Messages and Strategy

The formative research for the development of the BCC strategy in Burundi will be led by FH and will include two primary activities: a Local Determinants of Malnutrition Study and a Barrier Analyses. Currently, the BCC strategy is designed to focus on a number of Essential Nutrition Actions (ENA) as well as Essential Hygiene Actions (EHA). IFPRI will work with FH to support their planned formative research activities by providing feedback on tools, design, and interpretation of results as requested and to ensure the adequate integration of messages related to infant and young child feeding.

A preliminary list of lesson plans is presented in Appendix G. A more detailed design and implementation plan for the BCC messages and strategy will be developed in the fall of 2009 and the spring of 2010.

7.6. Operations Research

Operations research will be used to assess the quality of implementation and of service delivery and to identify operational and utilization constraints, aiming to identify improvements in the design and implementation approaches. In addition, perceptions of the program-by-program implementers and beneficiaries will also be assessed through this research in order to identify any factors that may be influencing program participation or optimal utilization or uptake of the program services. The operations research will be based on the program theory framework that will be developed in coordination with CRS, IMC, FH, and Caritas. This framework will clearly outline the primary program components, factors that may affect the optimal delivery and utilization of the different program components and the underlying assumptions that are necessary for the program to have the desired impacts according to the program impact pathways. The three primary components of the *Tubaramure* program are the distribution of food rations, BCC delivered to beneficiaries by lead mothers, and attendance at preventive health services.

A combination of quantitative and qualitative assessments will be used to collect information about all of the essential steps in the program theory framework. By examining each of these steps, we will be able to identify program bottlenecks in operations, service delivery, or utilization. This information will then be used to design corrective measures for poorly functioning or underused program components to ensure that the *Tubaramure* program is able to

attain optimal impacts. In addition, by documenting and understanding these aspects, we will have a better understanding of how the program works to improve children's growth.

Some examples of the different steps likely to be included in the program theory framework and data collection methods for each of these steps is illustrated in Table 7.7. This preliminary table will need to be refined once the program theory framework for *Tubaramure* is developed in collaboration with CRS, IMC, FH, and Caritas and will need to be further refined to account for differences in the treatment arms of the study.

Given that the operations research will be use proactively, we will also carefully document the costs of this component. This information will be of interest to other programs.

7.7. Ethics Review

The research protocol and all data collection instruments will be submitted to IFPRI's Institutional Review Board prior to conducting the fieldwork. Approval will also be sought from Burundi's Ministry of Health.

Informed consent will be sought from all respondents. It will be made clear to all respondents that participation is voluntary and that not participating in or withdrawing from the study will not affect the benefits they receive from *Tubaramure* or any other program or project.

Table 7.7: Steps in program theory and examples of data collection methods

Step in program theory	Examples of potential data collection methods
Inputs	
Food supplement for pregnant and lactating women and children 6-24 months of age	Ration availability check, observations of food distribution points
Trained staff for food distribution, preventive health services, and BCC	Review of training protocols, observations of training, assessment of staff skills and knowledge
Equipment and space	Facility assessments and equipment checks, review of BCC materials
Process	
Lead mothers effectively communicate with caregivers about the importance of utilizing the program services	Focus group discussions with health workers and caregivers, exit interviews with caregivers, observations of mothers' clubs/other education sessions
Lead mothers provide a good learning environment for BCC sessions	Observations of mothers' clubs/other educational sessions, interviews with caregivers and health workers, group discussions on constraints faced by health workers
Caregivers collect supplement from distribution point	Distribution check, reweighing of rations received, quality check of commodities
Caregivers attend BCC sessions	Attendance monitoring, focus group discussions and interviews with caregivers and staff to identify barriers and facilitators to attending BCC sessions
Caregivers utilize preventive health services	Attendance monitoring, focus group discussions and interviews with caregivers and staff to identify barriers and facilitators to utilizing services
Outputs	
High quality BCC program operating and being utilized as planned	Observations, focus group discussions with caregivers and health workers, surveys of program use and exposure
Caregivers understand and utilize the BCC messages	Exit interviews, focus group discussions, surveys of program use, exposure, and adoption of program recommendations
Outcomes	
Children regularly consume rations and other recommended foods, and are fed appropriately for their age.	Interviews with caregivers on use of rations, infant and young child feeding, etc.
Children receive appropriate preventive health services	Observations of health facilities, tracking using child card that records services received, interviews with caregivers through surveys

8. Cost and Cost-effectiveness Study

8.1. Objectives

This study component is designed to estimate the costs of the PM2A programs in Guatemala and Burundi. A direct result of the cost study will be an estimate of the total cost of both programs and their different treatment arms. An equally important objective of the cost study is to generate evidence on what it will cost to maintain, scale-up, or replicate the PM2A programs. Additionally, the cost information combined with the effectiveness estimates from the impact evaluation component will be used to estimate the cost-effectiveness of the different treatments. Finally, this study will add to the very small body of literature on the cost of nutrition programs (Waters et al. 2006).

8.2. Methodological Approach

The cost study will use a bottom-up methodology, more specifically a combination of activity-based costing (ABC) and the "ingredients approach." As suggested by its name, ABC defines the main activities of the individuals who work in the PM2A program, identifies the cost of these activities, and then traces costs from these activities to the program's products and services. In contrast with traditional costing procedures in which indirect costs are allocated to products based on relative production figures, indirect costs in ABC are attributed based on time allocation (Waters et al. 2006; Waters, Abdallah, and Santillan 2001; Fiedler and Chuko 2008; Johns, Baltussen, and Hutubessy 2003).

The ingredients approach identifies the different types, quantities, and costs of the inputs required to produce the program activities. The use of the ingredients approach is important for two reasons. First, it gives a much clearer idea of how the costs were estimated. Second, it makes the analyses useful to a wider group of users. Policymakers and program planners from other countries can easily assess to what extent the estimations need to be modified to be applicable to a new setting. They can change the types of inputs, the quantity of these inputs, and their cost. This cannot be done if only total expenditures are used for the analyses (Tan-Torres Edejer et al. 2003).

