



USAID
FROM THE AMERICAN PEOPLE

Decision-Making and Lessons Learned in Field Study Design, Implementation, and Dissemination

A Report by the Food Aid Quality Review

Prepared By:

Ayten Salahi
Lindsey Ellis Green
Ilana Cliffer
Stacy Griswold
Breanne Langlois
Ye Shen
Devika Suri
Shelley Walton
Maria Wrabel
Kristine Caiafa
Mary Kathryn Cohen
Natalie Volin
Christine Van Fossen
Beatrice Rogers
Patrick Webb

MAY 2021

This report was made possible by the generous support of the American people through the support of the United States Agency for International Development's Bureau for Humanitarian Assistance (USAID/BHA) and the legacy Office of Food for Peace (FFP) under the terms of Contract No. **AID-OAA-C-16-00020**, managed by Tufts University.

The contents are the responsibility of Tufts University and its partners in the Food Aid Quality Review (FAQR) and do not necessarily reflect the views of USAID or the United States Government.

The authors have no conflict of interest to declare.

Recommended Citation:

Salahi, Ayten; Green, Lindsey Ellis; Cliffer, Ilana; Griswold, Stacy; Shen, Ye; Suri, Devika; Langlois, Breanne; Walton, Shelley; Cohen, Mary Kathryn; Volin, Natalie; Van Fossen, Christine; Rogers, Beatrice; Webb, Patrick. 2021. Decision-Making and Lessons Learned in Field Study Design, Implementation, and Dissemination. Report to USAID. Boston, MA: Tufts University.

This document may be reproduced without written permission by including a full citation of the source.

For correspondence, contact:

Patrick Webb
Friedman School of Nutrition
Science and Policy
Tufts University
150 Harrison Avenue
Boston, MA 02111
patrick.webb@tufts.edu

ACRONYMS

ACDI	Agricultural Cooperative Development International
BMCs	Beneficiary Mothers and Caregivers
CRS	Catholic Relief Services
CSB	Corn-Soy Blend
CSB+	Corn-Soy Blend Plus
CSWB	Corn-Soy-Whey Blend
CIOMS	Council for International Organizations of Medical Sciences
DFSA	Development Food Security Activity
DMAP	Data Management and Analysis Plan
DMP	Data Management Plan
DQAP	Data Quality Assurance Plan
FAO	Food and Agriculture Organization of the United Nations
FAQR	Food Aid Quality Review
FBF	Fortified Blended Food
FFP	Office of Food for Peace (USAID)
FSN	Food Security and Nutrition
FVO	Fortified Vegetable Oil
ICF	Informed Consent Form
IRB	International Review Board
IRSS	<i>Institut de Recherche en Sciences de la Santé</i> (Research Institute of Health Sciences)
LNS	Lipid-Based Nutrient Supplement
MAM	Moderate Acute Malnutrition
MOU	Memorandum of Understanding
MUAC	Mid-Upper Arm Circumference
PASS	Power Analysis and Sample Size
PPB	Project Peanut Butter
RA	Research Assistant
RAM	Responsibility Assignment Matrix
RCT	Randomized, Controlled Trial
RUSS	Research Uptake and Sustainability Strategy
SAM	Severe Acute Malnutrition
SC+	Super Cereal Plus
SFP	Supplementary Feeding Program
USAID	United States Agency for International Development
ViM	<i>Victoire sur la Malnutrition</i> (Victory Against Malnutrition)
VOCA	Volunteers in Overseas Cooperative Assistance
WFP	World Food Programme
WHO	World Health Organization

TABLE OF CONTENTS

ACRONYMS..... 3

EXECUTIVE SUMMARY 5

1: INTRODUCTION..... 6

2: METHODS AND OBJECTIVES 7

3: CONCEPT PHASE..... 7

 3.1: IDENTIFYING RESEARCH QUESTIONS 7

 3.2: SELECTING GEOGRAPHIES AND TARGET POPULATIONS..... 8

 3.3: CONDUCTING FORMATIVE RESEARCH..... 9

 3.4: ESTABLISHING PARTNERSHIPS 10

 3.5: ASSESSING FEASIBILITY OF STUDY IMPLEMENTATION 11

4: DESIGN PHASE..... 12

 4.1: DEVELOPING A RIGOROUS RESEARCH DESIGN..... 12

 4.2: ESTABLISHING A SAMPLING FRAME..... 17

 4.3: BUILDING A STRONG DATA MANAGEMENT AND ANALYSIS PLAN 19

 4.4: DEVELOPING DATA COLLECTION TOOLS..... 20

5: IMPLEMENTATION PHASE..... 22

 5.1: DEFINING AND ADAPTING ROLES AND RESPONSIBILITIES..... 23

 5.2: OBTAINING ETHICS COMMITTEE APPROVALS FOR RESEARCH 25

 5.3: COLLABORATING WITH LOCAL IMPLEMENTING PARTNERS..... 25

 5.4: CULTURAL SENSITIVITY TO ENSURE EQUITABLE PARTNERSHIPS 26

 5.5: TRAINING AND MANAGING RESEARCH STAFF IN THE FIELD 30

 5.6: RECRUITING STUDY PARTICIPANTS FOR ADEQUATE SAMPLE SIZE..... 33

 5.7: ADAPTING TO UNANTICIPATED EVENTS 33

6: LEARNING PHASE..... 36

 6.1: ANALYZING THE DATA AND FIDELITY OF PROGRAM IMPLEMENTATION..... 36

 6.2: DEBRIEFING PARTNERS, FUNDERS AND RECIPIENT COMMUNITIES 37





 6.3: RESEARCH DISSEMINATION 38

7: KEY TAKEAWAYS..... 41

EXECUTIVE SUMMARY

This report provides guidance on field-based study design and implementation for food assistance for nutrition research. Rigorous research is needed to strengthen the evidence base for food-supported programming and products to improve survival and nutrition outcomes for vulnerable individuals worldwide. The Friedman School of Nutrition Science and Policy at Tufts University has partnered with the United States Agency for International Development (USAID) Bureau of Humanitarian Assistance (BHA) and several international stakeholders to respond to this urgent need through the Food Aid Quality Review (FAQR) project. The FAQR team implemented three field studies to test recommended changes to food aid formulations and programming methods during USAID/FFP Title II Development Food Security Activities (DFSAs) in Southern Malawi, Centre-Nord Burkina Faso, and Southern Sierra Leone.

The FAQR report, *Decision-Making and Lessons Learned in Field Study Design, Implementation and Dissemination*, consolidates standards of practice to prepare for each phase of study execution in nutrition assistance research, alongside real-world examples of how the FAQR team adapted to shifting conditions to ensure the success of our research program. With this report, we aim to provide a practice-based reference tool for the research community addressing food aid for nutrition that might serve to improve the efficiency of future research. To organize our approach, FAQR began by distilling insights into four discrete phases of study execution. Each phase answers distinct questions laid out in **Table I. Phases of Study Execution**:

 <p>CONCEPT</p>	<p>What is the specific research question you hope to answer, and what are the most feasible locations and partnerships needed to actualize your study in the field?</p>
 <p>DESIGN</p>	<p>What methods are needed to operationalize research questions in an applied setting, with statistical rigor and realistic resource allocation?</p>
 <p>IMPLEMENTATION</p>	<p>How can you oversee, adapt, and refine your team's approach, while keeping the vision of the research top of mind?</p>
 <p>LEARNING</p>	<p>How can you apply the results of your study to point the way forward for future research, policy, and programming priorities?</p>

Several themes are foundational to the success of field research programs. Each phase of study development and execution requires a balance of both careful planning and strategic adaptation. Realistic and conservative estimates for timelines and resources serves as the footing from which key priorities are set and decisions are made. Geographical, cultural, and programmatic settings are also central to the applicability of research results to decision-making. Clear and frequent communication within study teams and between partners is critical to facilitating smooth collaborations and quick adaptations to evolving study conditions. During design and implementation, careful selection of data collection tools, deliberate data management procedures, and technological troubleshooting in the field ensure high-quality data capture. A rigorous process for selecting, training, and periodically retraining research staff improves the reliability and precision of data collection. Finally, planning research uptake strategies early on in study conceptualization helps to ensure that field study results continue to achieve maximum impact to inform nutrition assistance programs and policies.

I: INTRODUCTION

In 2009, the United States Agency for International Development’s Office of Food for Peace (USAID/FFP) (now incorporated into the Bureau for Humanitarian Assistance – BHA) initiated the Food Aid Quality Review (FAQR) project to provide actionable recommendations to improve nutrition among vulnerable people for whom the direct distribution of food aid could make a significant impact. To achieve this aim, the FAQR project began with a review of nutrition science and a summary of recommendations for changes to product formulations and programs for food-supported interventions (Phase I). Food-supported interventions are interventions that:

- use food assistance products;
- use foods that have been nutritionally enhanced; and
- include study-specific ingredients that are intended for use in food aid.¹

The results of the FAQR Phase I review are accessible in several forms:

- [Improving the Nutritional Quality of U.S. Food Aid: Recommendations for Changes to Products and Programs report](#);
- [Delivering Improved Nutrition: Recommendations for Changes to U.S. Food Aid Products and Programs report](#); and
- Articles published in a special edition of the [Food and Nutrition Bulletin](#).

The reports outlined recommendations to:

- reformulate fortified blended foods (FBFs) to add a dairy source protein;
- update the micronutrient premix;
- increase the amount of fortified vegetable oil (FVO) in the final ration as prepared and consumed; and understand how food aid products are used to inform their programming.

USAID/FFP accepted these recommendations and awarded an extension contract to Tufts University to help USAID put the recommendations into practice in FAQR Phase II. This work focused on devising evidence-based reformulations of FBFs, adding lipid-based products to the FFP commodity list, and generating empirical evidence on the programming of such products. Accomplishments from this period are summarized in the [Food Aid Quality Review Phase II Closeout Report](#).²

The Tufts team then implemented [three field studies](#) to test the program modifications recommended in the Phase I and Phase II reports, with the aim to strengthen the evidence base for use of specialized food products for targeted nutrition goals. These field studies were implemented during FAQR Phase II and III and were conducted in three settings:

- **Southern Malawi:** Feasibility and Acceptability Study of Preparing Corn Soy Blend with Fortified Vegetable Oil in Malawi
- **Centre-Nord Burkina Faso:** Comparative Cost-Effectiveness of Four Supplementary Foods in Preventing Stunting and Wasting in Children 6-24 Months in Burkina Faso
- **Southern Sierra Leone:** Comparative Cost-Effectiveness of Four Supplementary Foods in Treating Moderate Acute Malnutrition in Children 6-59 Months in Sierra Leone

2: METHODS AND OBJECTIVES

The present report consolidates key findings of best practices for research on food assistance for nutrition, alongside their real-world applications in FAQR field studies. Qualitative interviews and focus groups were conducted with the FAQR co-principal investigators (PI), field research managers, project managers, and statistician. Successful strategies applied during the concept, design, implementation, and learning phases of each field study were extracted from transcripts recorded during focus group discussions and interviews. In addition, case studies were collected from field staff to share experiences and lessons learned during study execution.

The FAQR team reviewed the interviews and focus group transcripts, as well as the submitted case studies and summary tables. Reoccurring themes of field research challenges were identified, and examples of successful strategies were incorporated into this report. Findings were then distilled into brief and actionable recommendations for stakeholders engaged in the broader research and programming communities involved in food aid for nutrition.

The objectives of this report are to draw from FAQR's field research experience to:

- Highlight best practices and common challenges faced by researchers and implementing partners throughout each stage of study execution;
- Share effective and contextualized strategies to navigate these challenges; and
- Provide real-world cases that illustrate how challenges encountered and strategies employed are balanced to maintain the highest standards of scientific rigor.

3: CONCEPT PHASE

The concept phase of study design involves an iterative period of formative research that is used to identify key research questions, geographies, populations of interest, potential collaborators, stakeholders and funding sources. The FAQR Phase I recommendations provided to USAID/FFP in the [Delivering Improved Nutrition: Recommendations for Changes to U.S. Food Aid Products and Programs](#) report initiated the concept phase of FAQR field research activities. In the process of developing ideas for field studies that could answer the research questions identified in Phase I of FAQR's work, the following themes arose as integral to the concept phase:

- 3.1:** Identifying Research Questions
- 3.2:** Selecting Geographies and Target Populations
- 3.3:** Conducting Formative Research
- 3.4:** Establishing Partnerships
- 3.5:** Assessing Feasibility of Study Implementation

3.1: Identifying Research Questions

Study conceptualization begins by crafting clear research questions and hypotheses based on the best and latest available evidence in a chosen topic area. Articulating research questions is a critically important step in study development, as research questions both inform subsequent steps in study execution and ensure that results are meaningful and actionable. Once clear and concise research questions are established, researchers must then carefully translate research questions into variables that can be measured.

As a team develops a research question, the objectives must be both clear and aligned with the aims of organizations conducting the research and their funders. To articulate research questions in a manner that will increase the likelihood of producing meaningful results, it is useful for the research team to ask:

- What are the types of conclusions you aim to draw from your study?
- What will be done differently as a result of the study?
- Have you formulated the questions in a way that helps reach those conclusions?³

We draw attention to these considerations to illustrate that the specific phrasing of research questions will have critical implications for the types of conclusions that will be drawn from a proposed study. The implications of research question phrasing should be communicated to all necessary stakeholders early and regularly. This ensures that the conclusions drawn from proposed research will meet the objectives of all relevant parties. If they do not, stakeholders must describe what research question components would need to change in order to ask the right question for actionable results. The process of finalizing research questions is often lengthy and challenging, but the significance of this step leading into study design cannot be overstated. It is worthwhile to invest substantial time early in creating research questions that are clear, measurable, meaningful, and aligned with the aims of all key parties.

The following research questions were articulated by FAQR to field test the recommendations arising from its earlier reports:

- What is the feasibility of caregivers adding the recommended amount of oil to corn-soy blend (CSB) porridge given to children enrolled in a moderate acute malnutrition (MAM) treatment program?
- What is the relative effectiveness and cost-effectiveness of four supplementary foods in the prevention of stunting and wasting in children 6 to 23 months of age?
- What is the relative effectiveness and cost-effectiveness of four supplementary foods in the treatment of MAM in children 6 to 59 months of age?

3.2: Selecting Geographies and Target Populations

Identifying study locations and target populations is an integral component of the concept phase. Occasionally, key geographies, populations and subgroups arise as being particularly relevant to the research topic. For example, in the case of food assistance for nutrition, study populations should be those in which the prevalence of MAM or severe acute malnutrition (SAM) is high enough to make such a study relevant. When collaborating with an implementing partner, target populations may be determined by the program, and its appropriateness to the research goals needs to be established prior to study design. When selecting a study location, the goal is to identify a location with a study population large enough to observe differences attributable to an intervention. Locations must also be safe to work in, with expected low attrition, and without multiple intervention programs working in the same space.

To select locations for FAQR field studies, research team leadership first established key selection criteria for target locations. The search criteria included countries operating multiyear FFP development activities with at least a three-year duration on their project and a food aid component. A list of all participating countries that met these criteria was established, and key

collaborating partners in each country were identified and contacted to gauge interest in a potential research partnership.

When selecting a study location, it is also critical to assess population baseline criteria to ensure that the research question is relevant to the proposed study population. For example, the [FAQR Four Foods Treatment Study](#) was implemented in the Pujehun District of Sierra Leone. Baseline research had been conducted previously at the national level, which demonstrated that this region in Sierra Leone had a high prevalence of MAM. However, following research initiation, the study team encountered challenges with low enrollment. After investigating potential causes for these enrollment issues, the team discovered that the available dataset used for baseline research overestimated the prevalence of MAM in the Pujehun District. Despite this challenge, the baseline research conducted by FAQR was critical in identifying criteria that made the Pujehun District an appropriate location for the study, namely the lack of an existing supplementary feeding program.

Collecting your own baseline data is preferred in cases for which baseline data are scant, outdated, unreliable, or non-existent. When primary baseline data collection is infeasible, it is important to validate any pre-existing data by confirming sources and verifying findings with other agencies involved in food assistance for nutrition before moving forward with the study.

Other factors that influence study location choice are the priorities of both the potential host government and any local implementation partners. Buy-in and support from relevant government ministries, local health offices, and in-country implementation experts is vital to relationship-building and mapping existing nutrition and food assistance programs operating at the local, regional, and national levels. When researchers collaborate with local agencies to select study sites, challenges related to limited local resources and the transportation of project staff and equipment may be discussed and effectively addressed in advance. Finally, as a practical consideration during location selection, it is important to maintain communication with country missions, determine if clearances are needed, and be alert to the need for non-tourist visas. These steps are relevant as early as the scoping trip and are essential by study start.

3.3: Conducting Formative Research

After identifying key research questions and selecting relevant study locations, landscape and literature reviews and formative research should be used to inform the specifics of the study. A landscape review is a type of research synthesis (distinct from a ‘systematic review’) that maps out the relevant literature – published and ephemeral – on a given research topic. In the case of FAQR, USAID/BHA commissioned a landscape review to respond to a call for changes to the specifications of key Title II commodities. This review included the latest evidence on nutritional needs of recipient populations across the developing world and the role of specially formulated commodities in meeting defined nutritional needs.

While landscape reviews map empirical literature relevant to a research question, formative research accesses and studies relevant populations in order to maximize the local relevance of the research.⁴ One benefit of formative research is to identify any organizations conducting similar research in the populations of interest. These organizations may develop into partnerships, or they may signify redundancy of research. Further, they may have valuable insights and strategies they used to overcome unforeseen data collection obstacles. For example, assessment of changes in cognitive function in children recovering from MAM or SAM, may use a variety of indicators. Those who have conducted similar research may have insights on the feasibility of one or another method. Formative research is both theoretical and experiential. After reviewing relevant studies,

observing the implementation of programs or research on the ground allows a realistic assessment of the feasibility of a given approach.

3.4: Establishing Partnerships

Consultations and partnerships develop during study conceptualization and carry through the duration of study. Of course, a key relationship is that between the funder and the research group; expectations, roles and responsibilities need to be clear from the beginning.

The FAQR project was funded by USAID/FFP, and the research team works closely with that office, including regular updates on study developments and anticipated outcomes. It is good practice to clarify whether funders expect to be involved in the conduct of the research. Clear and consistent communication with funders allows for collaborative decisions if changes in the research are needed.

Research on food aid programs often requires partnering with existing programs that implement either direct distribution of food aid or food-supported interventions. This means accommodating the processes already in place and working collaboratively to design a rigorous research trial that is minimally disruptive to the daily activities of the programs. It is usually a good idea to hire an in-country research manager who speaks the local language and knows the country context.

Local communities and government agencies are also key stakeholders in studies of food aid programs, and researchers should establish partnerships to ensure, to the extent possible, that the research align with local priorities and national policies and practices. Early collaboration with local stakeholders allows for feedback from local communities, while also increasing local ownership over the research process and boosting the likelihood of smooth implementation.⁵ Table 2 shows the international and local partners involved in FAQR field studies.