8.3. Research Activities

The steps for the cost study are based on studies by Waters, Abdallah, and Santillan (2001), Fiedler and Chuko (2008), and Fiedler (2009).

Step 1: Planning—The program's existing accounting system will be reviewed and the availability of cost data will be assessed. Based on this information, the need for additional data will be determined.

Step 2: Identify activities—In this step, the major activities of each organizational level of the program will be identified. Activities are generally defined to include a verb and a noun and will include things such as training of health promoters and repacking food. These activities are the cost centers of the study. The program theory framework will be used to guide the

identification of the activities. We will also use the available program information (the MYAP Proposals submitted to FFP) and conduct interviews with key program staff. This step will yield a list of activities and an updated program theory framework.

Step 3: Define unit cost algorithms—For each of the identified activities, a unit cost algorithm will be defined. These algorithms identify the types, quantities, and costs of inputs necessary to "produce" the activity. If activities are implemented at more than one organizational level, distinct algorithms will need to be defined.

It is important to note that special attention will be paid to quantifying all time inputs, including that of program volunteers (e.g., the Leader Mothers in *Tubaramure*). This is important for two reasons. First, it will provide insights into the value of volunteers' time and contribution, and can help decisions about the need to provide them with some financial or other type of incentives. Second, it makes it easier to apply the results of the cost study to new contexts.

Even though program staff is likely to think in terms of these input-activity relationships, they are seldom called "algorithms." In case the PM2A programs do not have detailed protocols, we will interview key staff to identify and collect the necessary data to develop the algorithms.

A participatory approach is used for steps 2 and 3. The advantage of this approach is that it allows the program staff to understand the methodology and buy into the cost study, and it motivates them to make use of the results. Additionally, the formalized algorithms can be used to better structure the program, for instance, by assigning the responsibility for specific activities to particular persons.

Step 4: (Cost) data collection—Data will be collected using the program's accounting system, through interviews and surveys. The need to adapt routine data collection will be identified early on and adjustments will be made accordingly.

Step 5: Estimate activity and total costs—To estimate the total cost of a specific activity, the unit cost algorithm for the activity is multiplied by the number of units. The total cost of the program is the sum of cost of all activities.

8.4. Data Sources

Program data—Program data needed for the analysis include quantities of inputs (number of staff, quantities of food distributed, number of BCC sessions organized, etc.) and the costs of these inputs. This data will be obtained from the program's records and accounting system. Where needed, it will be supplemented with information from interviews.

Interviews—A series of interviews will be needed to collect the necessary data.

- **Definition of activities—**Interviews will be conducted to identify the program's activities.
- **Cost algorithm—**The objective of these interviews is to collect the data necessary to map how inputs are linked to program activities. This will require interviews with staff at all program levels.

- **Time allocation—**Interviews with program staff and volunteers at all levels to determine how they allocate their time among the identified key activities.

Surveys—Whether surveys will be necessary for the cost study depends on the homogeneity of the program, i.e., the degree to which there are variations in the program's coverage, activities, and inputs. If considerable heterogeneity exists, surveys will be necessary to document the program's diversity in inputs and costs. The sample will be purposive and designed to capture the different program typologies.

8.5. Analyses

Activity and total costs—The cost for each activity will be calculated by multiplying the unit cost algorithm for the activity by the number of units "produced." Indirect costs will be attributed based on time allocation. The total cost of the program will be calculated as the sum of the cost of all activities.

Cost-effectiveness—The cost of the intervention will be expressed in terms of the effectiveness of the program. This will be done by calculating the cost per case of stunting averted and the cost per cm of linear growth (or HAZ) gained.

9. Overall Time Frame and Project Deliverables

The overall time line is provided in Table 9.1.

Table 9.1: Summary time line*

Year	Month	Guatemala	Burundi
2010	**Jan**		
	Feb		
	Mar		
	Apr		
	May		
	Jun		
	Jul		
	Aug		
	Sep		
	Oct		Start baseline survey (0-42 mo)
	Nov		
	Dec		End baseline survey (0-42 mo)
2011	**Jan**		
	Feb		
	Mar		
	Apr		
	May		
	Jun		
	Jul		
	Aug	Start enrollment survey	
	Sep		
	Oct		Start operations research round 1
	Nov	Start 1 month survey	
	Dec		
2012	**Jan**	Start 4 month survey	End operations research round 1
	Feb		
	Mar	Start 6 month survey	
	Apr	Start operations research round 1	
	May		
	Jun	Start 9 month survey	
	Jul	End operations research round 1	
	Aug		
	Sep	Start 12 month survey	
	Oct		Start first follow-up survey (0-24 mo)
	Nov	End enrollment survey	
	Dec		End first follow-up survey (0-24 mo)
2013	**Jan**		
	Feb		
	Mar	Start 18 month survey	
	Apr		
	May		
	Jun		
	Jul	End 1 month survey	
	Aug		
	Sep	Start 24 month survey	Start operations research round 2

Year	Month	Guatemala	Burundi
	Oct	End 4 month survey	
	Nov		End operations research round 2
	Dec	End 6 month survey	
2014	**Jan**		
	Feb		
	Mar	End 9 month survey	
	Apr	Start operations research round 2	
	May		
	Jun	End operations research round 2 End 12 month survey	
	Jul		
	Aug		
	Sep		
	Oct		Start second follow-up survey (24-42 mo)
	Nov		
	Dec	End 18 month survey	End second follow-up survey (24-42 mo)
2015	**Jan**		
	Feb		
	Mar		
	Apr		
	May		
	Jun	End 24 month survey	
	Jul		
	Aug		
	Sep		
	Oct		
	Nov		
	Dec		

* Data for the cost study are collected on an ongoing basis.

The deliverables for this project are shown in Table 9.2.