Table 2. FAQR PARTNERS		
Project Partners	<ul style="list-style-type: none"> • United States Agency for International Development Bureau for Democracy Conflict and Humanitarian Assistance Office of Food for Peace (USAID/DCHA/FFP) • Tufts University Friedman School of Nutrition Science and Policy 	
	International Partners	Local Partners
Sierra Leone	<ul style="list-style-type: none"> • Project Peanut Butter (PPB) • Washington University in St. Louis (Wash U) • World Food Programme (WFP) • University of Eastern Finland (UEF) 	<ul style="list-style-type: none"> • Caritas Bo • Sierra Leone Ministry of Health and Sanitation Directorate of Food and Nutrition (DFN/MoHS)
Burkina Faso	<ul style="list-style-type: none"> • Agricultural Cooperative Development International/ Volunteers in Overseas Cooperative Assistance (ACDI/VOCA) • Save the Children International (SCI) 	<ul style="list-style-type: none"> • Institut de Recherche en Sciences Appliquées et Technologies (IRSAT) • Institut de Recherche en Sciences de la Santé (IRSS) • Laboratoire Nationale de Santé Publique (LNSP)
Malawi	<ul style="list-style-type: none"> • Africare • Catholic Relief Services (CRS) • Project Concern International (PCI) • Save the Children International (SCI) 	<ul style="list-style-type: none"> • Pakachere Institute for Health Development and Communication (PIHDC) • University of Malawi Centre for Social Research (CSR)

3.5: Assessing Feasibility of Study Implementation

The feasibility of a study is a balance of scientifically defensible design, local conditions, and resource availability. The research planning process involves developing the protocol, then developing a budget that covers all activities (planning, scoping trips, all steps in data collection, which may involve contracts with local laboratories or even shipment to international labs, as well as analysis and dissemination). Budgets should allow for the usual unanticipated expenses and, in the experience of the FAQR research staff, should prioritize the assurance of high-quality data collection. Once these are developed, modifications may be needed to accommodate the local context or budgetary constraints; this may require reducing the scope of the research but should not reduce the rigor of the research design. In some cases, local conditions or resource constraints may make the research infeasible.

Scoping trips can be critical to evaluate the feasibility of the study to see how partnering programs operate, to identify key local stakeholders, and to identify and resolve potential obstacles to the research. They also serve to establish a research presence in a given location before a study begins. Prior to a scoping trip, assessment criteria for both the potential location and implementation partners should be established. Categories for assessment may include geographical barriers, transport needs, staffing, existing processes, procedures and conditions of the local programs, flexibility of the implementing partners to adapt their processes to the needs of the study, research experience, and cultural considerations.

Dissemination and uptake of the study results should be an integral part of the research plan from the beginning. Involving both local and non-local strategic partners in the uptake strategy can maintain stakeholder engagement throughout the study, maximize exposure of the target audience to the research, and keep the overarching aims of the research top of mind.

CONCEPT PHASE TAKEAWAYS

Identifying Research Questions	<ul style="list-style-type: none"> • Align with the overarching aims and objectives of the implementing organization and funders. • Formulate research questions to support the objectives of the research.
Selecting Geographies and Target Populations	<ul style="list-style-type: none"> • Identify locations and populations appropriate to the research questions. • Conduct your own baseline research when possible or validate existing data. • Collaborate with the host government, relevant agencies, and implementing partners to select specific study sites and adjust research design to accommodate local conditions.
Conducting Formative Research	<ul style="list-style-type: none"> • Explore literature and identify agencies and organizations conducting similar research in comparable settings. • Identify feasible methods for measuring outcomes and indicators of interest. • Observe the implementation of relevant programs or protocols on the ground.

<p>Establishing Partnerships</p>	<ul style="list-style-type: none"> • Establish a clear relationship with funders that enables bidirectional feedback. • Work closely with local implementing partners to design a rigorous trial that is minimally disruptive to the local context. • Include local communities, as well as national and global collaborators, as key stakeholders in the study execution.
<p>Assess Feasibility of Study Implementation</p>	<ul style="list-style-type: none"> • Establish criteria for selecting locations and implementation partners, and confirm all parties agree on assessment criteria. • Identify, meet, and discuss research aims and local priorities with local stakeholders. • Resolve outstanding questions and knowledge gaps in formative research during a scoping trip. • Critically assess whether the study can be conducted to yield meaningful results given the context and available resources.

4: DESIGN PHASE

The design phase of the study establishes a roadmap for study execution by defining and operationalizing key measures needed to answer the research question(s), determining how metrics will be collected in the field, and establishing a plan for how to track and quality check incoming data. This phase details both the logistical and methodological considerations needed to conduct the study in an applied setting, with statistical rigor. Each of the three FAQR field studies had distinctive locations, study designs, and outcome measures, as reflected in **Table 3**.

Each of these studies was designed with attention to the realities of its programmatic setting, as explored during scoping visits and study conceptualization. The following themes were key considerations in the design phase for FAQR field studies:

- 4.1:** Developing a Rigorous Research Design
- 4.2:** Establishing a Sampling Frame
- 4.3:** Building a Strong Data Management and Analysis Plan
- 4.4:** Developing Data Collection Tools




4.1: Developing a Rigorous Research Design

The cornerstone of a strong study protocol is a rigorous research design that is developed in collaboration with expert statisticians who help to ensure that the study evaluates or observes the intended outcomes and indicators in a population of interest while:

- maintaining both internal and external validity;
- maximizing statistical power; and
- accounting for both contextual and resource constraints.

As described in [3.1: Identifying Research Questions](#), this stage requires defining the specific relationships to be studied and operationalizing the concepts, that is, turning them into measurable

Table 3. FAQR FIELD STUDY DESIGNS AND OUTCOME MEASURES

	Design	Primary Outcome	Secondary Outcome
 Malawi	<p>A repeat cross-sectional study to assess the extent to which recipients could be encouraged to use fortified vegetable oil in porridge preparation.</p> <p>The study also assessed the impact of packaging changes (providing CSB in 2 kg packages rather than in bulk) in conjunction with printed behavior-change messages on the correct use of CSB and oil.</p>	<p>Mean FVO:CSB ratio (i.e., grams of FVO per 100 grams of CSB) in prepared porridge as determined by lab analysis of the porridge samples taken from recipient households.</p> <p>Cost effectiveness measured as cost per caregiver reaching the target FVO:CSB ratio, assessed for two interventions (extra oil and SBCC; those plus packaging with printed instructions) relative to no intervention.</p>	<p>Percentage of recipient mothers and caregivers (BMCs) reaching or exceeding an FVO:CSB ratio of 30:100, as determined by lab analysis of the porridge samples taken from recipient households.</p>
 Burkina Faso	<p>A prospective, geographically clustered effectiveness trial to test the relative effectiveness and cost-effectiveness of four supplementary foods in the prevention of MAM and stunting in normal programmatic settings.</p>	<p>Incidence of acute malnutrition during the treatment period and prevalence of stunting at 24 months of age.</p> <p>Cost effectiveness: cost per case of MAM or stunting averted relative to the standard care (CSB+ with oil).</p>	<p>Behavioral factors affecting outcomes.</p>
 Sierra Leone	<p>A prospective, cluster-randomized, controlled trial to assess the effectiveness and cost-effectiveness of four supplementary foods in the treatment of MAM in children 6 - 59 months old.</p>	<p>Recovery from MAM within 12 weeks (other outcomes: failure to recover, death, development of SAM, transfer to hospital for inpatient care, default).</p> <p>Cost effectiveness assessed differences among the four study arms in cost per case of MAM recovered.</p>	<p>Rates of weight, height, and MUAC gain, time to graduation, percent of recovered children who sustained recovery after one month, and any possible adverse effects from the supplementary foods.</p> <p>Cost effectiveness assessed as cost per recovered case that sustained recovery at one month.</p>


variables. A data analysis plan should be developed at this stage, one that outlines the step-by-step statistical procedures that will be used to answer your research questions, to ensure that data collection supports the planned analyses.

The randomized, controlled trial (RCT) is often considered the “gold standard” of experimental study design necessary to attribute cause and effect to a relationship between variables, and every attempt should be made to design an RCT for effectiveness research on food assistance for nutrition. When random assignment is to a treatment or a non-treatment control, it is common to assure that communities or individuals assigned to the control group will be first in line to receive treatment when the trial is completed. RCTs may still be subject to systematic biases due to unplanned differences in implementation or data collection, differential attrition, or systematic differences among the geographic groupings of the study arms despite random assignment. One way to counter the latter is to create pairs of clusters based on similarities in key characteristics, and then randomly assign one of each pair to treatment and control. It is still necessary to remain alert to issues related to selection and attrition biases, quality of implementation, data quality, and final sample size, as well as to collect information on demographic, socioeconomic, and environmental variables that may be needed as covariates in controlling for bias in the analysis phase.

In food aid research – and particularly in field studies that involve collaborations with implementing partners or existing food aid distribution programs – the realities of the field may dictate that an RCT is not feasible or ethical in a given context. To compare groups without randomization, a quasi-experimental study design can be implemented by adequately controlling for variables that might influence the results, though this approach is limited by the ability to identify those variables correctly and measure them. Selecting a suitable study design often requires weighing the costs and benefits related to statistical rigor, data collection, participant recruitment, randomization, and the real-world constraints of implementation. An FAQR example from Burkina Faso is illustrated in **Case Study I**.

Case Study I

Designing and Conducting an Effectiveness Study in a Programmatic Setting

<p>Author Ilana Cliffer, Study Lead, Burkina Faso</p> <p>Study <i>Comparative Cost-Effectiveness of Four Supplementary Foods in Preventing Stunting and Wasting in Children 6-24 Months</i></p> <p>Location Sanmatenga Province, Burkina Faso</p> <p>BACKGROUND Aid organizations and governments spend billions of dollars on food assistance yearly,</p>	 <p>but the cost-effectiveness of the products and programs used to prevent and treat malnutrition remains unclear.^{6,7,8} In the 2011 report Delivering Improved Nutrition: Recommendations for Changes to U.S. Food</p>
--	--

Case Study I

[Aid Products and Programs](#), FAQR suggested changes to improve food aid products.⁹ These included the addition of whey protein concentrate to the standard corn-soy blend and an increase to the caloric density of the food products by delivering them with a larger quantity of fortified vegetable oil. In addition, the report emphasized the importance of cost-effectiveness trials to test the theoretical basis for changes in food products and programs and determine whether added benefits of one food over another are worth additional costs.

OBJECTIVES

The aim of this study was to determine whether a new formulation of corn-soy blend with whey protein concentrate was more effective and more cost-effective than the standards of care for both USAID and WFP, CSB+ with oil. Two other foods were compared, a lipid-based nutritional supplement (RUSF) and a WFP product, Super Cereal Plus (SC+), a CSB product with oil already added to the flour rather than requiring it to be added during preparation.

The purpose was to understand the cost-effectiveness of these four supplementary foods in the prevention of stunting and wasting in children 6 to 23 months in a real-world programmatic setting. To achieve this aim, the study was built into an existing blanket supplementary feeding program implemented by ACIDI/VOCA and Save the Children, called the ViM program (Victoire sur la Malnutrition/ Victory against Malnutrition). The goal was to test the effectiveness of these food products as part of a typical food assistance program.

The primary outcomes, stunting and wasting, were assessed through anthropometric measurements (recumbent length, weight, MUAC) of the 6,000 children included in the study during monthly food distribution sessions. Children were enrolled in the study at 6 months and followed monthly for 18 months while receiving one of the four foods.

IMPLEMENTATION CHALLENGES

While using an existing distribution program was essential to understanding what occurs when programs are implemented in the field, there were several challenges related to integrating this study into a pre-existing distribution program.

They included:

- Less flexibility than a study that implements its own intervention. If one is designing a study from scratch, the design of the intervention will be under the control of the research team. In studying the existing program (ViM), we were constrained by its structure and logistics, and often had to make concessions that influenced our study design and data collection. For example, our study was originally designed as a cluster-randomized trial, in which food distribution points would be randomly assigned to one of the four foods to avoid homogeneous characteristics in one study arm that could bias the results. However, we adapted the study to a geographically clustered trial, where each food was randomly assigned to an entire geographic area within the province. The ViM program already had a specified budget, a contract with a transporter, and set methods for the logistics of food transport, delivery and distribution. Working within their structure, the only way to deliver the foods to sites spread over the geographic region instead of contiguous sites would have been to load all four foods onto one truck that would drop different foods at different sites. The potential for mixing up the foods and cross-contamination was too great with this scenario, so we opted to change our study design to geographic clusters and adjust for the geography effects in our analyses.
- Program implementation does not necessarily demand the same precision in record keeping and data collection as is required by scientific studies. In a food distribution program, the most important

Case Study I

priority is for the foods get to the recipients. Food is often distributed in different ways due to unforeseen circumstances like inclement weather or vehicle breakdowns. Conversely, studies require reliability and accuracy in data collection methods, which means consistency in food distributions and recipient data. While it may not be worth the additional resources needed for a program to confirm, for example, that every child's birth date is precisely correct in a food distribution program, a correct birth date is essential for a study such as ours in which both enrollment and key outcome variables (e.g., height for age) depend on the exact age of the child. While we could collect our own data on children's birth dates to use in data analyses, discrepancies between health cards and those in the ViM system affected enrollment procedures for the study. The automatic transition from the "mother" ration to the "child" ration did not always happen at 6 months of age, which we had planned to use as our enrollment trigger. It was a delicate balancing act to enforce scientific rigor while keeping the program true to typical implementation to study its actual effectiveness.

- When a data collection team comes into an existing program, it is important that the program implementers understand that you are not doing an evaluation of them, but rather assessing the impact of the program they are running. The perception of being evaluated can cause tension and potentially alter people's behaviors, influencing the true nature of the program under study. It can also be hard for the program participants to understand that the data collection team members are separate from the program implementation team and have no control over how the program functions. Confusing the teams may lead the recipients to be less comfortable communicating honestly with the data collection team about their experiences with the program.

RECOMMENDATIONS

1. Have a clear data analysis plan. Ensure that decisions about study design do not jeopardize data quality; ensure that sufficient information is collected to permit appropriate statistical adjustments for covariates that may otherwise cause bias.
2. Focus on strong collaboration and communications among the research and implementation partners. We held weekly meetings among all partners involved in the study, which allowed us to air out any issues, discuss challenges as they arose, and brainstorm solutions that worked for all parties.
3. Seek solutions that allow the program to function as much as possible as it would have if the study team were not present.
4. Ensure that the distinction between the study team and the implementation team is clear. To make this distinction clear, our data collection enumerators had different types of motor bikes and different badges identifying them as part of a study team. They were also trained to introduce themselves to recipients as a separate organization. Equally important, we established positive connections and collaborations between the two field teams and made sure that everyone on the implementation side was informed (and retrained occasionally) about the purpose of the study.

CONCLUSION

Studies that address the question of effectiveness are essential to designing food aid products and programs that work as expected. The challenges in conducting such studies can be surmounted with collaboration, communication, and strong study design.

4.2: Establishing a Sampling Frame

The purpose of a sampling frame is to create a clear, operationalized tool to enumerate, randomize, and sample eligible subjects at specified times and frequencies. The sampling frame and sampling plan must be designed in a way that can feasibly be applied and verified under the logistical constraints of the study. This is especially important in large-scale, longitudinal studies with complex randomization protocols, but is relevant to all food aid research. It is equally important to determine in advance how to handle missed visits by study participants and to decide at what point study participants are considered defaulters.

In the context of field studies on food aid for nutrition, there are two common approaches to sampling: recipient-based and community-based. In the recipient-based approach, sampling frames are designed to include a representative sample of program recipients. In this sampling structure, a representative sample of recipients who use a particular food aid product or program (or one of several being compared) are observed as a stand-alone group, and the effects are assessed among recipients only. In the community-based approach, sampling frames are constructed to include a representative sample of all members in the community. The latter sampling structure allows for assessment of a program’s effect on the community as a whole. Community-based sampling permits a host of other program-impact evaluations including program reach, use, and barriers to use, among others. Of course, study enumerators must speak the local language and must be able to ensure the accurate implementation of sampling methods.¹⁰

The FAQR field studies were designed using a recipient-based sampling approach. To field-test recommendations for reformulations of food aid products, a recipient-based sampling frame was ethically necessary, both to achieve a representative sample of recipients and to ensure that no participant was randomly assigned to be excluded from treatment. Sample size estimations should be sufficient to identify the smallest meaningful or expected difference among foods being compared, such as differences in MUAC, or percent of recovery in treatment program studies, with appropriate power (typically .8) and significance (typically $\alpha < .05$). These calculations should also account for the design effect in a cluster-randomized trial. Power analysis and sample size (PASS) software was used to perform sample size calculations for the FAQR field studies. For a more detailed description of how the Burkina Faso research team developed and implemented their sampling frame in the context of a programmatic setting, refer to **Case Study 2**.

Case Study 2	
Establishing a Clear Sampling Frame	
<p>Author Ilana Cliffer, Study Lead, Burkina Faso</p> <p>Study <i>Comparative Cost-Effectiveness of Four Supplementary Foods in Preventing Stunting and Wasting in Children 6-24 Months</i></p> <p>Location Sanmatenga Province, Burkina Faso</p>	<p>IMPLEMENTATION CHALLENGES</p> <p>The study used a two-stage sampling approach. In the first stage, distribution points were grouped geographically, and each group was randomly assigned to one of the study foods. In the second stage, the sampling frame was a list of all program recipients from which study participants are selected. Typically, this list can be generated by obtaining a list of all enumeration areas, such as villages or neighborhoods, or making a list of all potential</p>

Case Study 2

study participants in a specified geographic area. Generating a sampling frame for the study described here was challenging given that the study was embedded into an existing blanket supplementary feeding program, and the research team relied on documents from the implementers.

The lists used to build the sampling frames included mistakes or had not always been updated. As mentioned in the accompanying **Case Study 1: Designing and Conducting an Effectiveness Study in a Programmatic Setting**, program resources are spent on ensuring timely distribution to the recipients rather than sticking to exacting criteria for record-keeping. Incorrect sampling frames can lead to selection bias. Due to this, the research team had to devise a way to adjust study procedures to ensure logistically feasible and scientifically defensible study enrollment. The following example illustrates this point and can serve as a guide for dealing with sampling frame issues.

Prior to study implementation in Burkina Faso, the research team set the enrollment criteria to include all children age 6 months whose mothers had been participating in the ViM program as pregnant and lactating women. The food ration would get transferred from the mother to the child when the child reached 6 months of age and could begin complementary feeding, at which time the child would be enrolled in the study. The study team requested monthly lists of recipients who were turning 6 months old and would be receiving the ration for the first time, under the assumption that this list would be an accurate sampling frame from which children could be enrolled before they started consuming the ration.

However, the ViM lists often had the wrong birth dates, meaning that children who were younger or older than 6 months could be on the list for ration transfer from the mother to the child. In addition, the study team had to consider that these monthly lists provided by

the ViM program did not include children who had already been transferred but had not yet come to the distribution site to receive their ration.

The team worked with ViM staff to correct the sampling frame at the distribution site each month in order to find and enroll all children who met enrollment criteria and to exclude those who did not. Since the study was examining the effectiveness of a real-world distribution program, the most important criterion was that the child be enrolled once the ration was officially transferred from the mother to the child, even if this was done prior to or after 6 months of age.