Table 9.2: Deliverables

Deliverable	Guatemala	Burundi
1. Revised proposal and work plan	November 20, 2009	November 20, 2009
2. Cost study protocol	February 28, 2010	February 28, 2010
3. Report formative research	January 10, 2011	-
4. Baseline survey protocol and fieldwork manuals	February 21, 2010	January 31, 2010
5. Baseline survey report	-	Novemer 30, 2011
6.Report on first round of operations research	March 30, 2013	October 5, 2012
7.Guatemala longitudinal enrollment survey report	February 28, 2013	--
8.Final operations research report	March 30, 2015	December 15, 2014
9.Final report	December 15, 2015	First follow-up report: December 15, 2013 Second follow-up report: December 15, 2015
10. Cost study report	June 30, 2016	June 30, 2016

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Appendix A: Estimated Time to Enroll the Cohort

Two types of data are necessary to calculate the time it will take to enroll the cohort: the birthrate and the size of the population in each cluster, i.e., the population served by each convergence center.

Birthrate—The estimated birthrate in Guatemala is 27.98 births/600 inhabitants (CIA 2009a).[20]

Population size in each cluster—We used the available data from the Ministry of Health. Data on the 466 convergence centers serving 1,163 communities in seven municipios that will be served by PROCOMIDA (Cahabon, Chahal, Coban, Panzos, San Pedro Carcha, Santa Catarina la Tinta, and Senahu) were analyzed. Each convergence center serves on average 867 people (median 967); the mean number of communities per each convergence center is 2.5 (median 2).

The sample of convergence centers for the longitudinal study will be drawn with probability proportional to size (PPS), i.e., the probability that a convergence center is selected is proportional to the size of the population it serves. Based on a simulation drawing 100 random PPS samples, we found the mean population size per sampled convergence center (or cluster) to be 1,266 people.

Time to enroll the cohort—With 1,266 people in each cluster, every study arm will be 25,320 people in size. The estimated birthrate of 27.98 births/600 inhabitants therefore gives us a total of 708 births per year in each treatment arm. Enrolling the required 600 children per arm will thus take 10 months and 6 days.

[20] The birthrate in Alta Verapaz is most likely higher than this. The estimated time to enroll to cohort is thus a conservative estimate.

Appendix B: Nutrient composition of LNS and MNP supplements

		LNS		MNP	
	Unit	Child	Mother	Child	Mother
Daily dose	g	20 g (two 10g sachets)	20 (1 sachet)	4 g (two 2g sachets)	4 g (two 2g sachets)
Energy	kcal	118	118	-	-
Proteins	g	2.6	2.6	-	-
Fat	g	9.6	10	-	-
Linoleic acid	g	4.46	4.6	-	-
α-Linolenic acid	g	0.58	0.6	-	-
Calcium	mg	280	280	280	280
Copper	mg	0.34	4	0.34	4
Folic Acid	µg	150	400	150	400
Iodine	µg	90	250	90	250
Iron	mg	9	20	9	20
Magnesium	mg	40	65	40	65
Manganese	mg	1.2	2.6	1.2	2.6
Niacin	mg	6	36	6	36
Pantothenic acid (B5)	mg	2	7	2	7
Phosphorus	mg	190	190	190	190
Potassium	mg	200	200	200	200
Riboflavin (B2)	mg	0.5	2.8	0.5	2.8
Selenium	µg	20	130	20	130
Thiamine (B1)	mg	0.5	2.8	0.5	2.8
Vitamin A	µg	400	800	400	800
Vitamin B12	µg	0.9	5.2	0.9	5.2
Vitamin B6	mg	0.5	3.8	0.5	3.8
Vitamin C	mg	30	100	30	100
Vitamin D	mg	5	10	5	10
Vitamin E	mg	6	20	6	20
Vitamin K	mg	30	45	30	45
Zinc	mg	8	30	8	30

Appendix C: Assumptions sample size calculation Guatemala

This appendix describes the assumptions underlying the sample size calculations for the longitudinal study.

General Approach

A three-step approach was used to determine the study sample size:

- Step 1: Determine the required sample size to answer research questions 1, 2, 3, 4, and 6. Note that these research questions correspond to an *a priori* hypothesis that the intervention will have a *positive* impact on child growth.
- Step 2: Determine the required sample size to answer research questions 5, 7, and 8. It is important to note that there is no *a priori* hypothesis regarding the direction of effect (i.e., positive or negative differences between the groups) for these comparisons. The key challenge here is to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the cost of the study) under control.
- Step 3: Determine the sample size for the other outcomes (food security, feeding practices, etc.).

Type 1 error

- **Evaluation of impact against the control group (research questions 1, 3, 4, and 6)**
  The intervention study has clear *a priori* hypotheses, namely that the interventions will improve child nutritional status. This means that one-sided tests are appropriate (Snedecor and Cochran 1989). The *a priori* hypothesis for specific study objective one is based on the evidence from the literature (and the experience in Haiti) that these types of programs improve child growth.
- **Evaluation of the effect of the family ration (research question 2)**
  As explained below, the *a priori* hypothesis is that the family ration will have a positive effect on growth. This requires a one-sided test.
- **Evaluation of the differential effects of LNS, Sprinkles, and CSB (research questions 5, 7, and 8)**
  The null hypotheses to be tested for these research questions is that there is no difference between the treatments. This implies the use of two-sided tests.

Power

We set power to 90 percent. Setting statistical power to a conventional 80 percent means that there is a 20-percent probability of not detecting a beneficial effect. This is the first study to evaluate the PM2A approach following the Haiti study and the first study that will compare the PM2A approach to a control group. Therefore, a smaller probability of not detecting a benefit (10 percent versus 20 percent) is highly desirable in this "proof of concept" stage of PM2A research.

Minimal detectable difference

Effect of *PROCOMIDA* (research question 1)—The preventive model in Haiti was estimated to lower the prevalence of stunting by 15.8 ppt. Mean HAZ increased by a estimated 0.339 (Donegan et al. 2009). Since we will use a double difference estimating approach, in which every child is compared to itself, the sample size calculation is based on the mean HAZ impact in Haiti. The mean HAZ in Guatemala is significantly lower than in the study area in Haiti. As a consequence, the potential to benefit is larger. We thus expect a minimal impact on HAZ of 0.339.

Effect of PROCOMIDA with a reduced family ration (research question 2)—The reduced family ration provides approximately half of the calories of the full family ration. The estimated effect size is therefore set to 0.325 HAZ, the mean of 0.339 (the research question 4) and 0.310 (the effect found in a study in Peru without a family ration—see research question 4).