This example reflects the reality of such programs and leads to more generalizable results. This meant that the enrollment criterion related to age was relaxed, and if children were given the ration earlier or later than 6 months, they were still enrolled. In addition, the Health and Nutrition Promoters who supervised each distribution would also sometimes transfer children to the child ration even if they were not on the list, if they noticed their birth dates were wrong and that they should have been transferred. The enumerators worked with the promoters to make sure these children got added to the lists and were enrolled.

After each distribution, the study team made lists of any children who had been on the list of eligible children that month who had not come to the distribution sites. Children were removed from these lists once they were either enrolled or reached 12 months of age (set as the upper limit on enrollment in accordance with the ViM program's age limit for enrollment). These lists were added to the ViM lists to complete the sampling frame. In addition, retrospective information on caregiver's program participation and exposure of the child to the program prior to study enrollment was collected and included in regression analysis. These methods

Case Study 2

were meant to minimize selection bias and enrollment error (e.g., children incorrectly transitioned) among study arms.

RECOMMENDATIONS

1. A clear sampling frame is essential to minimize selection bias. Prior to study implementation, researchers must understand how the sampling frame will be established.
2. A pre-testing of enrollment procedures should be used to test sampling frames
3. Researchers should expect that adaptations to sampling procedures may be needed. Sampling methods should be designed to minimize potential sampling error (e.g., differential willingness to participate; differential attrition) among the study arms.

and anticipate any issues. This will allow for sample size calculations to be adjusted if necessary, and for the addition of any necessary data collection questions that correct for selection bias based on problematic sampling frames.

4.3: Building a Strong Data Management and Analysis Plan

A data management and analysis plan (DMAP) outlines the specifics of data collection, entry, verification, validation, privacy, and analysis to be used in a study. The purpose of the DMAP is to ensure that analytic plans have been fully specified in advance, so that all essential information is included in data collection plans, including variables to be modeled and covariates to control for confounding or bias. Explicit criteria for handling missing data (e.g., loss to follow-up, missed visits, refusal) and outliers (e.g., implausible anthropometric or age variables) should be specified. The DMAP is developed as part of study design, ensuring that each research objective is fully supported by the data to be obtained; it may be modified during the study in response to new information from the field.

A strong DMAP outlines strategies for routine systematic monitoring of data quality. At a minimum, the DMAP should include descriptions of:

- protocols for data collection, data entry (when needed, e.g., for paper-based methods or transcriptions of audio recordings), data cleaning, organizing, and sharing;
- processes for routine cross-checking and verification;
- strategies for responding to data quality problems; and
- financial resources and logistical support to assure timely performance, database entry procedures, and data management coordination across partners. (USAID and the Food Security and Nutrition (FSN) Network provide further guidance on [essential elements of a DQAP](#).)

These data quality procedures function as the first line of defense against systematic errors in data collection and can reduce estimation and measurement error and bias, transcription errors, and data processing errors. For example, during one of the regular data checks in the field for the FAQR Sierra Leone [Four Foods Treatment Study](#), a data clerk was able to discern a systematic error in the incorrect translation of one survey question in one study region. This resulted in systematically different responses from participants in that region. Research staff administering the surveys were re-trained in the survey language, and data were successfully re-collected for subjects affected by the error. By conducting data checks in real time throughout study implementation, it is possible to catch and correct such systematic errors.

Procedures involved in data checks (e.g., timely data entry, double data entry, data backups, query issuing and resolution) should also be established and clearly described in the DMAP, and all relevant staff must be trained to comply with these expectations. Conducting data checks only at the end of the study can result in the considerably more difficult task of troubleshooting systematic errors in data collection without the possibility of correction.

4.4: Developing Data Collection Tools

Selecting a method for data collection depends on budget and context. Tablet-based (digital) data collection allows data to be uploaded directly into a database without the separate stage of data entry, though quality checks and resolution of inconsistencies are still needed. Aside from the cost of tablets, programming, and software, there are the added challenges of keeping tablets charged (e.g., there must be access to electricity or solar chargers) and having the financial and human resources to repair them when necessary. Paper-based data collection requires the additional step of data entry, a system for delivering completed questionnaires to headquarters for storage, and tracking their status from “delivered” to checked with inconsistencies resolved, to entered and cleaned. The staff needs and the delay imposed by the need to enter and double-enter data manually can be considerable, potentially outweighing the cost savings from forgoing the use of tablets. However, paper forms may be appropriate for some types of data. For example, in the Sierra Leone [Four Foods Treatment Study](#), paper clinic cards were kept at the clinic as long as a child was in treatment. The data collection teams must become familiar and comfortable with the data collection method chosen.

In the case of the FAQR Malawi field study, due to technological constraints in the field preventing earlier entry, data were collected on paper forms and double-entered into a data management system at the end of the study. Datasets were therefore not available for quality checking or interim analyses. This limitation led to considerable data analysis challenges. After the close of the Malawi study, the team set out to explore more efficient, consistent methods to collect, manage, and analyze data in future FAQR field studies.

As a result of this exploration, FAQR field studies in Sierra Leone and Burkina Faso employed a combination of paper-based and digital data collection. Field staff for the Sierra Leone study used a tablet-based data collection system, which included tablets, SIM cards, and [KoBo Toolbox](#) (an open-source data collection app developed by the [Harvard Humanitarian Initiative](#)). To streamline the data collection process using these tools, clinic-card data were collected on paper and then double-entered into a web-based form offline by proficient, trained data clerks. Focus group transcriptions from the Sierra Leone study were similarly transcribed, double-translated, reviewed by the field research manager, and entered into an offline form on study tablets. Offline forms were then periodically uploaded from SIM cards to the study server, at which point study managers would use KoBo Toolbox to confirm that all study activities planned for the month had been completed so that remote data managers and research analysts at headquarters could remotely access, review, and clean data. The digital approach was not without its own challenges, particularly in resource-constrained study settings. Web forms accessed on the tablet slowed down as research staff added more data to them, and delays in web form accessibility necessitated a return to paper forms for a period of time while workarounds were identified (demonstrating the need for a backup plan). By opening forms 24 hours prior to the study visit during which they would be needed, web-based case report forms were able to be used again in the field. Frequently clearing tablet web caches also considerably improved web speed for FAQR’s digital data collection.

The studies used a mix of qualitative and quantitative data collection methods, including key informant interviews and focus group discussions (qualitative), clinic data collection forms (Sierra Leone and Burkina Faso), in-depth interviews with recipient caretakers, direct observation of the entire food distribution process, and in-home observations of recipient households. In-home observations were conducted over four or five consecutive days in a subsample of recipient households to collect information on how the food supplement was stored, prepared, and fed to the recipient child; whether the food was shared with other family members or others outside the household; and other aspects of feeding of the recipient child, including breastfeeding and other complementary feeding. Data collection was paper based in Malawi and in Sierra Leone and tablet based in Burkina Faso. A female enumerator visited the household from early morning and stayed till dusk in Sierra Leone and till after the last meal of the day in Burkina Faso; they recorded relevant activities along with the start and end time of each activity. The data collection forms allowed for recording multiple simultaneous activities and for recording who participated in each activity.

The purpose of conducting these observations over multiple consecutive days was to allow households to become accustomed to the presence of the enumerator in case household members changed their behavior in response to being observed. The value of direct observation is to triangulate with data collected by self-report in in-depth interviews, and results showed that behaviors such as sharing the supplement with household members were underreported compared with direct observation but not significantly so. Direct observation also allowed for recording of behaviors that might not be reported in an interview simply because of a lack of salience: the caregiver might not be conscious of behaviors such as a child taking a small amount of food from the family pot or plate or the use of a previously used spoon to take food. The presence of enumerators in the household was largely well accepted; there were few refusals to participate. A challenge, though, was locating a safe place for the enumerator to stay overnight between visits. Arrangements were sometimes made with the village chief; in some cases, the enumerator arranged to stay in a different village household for pay. Another challenge was that households, unaccustomed to having a stranger present but not participating in the households activities, wanted to share meals with the observer or otherwise act as hosts. Enumerators were instructed to interact as little as possible, to eat before arriving and after leaving the household, to carry their own water and snacks for consumption during the observation period, and to be as unobtrusive as possible, but of course it was not possible to eliminate interaction entirely between the enumerator and the household. Nonetheless, in-home observations were a rich source of information on how the food supplements were used by recipient households.

DESIGN PHASE TAKEAWAYS

<p>Developing a Rigorous Research Design</p>	<ul style="list-style-type: none"> • Design the study to be maximally rigorous within the constraint of feasibility. • Evaluate participant selection, clustering, and randomization with statistical analysis in mind, while incorporating the realities of field conditions. Seek guidance from individuals familiar with the local context. • Revise research questions and design approaches as needed.
--	--

<p>Establishing a Sampling Frame</p>	<ul style="list-style-type: none"> • Develop a sampling frame and plan that are adapted to the logistical constraints of the study. • Consider whether a recipient-based or community-based sampling approach is more appropriate to answer specific research questions.
<p>Building a Strong DMAP</p>	<ul style="list-style-type: none"> • Build a data management and analysis plan as part of study design to ensure that all data needs have been addressed prior to data collection. • Ensure there are appropriate statistical mechanisms outlined in the DMAP to check for confounders and identify factors that might introduce bias to the study. • Clearly link every question asked to study participants and all data collected with the purpose or outcome you want to study.
<p>Developing Data Collection Tools</p>	<ul style="list-style-type: none"> • Choose a data collection method that facilitates ease of data collection, entry, quality checks, and analysis while staying within budget. • Have a pre-established plan for how to troubleshoot challenges that might inhibit regular data entry and quality checks.

5: IMPLEMENTATION PHASE

In the implementation phase, all preparatory work involved in previous stages of study development is actualized in the field. As with conceptualization and design, study implementation involves an iterative process of oversight, adaptation and refinement. It is not uncommon for a study protocol to undergo several revisions during implementation. Similarly, roles, responsibilities, logistics and resource needs often shift during study execution. As challenges arise, clear and consistent communication is a necessity. Leadership must define what is essential to successful implementation of the study design, and to keep this vision clear as the study progresses.

During the FAQR field studies, several challenges – some expected and some unanticipated – were encountered and overcome in the field. The following themes arose as key considerations in the implementation phase for FAQR field studies:

- 5.1:** Defining and Adapting Roles and Responsibilities;
- 5.2:** Obtaining Ethics Committee Approvals for Research;
- 5.3:** Collaborating with Local Implementing Partners;
- 5.4:** Cultural Sensitivity to Ensure Equitable Partnerships;
- 5.5:** Training and Managing Research Staff in the Field;
- 5.6:** Recruiting Study Participants and Minimizing Attrition; and
- 5.7:** Adapting to Unexpected Research Interruptions.


5.1: Defining and Adapting Roles and Responsibilities

Study implementation involves time-sensitive and detail-oriented activities. To maximize the likelihood that research processes occur as planned and that unforeseen challenges are resolved efficiently, all individuals involved in the study should be clear on their current roles and responsibilities. Staff must also expect that these roles and responsibilities might change over time based on needs in the field. To reduce duplicated efforts, confusion, and frustration, team members should share a mutual goal and understand how each individual’s work contributes to the overarching aims of the research. One way to achieve this clarity is by using a responsibility assignment matrix (RAM), which delineates roles, responsibilities, and expectations for large, cross-functional teams with a large variety of activities and deliverables shared among them. There are [many different RAM models](#), of varying specificity and complexity.¹¹ Select a model that is most suited to the needs of the study team, and frequently use the RAM to assess and revise workstream efficiency as study implementation progresses.¹²

Setting and reiterating expectations throughout study execution is also critically important. In both the Sierra Leone and Burkina Faso field studies, roles evolved in accordance with shifting study needs, and staff receptivity toward these shifts was variable. In some cases, staff may not be willing to perform critical research activities if those activities are not explicitly described in their scope of work or contract. In these circumstances, it is helpful to establish simple processes to update RAMs or work orders, as needed, if responsibilities change. It is also important to sensitize staff to the potential of role changes early on, to explain the importance of staff flexibility in research implementation, and to establish a clear threshold for when a role or responsibility change requires a contract amendment. Authority and responsibility for formalizing these changes lies with study team management. These considerations become even more important when collaborating with both local and international partners. An illustrative case study describing how FAQR handled these considerations in Sierra Leone can be found in **Case Study 3**.

Case Study 3

Implementation Logistics for Field Research With Multiple International Partners

<p>Author Lindsey Ellis Green, FAQR Project Manager</p> <p>Study <i>Comparative Cost-Effectiveness of Four Supplementary Foods in Treating Moderate Acute Malnutrition in Children 6-59 Months</i></p> <p>Location Pujehun District, Sierra Leone</p> <p>BACKGROUND The FAQR Four Foods Treatment Study in Sierra Leone was conducted in the rural Pujehun District of Sierra Leone. The field study involved a variety of local, national and international partners. Partners were involved</p>	 <p>in and responsible for different aspects of study implementation that operated independently but required close coordination to ensure all study objectives were achieved and that data were collected as rigorously as possible.</p>
---	---

Case Study 3

OBJECTIVES

Coordination among research partners requires effective systems, clearly outlined roles and responsibilities, and flexibility to make changes based on what is happening during study implementation.

IMPLEMENTATION CHALLENGES

- The FAQR team established systems for managing partnerships at study outset. This included formal subcontracts and memoranda of understanding (MoU) with clearly defined scopes of work and reporting lines for each partner. Care was taken to ensure that partners understood both their role and the roles of other partners. However, as the study was implemented, roles became more complex, and it was necessary to develop more detailed documents outlining the roles and responsibilities of each partner in relation to the others. These detailed documents can clarify responsibilities and avoid misunderstandings, duplication of effort, and lack of clarity as to who was ultimately in charge.
- The Four Foods Treatment Study research team was comprised of a local team based in Sierra Leone and an international team based at universities in the United States. It was important for the local and international “headquarters” teams to coordinate and communicate regularly to ensure smooth study implementation. Given the time difference, scope of research activities, staff turnover, and dynamics of implementing a rigorous research study in a challenging environment, it was often difficult to coordinate and communicate in an efficient and timely manner, but the importance of doing so was clear. Coordination and communication systems evolved during the life of the study to address these issues.
- A persistent challenge during study implementation with multiple partners was ensuring that time was made for

consistent, preemptive communication, rather than limiting communication to addressing specific problems as they arose. On a busy, fast-paced research team where there are multiple incidents occurring at once, with many priorities competing for time, the temptation was often to connect only when issues arose that needed to be addressed immediately. Communicating only when issues arise can also contribute to an isolation of research partners, which is ultimately detrimental to the overall study.

- Different research partners have different communication and coordination norms within their teams. It is important for other partners to be aware of the communications norms and decision-making “chain of command” among different partners and to be respectful of this when communicating.
- In addition to research partners, there are a variety of key partners supporting the research at the local and national level, and it is important to connect with them on a regular basis. However, without defined points of contact on the partner side or an identified “spokesperson” on the side of research partners, this task can be difficult, as local and national partners do not have a clear avenue for engaging on the research team and the research team does not have a unified plan for communicating with partners, which can lead to duplicated or delayed communication.

RECOMMENDATIONS

Field research on food assistance programs requires extensive partnerships. It is important to establish systems at the study outset focused on maintaining productive, positive and effective partnerships to ensure smooth study implementation.

- I. Establish a RAM document at study outset. This document can be bilateral or multilateral depending on the nature of the partnerships. This document

Case Study 3

- should define clear responsibilities for each partner—with as much specificity as possible—and also to establish systems for decision-making and communication among research team members.
2. Set up regular communication between the local and international research teams (e.g., weekly/biweekly check-ins). This is important for effective coordination among the entities and consistent information-sharing to identify and mitigate potential issues before they arise. Disagreements are likely to occur between partners, but having a consistent avenue for communication can go a long way in addressing disagreements productively, preserving the essential spirit of collaboration needed among research team members.
 3. Define the areas of decision-making delegated to certain team members and where full involvement of the research team is needed. There are hundreds of decisions that need to be made on a regular basis, so defining which decisions rise to the level of full team consideration is key.
 4. Ensure that scopes of work, partnerships, and roles and responsibilities are assessed and amended on regular basis (annually at a minimum) to confirm agreement on goals and objectives. Based on experience during study implementation, contractual language may need to be amended.
 5. Identify a point of contact for each participating partner to ensure clear lines of communication.

5.2: Obtaining Ethics Committee Approvals for Research

After finalizing the study protocol, data collection instruments, and informed assent and consent forms, you must apply for ethics committee approvals of the protocol and informed consent forms (ICF). The purpose of the approval process is to ensure that the welfare, rights, and interests of human study subjects are fully protected.¹³ Before it begins, any study must comply with the ethical approval process of the sponsoring institution or agency, country regulations, and the relevant in-country ethical review board.

Ethics approvals and regulatory requirements differ by country and by institution within countries. Researchers should be prepared to understand and comply with the different requirements. Preparing documents and obtaining approval from the relevant ethical review boards can require significant time prior to implementing any study activities; some review boards require payment of a submission fee. Given this variability, it has been very helpful in FAQR's field experience to have local research partners take the lead on this essential component of the research process. Regardless of who takes the lead on ethics committee submissions, it is important to respect the individuals involved in the process: go in person, explain the project in the local language, and ask for clarity on the submission process up front. Most institutions offer [guidance for the ethical review process](#).¹⁴

International studies must receive approval from all relevant ethical review boards (US and national) before study initiation.

5.3: Collaborating with Local Implementing Partners

There are several ways to cultivate successful research partnerships between US-based and local groups. First, partners can work together to establish expectations prior to study start. This can be

accomplished by collaboratively developing RAMs as described in the previous section. Next, study teams should prioritize regular meetings, in person when possible, with all the relevant partners to facilitate developing working relationships, discussing issues, and brainstorming solutions as challenges arise. It is best to include such meetings as a requirement of the contract, whenever possible, in order to ensure attendance, and also to arrange them as far in advance as possible out of respect for staff schedules. Lastly, consistent and reliable methods of communication should be used to disseminate routine updates to the entire research staff. Monitoring mechanisms should be put in place to ensure that updates are completed as planned and issues are reported to more senior levels as needed. This can be anything from posting updates on a corkboard at the study center or sending weekly email updates, as was done by the research teams in Burkina Faso and Sierra Leone, respectively.

It is important to notify staff of how they can expect to receive updates, how often to expect them, and how they are expected to act on them. They also give an opportunity to spotlight exemplary work done by research and implementing staff. In the FAQR Sierra Leone field study, study managers developed a monthly newsletter to communicate with staff in the field highlighting challenges encountered and how they were overcome. This proved especially useful when infrastructural and geographical barriers impeded in-person meetings with study teams.

5.4: Cultural Sensitivity to Ensure Equitable Partnerships

Research on food aid for nutrition is often conducted in environments that require heightened sensitivity toward awareness of differing cultures and local practices. In cases where members of a research team are foreign to the study location, it is necessary to practice humility and respect toward the local culture while also maintaining the authority and leadership needed to conduct the research trial.