Differential effect of the full, reduced and no family ration (research questions 3 and 5)—We are not aware of previous studies comparing the marginal effect of a family ration on child growth in the context of a program providing BCC and an individual ration. Given the limited evidence in the literature on what to expect from this comparison (and the small difference in effect size found in Haiti and Peru), the expected difference should theoretically be set to 0, but this would require an infinitely large sample size. The key challenge is thus to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the feasibility and cost of the study) manageable. Given the level of resources available for the study, we estimate that the sample size should not be greater than 600 children per arm. With 600 children per arm, the detectable difference is estimated to be 0.263 Z-scores.

Effect of PROCOMIDA without a family ration (research question 4)—A nutrition education project in Peru in a population with much lower rates of stunting had an impact of 0.31 on HAZ (Waters et al. 2006). We thus set the expected HAZ impact to 0.31.

Effect of PROCOMIDA with LNS or Sprinkles instead of the individual ration (research question 6 and 8)—No study has estimated the impact of an intervention combining a family ration with BCC and LNS or Sprinkles. It is to be expected that sharing with family members of the LNS and Sprinkles will be less of a problem than with the CSB. Second, it is unlikely that both products are diluted as has been reported for products like CSB. We thus set the minimal expected impact on HAZ to 0.339, since we expect that it would be at least the same as from the Haiti study.

Differential effect of LNS, Sprinkles, or CSB (research questions 7, 9, and 10)—As discussed in the introduction, only one small trial has compared the growth effect of LNS to that of a fortified flour (Phuka et al. 2008, 2009). It is not clear from this study why the short positive effects of the low energy LNS supplement were not sustained in time. Given the limited evidence, the expected difference should theoretically be set to 0, but this would require an infinitely large sample size. The key challenge is thus to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the feasibility cost of the study) under control. Enrolling and following a cohort of more than 600 children per study arm (or a total of 3,600 children in total) would be organizationally difficult to implement and may result in lower study quality. Given 600 children per arm sample, the detectable difference was estimated to be 0.263 Z-scores.

Standard deviation (SD) of HAZ measurements

The SD of the HAZ of children aged around 24 months of age living in rural areas in the Alta Verapaz area (ENSMI 2002) is 1.1. As a conservative estimate, we set the value slightly higher to 1.15.

Correlation between height measurements at 1 and 24 months of age

Data to estimate the correlation between baseline and follow-up measurements in the same children are not available for Guatemala. We used data from a study in Bangladesh, where data were collected repeatedly from 1 month to 24 months of age. Correlation values are shown in Table C.1. We use a correlation value of 0.45.

Table C.1: Correlation between repeated HAZ measurements

Age at measurement (month)	Correlation with measurement at month 1
1	1.000
2	0.660
3	0.637
4	0.639
5	0.537
6	0.524
7	0.544
8	0.527
9	0.496
10	0.490
11	0.483
12	0.463
15	0.445
18	0.383
21	0.420
24	0.492

Intracluster correlation and design effect

We attempted to use the 2002 ENSMI data to estimate the intra-cluster correlation (ICC) of child HAZ. The "loneway" command in Stata was used for the ICC estimations. For each child, the dataset provides information on the *municipio* and the *sector censal* level. Each cluster in this study will be composed of a number of *sectores censales*, i.e., the level of clustering will be between the *municipio* and the *sector censal* level. Unfortunately, the dataset has only a limited number of children in the Alta Verapaz region that are around 24 months of age (the age at which the impact of the program will be measured). As a consequence, the confidence intervals around the estimated ICC are very wide, rendering them useless.

We set the ICC for this study to 0.01. To determine the validity of this ICC, we evaluated the ICC in terms of the design effect (Deff). The Deff is the ratio of the variance for the cluster sample divided by the expected variance of a simple random sample of the same size. The relation between the ICC and the Deff depends on the number of observations per cluster and is given in equation (B.1).

$$Deff = 1 + (m\text{-}1)\, ICC, \qquad \text{(B.1)}$$

where *m* is the number of observations within a cluster, *m*. Table B.2 shows the relation between *m* and *Deff* for *ICC* = 0.01.

Table C.2: Deff as a function of the number of children per cluster (ICC = 0.01)

Number of children per cluster (*m*)	**25**	**30**	**35**
Deff	1.24	1.29	1.34

Number of clusters per treatment

For practical reason, the number of clusters per treatment arm was set to 20.

Data loss

Our calculations allow for a total data loss of 15 percent. This includes data loss due to missing values and outliers.

Appendix D: Estimating the Impact of *PROCOMIDA*

Treatment in the *PROCOMIDA* groups starts in pregnancy. As a consequence, the child may have benefited from the intervention by the time of the first measurement at 1 month of age. If this has a positive impact on child anthropometry, the double difference estimation strategy will lead to an underestimation of the program's full impact (see Figures C.1, C.2, and C.3). A double difference strategy will, in fact, estimate the added impact of receiving the program between month 1 and 24 months, after having received the program from enrollment in pregnancy up to 1 month of age. The question is how the full impact of the program can be estimated.

Three possible scenarios can be thought of: the control and treatment groups might be balanced (i.e., not different) at baseline, the control group may be better off than the treatment group, or the control group may be worse off than the treatment group.

Scenario 1: Treatment and control groups balanced at baseline (**Figure D.1**)—If the groups are balanced at baseline, the program's full impact can be correctly estimated by estimating the simple difference in means at 24 months.

Scenario 2: Control group better off than treatment (**Figure D.2**)—The program's full impact can be correctly estimated by taking into account the difference between both groups before the program started. More specifically, the impact could be estimated by adding the difference between both groups before the intervention to the difference at 24 months. Note that the simple difference between treatment and control at 24 months would underestimate the impact.

Scenario 3: Control group worse off than treatment (**Figure D.3**)—In this case, the impact could be estimated by subtracting the difference between both groups before the intervention from the difference at 24 months. Note that the simple difference between treatment and control at 24 months would overestimate the impact.

In summary, to correctly estimate the impact of *PROCOMIDA*, it is important to know whether the groups are balanced before the intervention starts. If they are not balanced, we will need to know how different the groups are. To evaluate group balance, we will measure the height and weight of the unborn children's siblings that are around 24 months of age. These measurements will be taken when the mother (and her unborn child) is enrolled in the study.

We will review the literature and consult with experts on longitudinal data analysis to identify the correct adjustments that need to be made when the groups are not balanced.

Figure D.1: Estimating impact when treatment (Tx) and control are balanced

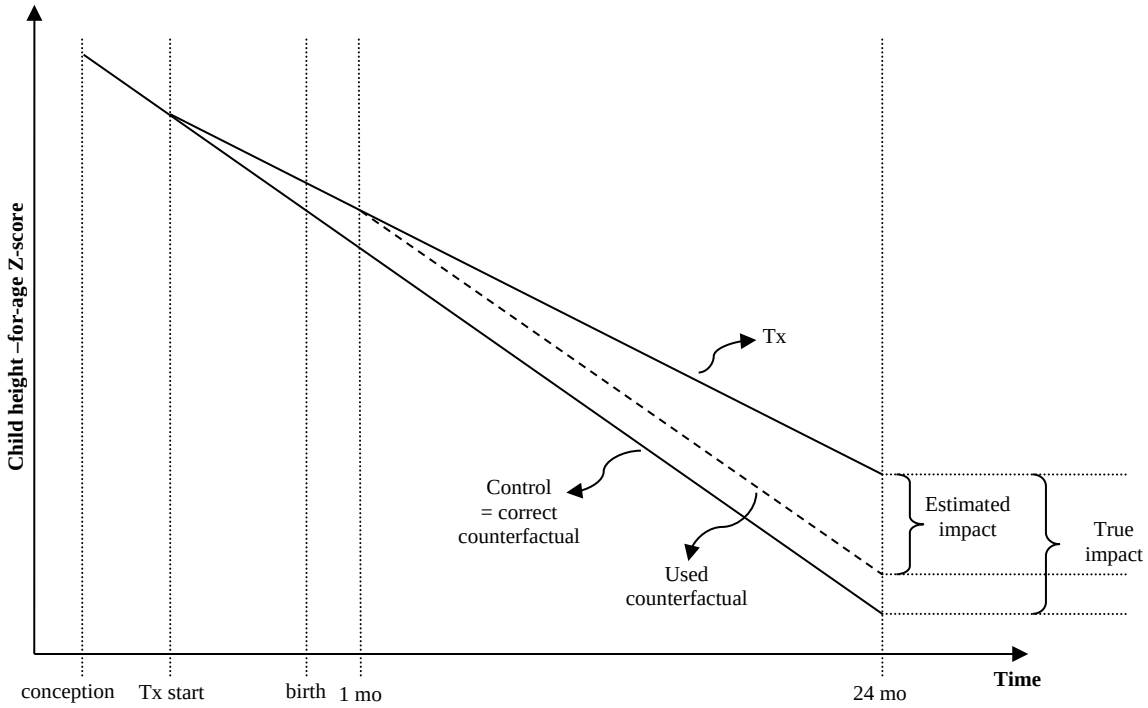


Figure D.2: Estimating impact when the control is better off than the Tx group

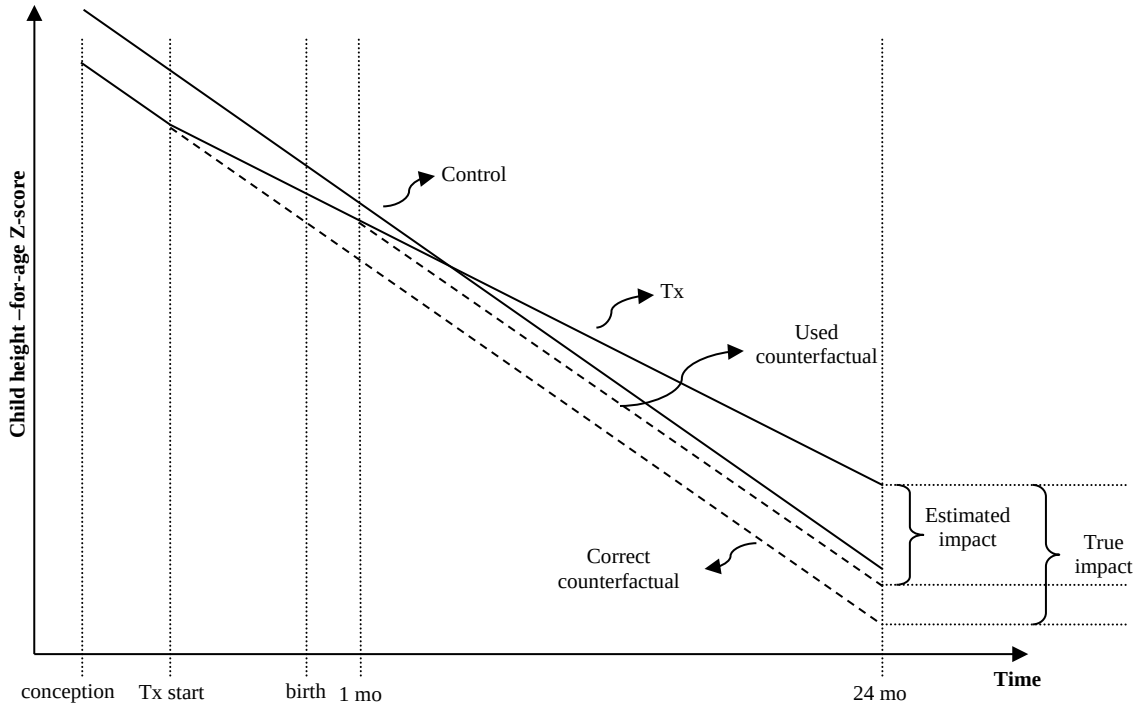
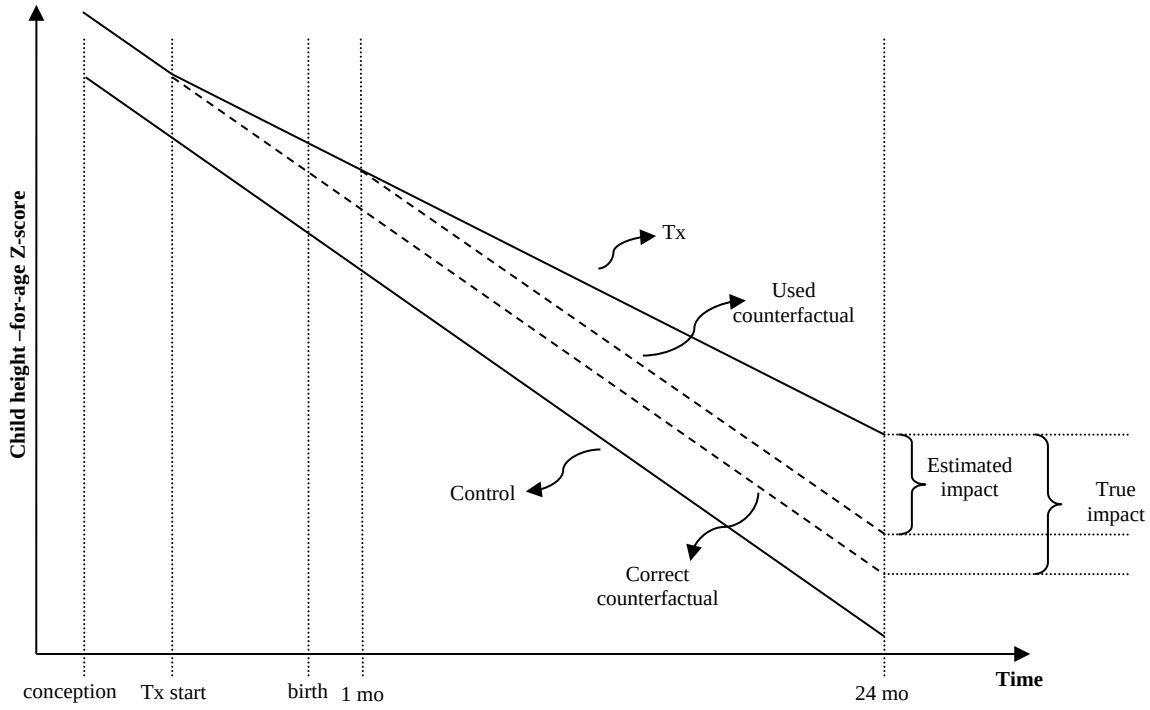