As a first step, researchers should take great care to sensitize local communities about a non-local, incoming research presence well in advance of study start. In practice, this may occur by identifying key local champions with influence in their communities and asking them to spread the word about researchers coming to conduct a study, describing how long they will be there and for what purpose. Local champions should be individuals involved in the formative stage of study design. In [3.4: Identifying Partners](#), we establish that local communities and government agencies should be considered key stakeholders in the process of study ideation and design. Early collaboration with local groups might help to ensure that research aims are consistent with local practices and needs.

Equally critical, building relationships with local communities early builds trust by providing an opportunity for the community to give feedback while also increasing the spirit of local ownership over the research process.¹⁵ People in-country must have ownership over some level of the project and this ownership must be reinforced throughout the duration of the study. For a real-world example of how the FAQR research team sought to achieve equitable partnerships, refer to **Case Study 4**.

Case Study 4

Ensuring Equitable Partnerships

Author

Laetitia Nikiema (IRSS) and Ilana Cliffer (Tufts)

working together resulted in a scientifically sound and strong study with important results to disseminate.

Study

Comparative Cost-Effectiveness of Four Supplementary Foods in Preventing Stunting and Wasting in Children 6-24 Months

In this case study, we highlight a few of the major collaborative sticking points that were tackled during three main study phases: concept and design, implementation, and learning. Our hope is that through this case study, others can learn from our experiences and mistakes to improve their own collaborative experiences.

Location

Sanmatenga Province, Burkina Faso

CONCEPT AND DESIGN PHASE

INTRODUCTION

Collaboration among multiple institutions, especially among those based locally and any international institutions, is essential to the success of any field research project, as it allows for reciprocal knowledge sharing and accomodation of differences of perspective that ultimately lead to stronger results.

Collaboration between entities began prior to conducting the field research in Burkina Faso. Ensuring equitable partnerships from the beginning stages of study conception and set-up establishes the tone for the duration of the collaborative period. Before IRSS was selected to collaborate with Tufts University, the Tufts team made an initial attempt to have the research protocol approved by the Burkina Faso ethics committee and was faced with a rejection. In their comments, the ethics committee required Tufts to identify a collaborative structure at the national level for study implementation. Not only was this necessary for ethics approval but it was essential to the overall success of the project.

The goal for such collaborations should be that they be equitable, open and respectful. Differences among the backgrounds, culture, communication styles and institutional expectations of different collaborators can pose challenges to smooth collaborative experiences. However, if these differences are understood by all partners before they enter into a collaboration, no issue is too large to be worked out.

Collaboration between IRSS and Tufts began when Tufts launched a call for applications to identify a collaborative structure in Burkina Faso for the implementation of the research. In response, IRSS compiled a multidisciplinary team composed of researchers in public health, nutrition, statistics, epidemiology, and sociology to compete with other local teams. The technical proposal submitted by the IRSS team included plans for study implementation procedures, quality control of data collection, practical and logistical organization in the field, and a budget proposal including justification of each budget line.

During a field research study on the comparative cost-effectiveness of four supplementary foods in the prevention of undernutrition, conducted in Burkina Faso, Tufts University and the Institut de Recherche en Sciences de la Santé (IRSS) were study implementation partners. Collaboration between the two entities was not always easy, but through trial, error, and rectification, ultimately, not only was the experience positive for both partners, but the combination of the two institutions

Once IRSS was selected as the partner,

Case Study 4

Tufts and IRSS held meetings to discuss the technical aspects of IRSS' proposal for study implementation in detail, enabling IRSS to justify the field procedures proposed. These discussions and the extensive experience of the IRSS team on similar projects in the context of Burkina Faso was essential in establishing a realistic research protocol that considered the realities on the ground.

In addition, IRSS took the lead in gaining ethical clearance in Burkina Faso, while Tufts took the lead in navigating the United States ethical approvals. Considering the specific needs and ethical requirements of each partner country, the combination of the two institutions' technical skills not only helped to improve the research protocol and data collection tools, but it also helped facilitate the swift approval by each country's ethics board.

IMPLEMENTATION PHASE

Challenges with collaboration during the study implementation phase occurred in two main areas: technical and administrative.

On the technical side, strong-willed and opinionated researchers from various scientific backgrounds did not always agree about the most appropriate, feasible and scientifically valid methods for study implementation steps such as enrollment, data collection, and data management. At the beginning of the collaborative process, debates centering around scientific points had the tendency to result in dead-ends or prickly conversations with resolutions that only satisfied one side or the other. After some time working together, however, a few changes greatly helped make this essential collaborative process into a truly mutually beneficial environment.

Concretely, the addition of a neutral third-party assistant to the team, who had extensive experience working as a cultural guide to Americans in Burkina Faso, was crucial in fostering better relationships among team members. She was able to see where communication breakdowns were happening

and counsel both sides toward more positive ways of communicating their ideas. Perhaps the most important realization for both entities was that individual players from each institution were so passionate about their arguments because they so badly wanted the research project to be successful. Discussions among the team about this realization were essential to laying tensions to rest and beginning anew with a true team spirit. Once all players realized that we were, in fact, one team, and needed to function like one team for the success of the project, the collaborative efforts became a true partnership where scientists could respectfully debate the merits of each other's arguments for the betterment of the project.

Administratively, differences between the two institutions' processes caused friction. Budget rectifications were one of the most challenging aspects of the partnership for several reasons. As IRSS was technically a sub-contractor of Tufts University, the IRSS team was required to submit budget rectifications to the Tufts administration. The Tufts administrative team had certain expectations and regulations that were difficult, and sometimes impossible, for the IRSS administrative team to comply with, causing frustrating delays in payment to the IRSS team. In addition, IRSS had a hard time adjusting their usual methods to fit the requirements of the Tufts administration, even when it was possible to do so.

Both partners made initial assumptions about how the funds would be handled, and it took time to get in sync with each other. For example, IRSS was not accustomed to supplying individual receipts for each transaction, producing documentation of the exchange rate supplied by the bank or doing monthly budget rectifications (as opposed to yearly budget rectifications). In addition, originally the IRSS team was expected to use all their advance money and rectify the expenses before getting the next tranche of funds for study activities. This was impossible for the IRSS team, because if they waited

Case Study 4

until they had spent all of their study funds to send in justifications, they would have no money to continue study activities for weeks at a time. This paradox of the Tufts team saying they needed IRSS to deplete their funds before sending more and IRSS not being able to front money on research activities during lag periods was a considerable hurdle in the study's beginning stages.

Eventually, through collaborative communication about this issue, the Tufts team agreed to send two months' funding at one time and allow the IRSS team always to have one month's worth of overlapping funds. Other issues with budget rectifications occurred when there were discrepancies between IRSS calculations and those of Tufts in terms of how much money had been spent. For the first few months of the project, IRSS was not keeping the funds in a separate bank account devoted only to this project, which made accounting difficult. Once IRSS obtained a bank account solely for our collaboration, solving such discrepancies became much easier.

LEARNING PHASE

During the data analysis phase of the study, both entities worked to maintain equitable contributions to, and ownership over the study and dissemination of the results. The combined IRSS-Tufts team worked together to come up with the analysis plan and ideas for papers, as well as to plan dissemination presentations and meetings. Clear expectations were set about authorship standards, and each paper idea was assigned a primary point person.

While Tufts members had final responsibility for and were required by the grant funder to be the primary point person on the main results documents, care was taken to distribute responsibility for any additional ideas between IRSS and Tufts members.

Challenges in this area stemmed from the unequal structural and human resources capacity of IRSS compared to Tufts. The

reality was that Tufts had more institutional bandwidth to conduct analyses, given the manpower dedicated solely to that task. The IRSS team was more constrained by limited time resources, since funds at IRSS were more limited, and there was not an equivalent staff member hired solely for data analyses. The senior IRSS team members would therefore have had to conduct the analyses themselves as well as write the papers and manage their numerous other projects. This inherent unevenness in resources was difficult to navigate in terms of equity in partner relationships.

Ultimately, each institution did what they could to support each other in their responsibilities, and authorship on the papers reflected the real level of input received from each individual, regardless of their institution. When appropriate and possible, authors from each institution were listed in a combined and equitable manner.

RECOMMENDATIONS

The following points stem from the lessons learned through trial and error during our research study in Burkina Faso. This list is not exhaustive but can serve as helpful reminders to those embarking on new collaborative projects:

1. Partners should see each other as equally important contributors to the research and assume that each institution's representatives want the best outcome for the project.
2. Roles, not only of each institution, but of each individual involved in the study from the different institutions, should be clear before the collaborative process begins. This can aid with transparency, avoiding duplication of efforts, and establishing trust and expectations between the institutions.
3. Presence of cultural guides who can mediate between different communication

Case Study 4

styles and scientific debate norms make communication and collaboration smoother.

4. Ensuring mutual understanding of each other’s administrative constraints and regulations is important to avoid frustrations and delays of project activities.

CONCLUSIONS

These lessons learned in fostering a true and equitable collaborative spirit are important to future research projects. While it is challenging to achieve, it is essential to both the success of the research study and the advancement of all institutions involved.

5.5: Training and Managing Research Staff in the Field

A rigorous process for selecting, training, and managing enumerators is needed for smooth study implementation. In the context of FAQR field studies, enumerators were charged with the responsibility to support all study activities on the ground, including survey pretesting, sampling, data collection, and participant follow-up. In general, enumerator training should ensure that field staff:

- understand the study protocol and how to implement it;
- understand the study’s data collection instruments and how to use them;
- adhere to data quality activities, as outlined in the DMAP;
- are aware of study data collection, sampling, and recruitment procedures; and
- understand when, how, and to whom to escalate issues that arise.