Figure D.3: Estimating impact when the control is worse off than the Tx group



Appendix E: Formative Research Topics, Guatemala

The primary topics that will be addressed through the formative research are shown in Table E.1. The topics that are currently included in both the Mercy Corps lists and the IFPRI lists are noted in bold, italicized, colored letters.

Table E.1: List of topics for the BCC in Guatemala (Mercy Corps)

Group[a]	Mercy Corps	IFPRI
Pregnant women	Danger signs during pregnancy	Maternal diet during pregnancy and lactation
	Deworming during pregnancy (twice per year)	Prevention of anemia (e.g., iron + folic acid supplementation, iron-rich foods, ***deworming***)
	Seeking antenatal care and advantages of delivery services	Early Initiation of Breastfeeding / Why Prelacteal Feeds Are Harmful
	Preparation of child delivery Tetanus and Typhoid immunization Postpartum care	
Lactating women	***Care of breasts***	Breastfeeding problems and ***care of the breasts***
		Optimal breastfeeding (e.g., timely initiation of breastfeeding, EBF until 6 months, breastfeeding day and night at least 10 times, correct positioning and attachment, empty one breast before switching to the other)
	Vitamin A supplementation after delivery	***Vitamin A supplementation after delivery***
Children	***Feeding during and after illness***	***Feeding of the sick child (e.g., increase breastfeeding during and after illness and appropriate therapeutic feeding)***
	General danger signs of childhood illness	Appropriate complementary feeding (e.g., introduce proper complementary foods at 6 months, continue BF until 24 months and more, use of snacks, increase the number of feedings with age, increase density, quantity and variety with age, responsive feeding and ***ensure good hygiene [use clean water, food, and utensils]***)
	Vitamin A supplementation	Prevention of vitamin A deficiency (e.g., ***vitamin A supplementation***, vitamin A-rich foods, foods fortified with vitamin A)
	Worms and deworming (twice per year)	Prevention of anemia (e.g., iron-rich foods, foods fortified with iron, iron supplementation, ***deworming***)
	Importance of growth monitoring and promotion	Recipes: Proper Use of Rations
	Diarrhea prevention and treatment	Use of MN supplements (LNS or Sprinkles)
	Signs of dehydration and why dehydration is deadly	
	Prevention of dehydration with ORT	
	Immunization	

Group[a]	Mercy Corps	IFPRI
Other	Hygiene (e.g., hand washing and proper disposal of feces) ***Handling and storage of food*** ***Hygiene in food preparation*** Prevention and treatment of illness (e.g., dengue, malaria, and pneumonia) HIV/AIDS Family planning	Access and consumption by all families of iodized salt Identify delivery points for BCC messages—both primary and secondary delivery points Define age groups for the BCC (mother's groups)—what is logistically appropriate and technically relevant? Acceptability trials for LNS and Sprinkles
SIAS and health system topics	MoH Protocols—What are the services that are supposed to be provided through the SIAS system (at the Convergence Centers and at the community level)? Are the supplies necessary available at the Convergence Centers? • Running water, electricity, refrigerator • Equipment necessary to perform services included in the service contract (stethoscope, . . .) • Medicine, supplement and vaccine supply chain Are the services that are supposed to be being provided at the Convergence Centers and at the community level being provided if not why? • GMP • Health check-ups, etc. • Regularity of services • Opening hours • Waiting times • Cost How is the quality of the services being provided at the Convergence Centers and at the community level? Staff: • Training of the health staff • Use of clinical guides • Knowledge of staff • Motivation (salary, living away from home, having the proper equipment and supplies, . . .) • Treatment (humane, respectful) of patients What do beneficiaries know about the availability of health services and what are their perceptions of these services? • Knowledge of existence of health services	Health and nutrition related messages—what are the messages and who is providing them?

Group[a]	Mercy Corps	IFPRI
	• Perception of quality: convergence center compared to other providers (i.e., traditional healers, pharmacy, private doctor, . . .) • Perception of friendliness, respect, . . . of staff (as compared to other providers) • Perception of how respectful staff is • Where do patients believe they should be going for specific illness (e.g., bloody diarrhea in children, . . .) Knowledge of beneficiaries about when to seek health services • Recognition of danger signs • Where to go when child/mother has specific health problem Why or why not do they utilize these services? • Distance, cost of transportation • Autonomy • Flexibility of leave work or chores • Availability of other person taking care of children while seeking health care Who is evaluating the data that are collected by the SIAS	

[a] Note the group refers to the time at which the topic is relevant, not to the time when women should be introduced to the topic. The appropriate timing for each topic will be decided upon through the formative research.

Appendix F: Assumptions Sample Size Calculation, Burundi

General Approach

A three-step approach was used to determine the study sample size:

- Step 1: Determine the required sample size to answer research questions 1, 2, and 4. These research questions correspond to an *a priori* hypothesis that the intervention will have a *positive* impact on child growth.
- Step 2: Determine the required sample size to answer research questions 3 and 5. There is no *a priori* hypothesis regarding the direction of effect for these comparisons. The key challenge, therefore, is to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the cost of the study) under control.
- Step 3: Determine the sample size for the other outcomes[21] (anemia, IYCF practices, child development, and food security).

Type 1 error

- **Evaluation of impact against the control group (research questions 1, 2, and 4)** The intervention study has clear *a priori* hypotheses namely that the interventions will improve child nutritional status. This means that one-sided tests are appropriate (Snedecor and Cochran 1989). The *a priori* hypothesis for specific study objective one is based on the evidence from the literature (and the experience in Haiti) that these types of programs improve child growth.
- **Comparison of impact between treatment groups (research questions 3 and 5)** The null hypothesis to be tested for these research questions is that there is no difference between the two treatments. This implies the use of two-sided tests.

Power

We set power to 90 percent. Setting statistical power to a conventional 80 percent means that there is a 20 percent probability of not detecting a beneficial effect. This is the first study to evaluate the PM2A approach following the Haiti study and the first study that will compare the PM2A approach to a control group. Therefore, a smaller probability of not detecting a benefit (10 percent versus 20 percent) is highly desirable in this "proof of concept" stage of PM2A research.

Minimal Detectable Difference

Effect of *Tubaramure* (research question 1)—The preventive model in Haiti was estimated to lower the prevalence of stunting by 15.8 ppt and to change mean HAZ by 0.339. The mean prevalence of stunting in Burundi is significantly lower than in the study area in Haiti.

[21] Sample size calculations were not conducted for household food and nonfood consumption and expenditure, child morbidity, health seeking behaviors, and child anemia. Evidence shows that studies powered to detect meaningful impacts on child growth are sufficiently powered to detect differences in anemia as well.

As a consequence, the potential to benefit is larger. Another reason why the impact may be larger is that the impact in Haiti was estimated after 3 years and not after 4 years as in Burundi. We thus expect a minimal impact of 15.8 ppt in stunting and a minimal impact on HAZ of 0.339 (Donegan et al. 2009).

Effect of *Tubaramure NFP* (research question 2)—To our knowledge, no study has evaluated the impact of providing a MN supplement during pregnancy and a food nutrition postpartum on child nutritional status. We therefore set the estimated impact to the estimates used for question 1: lowering the prevalence of stunting by 15.8 ppt and increasing mean HAZ by 0.339 (Donegan et al. 2009). The assumption is that providing MN Sprinkles instead of CSB during pregnancy, followed by food rations from the time the child is born up to 24 months of age, will have the same impact on child nutritional status as providing CSB throughout pregnancy and the first two years (as in the regular *Tubaramure).*

Effect of *Tubaramure NFP* (research question 4)—There is no scientific literature to estimate to what extent not providing the program from 18 to 24 months of age might lower the program's beneficial effect. We assume that shortening the child's program participation by 25 percent (i.e., from 24 months to 18 months) will reduce its impact by an equivalent percentage. We thus lowered the Haiti impact estimates by 25 percent to 0.254 Z-scores for HAZ and 12.64 ppt in the prevalence of stunting.

Effect of food compared to MN Sprinkles during pregnancy (research question 3)—Given the limited evidence of the impact of food supplements compared to MN Sprinkles during pregnancy on child nutritional status at 24 months of age, the expected difference should theoretically be set to 0. This, however, would require an infinitely large sample size. The key challenge is thus to find a balance between defining the smallest meaningful difference between groups and keeping the sample size (and thus the feasibility and cost of the study) manageable. Given the level of resources available for the study, we estimate that the sample size should not be greater than 1,000 children 24 to 42 months of age per study group (or a total of 4,000 children 24 to 42 months of age total). With this sample size, the minimum detectable difference is estimated to be 0.222 Z-scores for HAZ and 7.8 ppt for the prevalence of stunting.

Effect of providing food between 18 and 24 months (research question 5)—Based on the assumption underlying the expected effect in research question 4 (i.e., a 25 percent reduction of the effect if giving the intervention up to 18 rather than 24 months), the expected difference in impact between *Tubaramure 18* and *Tubaramure 24* is 0.085 in HAZ and 3.16 ppt in stunting. Detecting this difference, however, would require 22 (rather than 15) clusters per arm and a total of 418,374 children per study group. With 1,000 children per arm (see previous paragraph), the detectable difference is estimated to be 0.222 for HAZ and 7.8 ppt for the prevalence of stunting.

Intracluster Correlation and Design Effect

We used the 2000 MICS data to estimate the intra-cluster correlation (ICC) for stunting of children 0 to 60 months of age at the commune and the sub-*colline* level. The "loneway" command in Stata was used. A cluster in this study will be composed of a number of *collines*, i.e., the level of clustering will be between the commune and the sub-*colline* level. The values are summarized in Table F.1. We set the ICC for this study to 0.006 for stunting and two 0.009

for HAZ. This is about twice the ICC found at the commune level in rural areas (Table F.1) and about one-tenth (HAZ) to one-sixth (stunting) of the ICC at the sub-*colline* level.

To determine the validity of the ICC, we also evaluated the ICC in terms of the design effect (Deff). The Deff is the ratio of the variance for the cluster sample divided by the expected variance of a simple random sample of the same size. The relation between the ICC and the Deff depends on the number of observations per cluster and is given in equation (F.1).

$$Deff = 1 + (m\text{-}1)\ ICC, \qquad \textbf{(F.1)}$$

where m is the number of observations within a cluster, m. Table F.2 shows the relation between m and *Deff* for $ICC = 0.006$ and $ICC = 0.009$. The values are well within the range of Deffs used in other studies. The Haiti PM2A study used a Deff of 1.5.

Table F.1: Intracluster correlation of the prevalence of stunting (95 percent confidence interval)

Level of clustering	Urban	Rural	Total
Prevalence of stunting			
Commune	0.11189 (0.00000-0.28172)	0.00326 (0.00000-0.01102)	0.00257 (0.00000-0.00933)
Sub-*colline* (entire country)	0.20047 (0.03415-0.36679)	0.06905 (0.03766-0.10043)	0.09827 (0..6465-0.13190)
Sub-*colline* (Cankuzo and Ruyigi)	*Sample size too small*	0.03805 (0.00000-0.12552)	0.03227 (0.00000-0.12119)
HAZ			
Commune	0.22258 (0.00000-0.48108)	0.00449 (0.00000-0.01345)	0.00454 (0.00000-0.01325)
Sub-*colline* (entire country)	0.26533 (0.08256-0.44809)	0.07857 (0.04600-0.11114)	0.12978 (0.09274-0.16681)
Sub-*colline* (Cankuzo and Ruyigi)	*Sample size too small*	0.02136 (0.00000-0.12552)	0.10494 (0.00000-0.13290)

Table F.2: Deff as a function of the number of children per cluster

Number of children per cluster (*m*)	50	75	100	125	150
Deff (ICC=0.006)	1.294	1.444	1.594	1.744	1.894
Deff (ICC=0.009)	1.441	1.666	1.891	2.116	2.341

Number of clusters per treatment

For practical reasons, the number of clusters per treatment arm was set to 15.

Data loss

Our calculations allow for a total data loss of 15 percent. This includes data loss due to missing values and outliers.

Appendix G: Preliminary lesson plan for the BCC in Burundi, developed by FH

#	Target	Module	Topic
Module 1: Care Group Orientation (6 lessons, ALL)			
1		1.1	Introduction to Care Groups; Project Vision
2		1.2	Educational Methods
3		1.3	Leader Mother Responsibilities
4		1.4	Using the CG Reporting Forms
5		1.5	All people have equal and intrinsic value
6		1.6	Things must Change / You can be an Agent of Change / Change Happens in Community
Module 2: ENAs/EHAs Actions and Other Important Care during Pregnancy (8 lessons, Pregnant women)			
7		2.1	Seeking Antenatal Care and advantages of delivery service
8		2.2	Maternal Nutrition & Anemia Prevention
9		2.3	Importance of TT Injections & Full Immunization of Children
10		2.4	Iodized Salt and Iron-rich Foods.
11		2.5	Hand Washing with Soap/ash
12		2.6	Creation of HH Hand washing Stations
13		2.7	Preventing Malaria in Pregnant Women; Malaria and HIV
14		2.8	Early Initiation of Breastfeeding / Why Prelacteal Feeds are Harmful
Module 3: ENAs and EHAs during Early Infancy (13 lessons, moms of 0 to 5 mo)			
16		3.1	Importance of Postpartum Care
17		3.2	Breastfeeding Technique / Positioning
18		3.3	Exclusive Breastfeeding, Why / Benefits; EBF when HIV+
19		3.4	Exclusive breastfeeding, How (e.g., on demand, both breasts) and Over-coming Barriers (e.g., hydration, work)
20		3.5	General Danger Signs during Childhood Illness
21		3.6	Breastfeeding Problems and Care of the Breasts
22		3.7	Importance of GM/P
23		3.8	Men's Involvement in BF and Child Care
24		3.9	Child Spacing
25		3.10	POU Water Purification
26		3.11	Proper Disposal of Feces
		3.12	Malaria Transmission and Prevention (incl. ITNs)
27		3.13	When a Child has Malaria: First Response and Home Care
Module 4: ENAs and EHAs during Late Infancy and Childhood (10 lessons, moms of 6 to 23 mo)			
28		4.1	Good Complementary Feeding
29		4.2	Use of Snacks & Continued BF
30		4.3	Recipes: Proper Use of Rations
31		4.4	Vitamin A rich Foods
32		4.5	Vitamin A Supplementation (children & postpartum)
33		4.6:	Worms and Deworming
34		4.7	Proper Storage/ Sanitary Food Preparation
35		4.8	Boosting Nutrients and Energy Content
36		4.9	Serving Size, Family Distribution of Foods
37		4.10	Consumption Survey & Counseling

#	Target	Module	Topic
Module 5: Management of Common Childhood Infections that lead to Malnutrition and Other Important Health Actions (8 lessons, all)			
38		5.1	Signs of Dehydration & Why Dehydration is Deadly
39		5.2	Prevention of Dehydration with ORT
40		5.3	Proper Feeding of Sick Children
41		5.4	Deadliest Types of Diarrhea – Dysentery and Persistent Diarrhea
42		5.5	Prevention of Pneumonia (hand washing, avoiding indoor smoke) and Care Seeking
43		5.6	Home Vegetable Gardening
44		5.7	Consulting your C-IMCI trained Leader Mother and compliance with antibiotics
45		5.8	Communication between Husbands and Wives, and Women's Participation in Decision Planning

Key

	All
	Pregnant women
	Mom's with kids -1 to 4/5 months
	Mom's with kids 4 to 24 months