It is useful to train more enumerators for the study than you will ultimately need, so there is a group of trained potential field staff to fill in in cases of illness or staff turnover. This strategy proved useful for the FAQR field study in Sierra Leone, which established a successful process for recruiting and training field enumerators. This process is outlined in greater detail in **Case Study 5**.

Case Study 5

Using Enumerator Training to Field Test Survey Tools

Author

Stacy Griswold, Study Lead

Study

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

Location

Pujehun District, Sierra Leone

BACKGROUND

Successful enumerator trainings require careful thought devoted to their design that considers mode of delivery, the subject material, and the background of both the enumeration team and the population being studied.^{16,17} During the training, the research team must standardize data collection protocols and survey questions by using participatory methods that engage adult learners effectively.^{18,19}

CHALLENGE

Unforeseen implementation delays prevented pretesting survey instruments before

Case Study 5

enumerator training began. The research team needed to provide opportunities for enumerators-in-training to practice the interviews in real-world settings and to pretest the survey without causing additional delays in data collection.

PROS:

- **Identifying enumerator bias:** Since the enumerators were more educated than respondents, there was a disconnect between what enumerators believed they were asking and what respondents believed they were being asked. The research team identified this issue in the first group of surveys pretested during the training and corrected these biases in a standardized way across enumerators in the classroom.
- **Empowering enumerators:** Enumerators transitioned between the roles of student and teacher, sharing with the class their experiences from pretesting. This approach encouraged enumerators to learn from each other rather than strictly from the researcher-trainer, giving them ownership of their learning process and improving the quality of interviews. Enumerators practiced lessons learned from colleagues during their own pretesting practice, rapidly improving the quality of practice interviews.
- **Pre-testing data collection tool changes:** Tools translated into different languages require adjustments to the translation to account for local dialects, slang, etc. Pretesting the survey during training gives the research team time to correct translation misalignments and gives the class an opportunity to discuss and agree upon the correct translation. This has the additional benefit of increasing knowledge retention resulting from the class/group discussion.
- **Cost-effective:** Using training time to pretest the survey removed the need for a separate pretesting activity either before

or following the training. When budgets are tight, this allows resources to be reallocated for refresher trainings or other field activities. For a study of several months or longer, refresher trainings are essential, especially after any vacation period.

CONS:

- **More time-intensive:** combining pretesting into enumerator training requires more planning and time from the research team both before and during the training. The team needs to: manage logistics for the training and for the pretesting; facilitate the translation of lessons learned into robust and common understanding among the enumerators; and capture all recommended changes to the survey tools. This level of multitasking increases the chance that the research team may inadvertently omit a recommended change or poorly facilitate a translation modification. Careful planning and time management are essential.

RECOMMENDATIONS

Cooperative learning techniques such as role plays and group-based problem-solving exercises are common training techniques meant to provide opportunities for practicing interviews (both quantitative and qualitative) and for the research team to give feedback to improve enumerators' interview skills.^{20,21,22,23} However, the usefulness of these techniques is limited by the imagination and may not reveal errors that could occur when enumerators are confronted with situations not considered in the classroom. They are also limited by time—the researcher needs to evaluate how well each enumerator can deliver the entire survey without either taking up limited classroom time or creating an unengaged class. To address these limitations, organizations have recommended incorporating survey pretesting activities into enumerator training to serve as the field setting practice module.²⁴

Case Study 5

In any case, enumerator training should include at least one field-based practice with a follow-up debrief in the classroom.

Ideally, pretesting would occur before enumerator training begins.²⁵ Unfortunately, for myriad reasons like logistics constraints or delays in ethical approval, pretesting may occur after enumerator training is complete. In such situations, it is critical to bring enumerators back into the classroom to share and agree on any changes made. Integrating pretesting into the training process allows researchers to observe their enumerators-in-training out of the classroom, pretest the survey instrument and ensure that enumerators are “up-to-date” on how to conduct the interview.²⁶ In Sierra

Leone, where FAQR implemented the Four Foods Treatment Study, survey pretesting was the last module in the enumerator training.

CONCLUSION

Combining survey pretesting with enumerator training is a dual-purpose approach to study implementation. It provides real-world opportunities for enumerators to practice conducting the interview and allows the research team to identify necessary changes to the data collection tools. However, this approach is labor intensive, requiring greater coordination and planning than if these two activities were discrete activities.

To summarize, the FAQR study team in Sierra Leone trained 40 potential enumerators for the study, who were competing for 20 total spots. Training activities included written, oral, and field exams that tested enumerators’ knowledge of the study protocol, sampling plan, and survey tools and allowed for observation of their behavior in the field. The training stage for enumerators served the additional purpose of survey pretesting and validation in the field. The competitive training environment among enumerators established a high standard for quality of field work, higher engagement in training sessions, and a practiced knowledge of study procedures prior to study start.

For survey research, enumerators must be trained not only on the survey questionnaire itself, but specifically on how to ask survey questions with awareness of local language nuances and the intent of each question to prevent systematic errors in data collection.²⁷ Enumerators must ask and explain survey questions consistently to all study participants, and it is the responsibility of research management to equip field staff with the knowledge and tools for consistent survey delivery. The local language in Sanmatenga Province, Burkina Faso is not a written language, so to ensure consistent translation from the (written) French, the local research staff recorded the correct phrasing to provide to enumerators. Creating audio recordings for enumerators was an effective strategy to ensure consistent survey delivery.

To increase the reliability of data, all field staff must be trained and periodically retrained to a rigorous standard of intra- and interobserver reliability on specific procedures and best practices for anthropometric measurements, questionnaires, and study objectives. Additionally, retraining should be done every 3 months to ensure skills do not deteriorate. Most research on food assistance for nutrition includes the collection of anthropometric measures of children, which are particularly difficult to collect in the field, especially when multiple field staff are involved. Having one regular staff member on site who is tasked with overseeing the collection of anthropometric data promotes consistency in how different field staff collect the data. It is standard practice to take each anthropometric measurement twice, nonconsecutively, and to take a third measure if the two diverge by more than a given value.

5.6: Recruiting Study Participants for Adequate Sample Size

Subject recruitment in the field may encounter challenges that require the recruitment plan to be adapted. For MAM and SAM treatment, recruitment is often conducted at clinics, where subjects are drawn as they are enrolled in supplementary or therapeutic feeding programs. Community screening events hosted by the research staff can also be organized to support study recruitment. In Sierra Leone, staff at clinics that were not part of the study knew that they could refer MAM cases to one of the clinics where the children could be enrolled.

In practice, recruitment strategies must align with the sampling plan and appropriately target the intended sampling unit as outlined in the study protocol.²⁸ In the Burkina Faso field study, for example, the sampling frame for one component of the study was a list of names of women identified as lead mothers in the Sanmatenga Province. “Lead mothers” are community role models elected by their communities to communicate behavior-change messages to program recipients. To access the intended sampling unit, lead mothers were randomly selected from the sampling frame, and enumerators were sent to find them using the subject’s latest documented address per implementation partners’ records. Some mothers included in the list were no longer serving as lead mothers; some names were incorrectly recorded; and the team was unable to locate some mothers. To address these challenges, FAQR research staff refocused their efforts to ask: what is the sampling unit that we are interested in accessing? In this study, their answer was: the position of the lead mother in that sampling region, not the particular individual who had held the position at one point in time. The research team then established a consistent process to be followed by enumerators: if the assigned lead mother was no longer in the position of lead mother, the new lead mother was identified by community members; the enumerator then interviewed that lead mother and updated study records accordingly. The example outlined above illustrates the value of adapting the recruitment plan based on the underlying purpose of the study.

Another challenge is that of sample size. If recruitment is falling short of targets, it may be that assumptions about the size of the target population were based on inaccurate information as was the case in Sierra Leone. Ideally, the validity of data used to identify study sites should be verified in advance of implementing the study. If this is not possible, and sample size is falling short of expectations, the options are to extend the period of the study until targets are reached or to add study sites. If neither of these is possible, then researchers will need to redo power calculations in order to determine the level of precision that is possible with the sample size that can be reached. It may be that inclusion and exclusion criteria are too restrictive. As inclusion and exclusion criteria are intended to control for potential confounding variables in the study, every effort should be made to ensure that these criteria stay consistent throughout the study. If it becomes necessary to revisit these criteria after subject enrollment has begun, changes in inclusion and exclusion criteria should be accounted for in data analysis and explicitly stated in dissemination of results.

5.7: Adapting to Unanticipated Events

While the design phase should consider potential challenges faced in the field, it can be difficult to plan for all situations. Unanticipated events like these must be addressed during the implementation phase. The first iteration of the FAQR [Four Foods Treatment Study](#) in Sierra Leone was interrupted in 2014 due to the West African Ebola Virus Disease epidemic, which made it impossible for research staff to travel to and from study sites, generated distrust of healthcare workers, and resulted in a decrease in enrollment of and participation by study subjects.²⁹ Data collection was

suspended at all 20 study sites in July 2014, and research activities were terminated in October of that year. The research team informed all recipients and peripheral health unit (PHU) staff of the suspension and provided a four-week supply of food to each site assigned based on current SFP enrollment. All contracts of local FAQR field staff were terminated by the end of August 2014, and the two field-based study coordinators returned to the United States to complete data entry and to identify potential countries to which the Four Foods MAM Treatment Study could be relocated. Ultimately, a new site was not selected, and research activities resumed in another district in Sierra Leone in 2017 when the outbreak was fully contained. Due to early termination, the study was limited in a number of important ways, including failure to achieve the targeted sample size, inability to collect sufficient cost data related to transportation and distribution of study foods to fully assess cost-effectiveness, and the possibility of bias being introduced between those who reached a particular study outcome prior to the suspension and those who did not and whose outcomes were therefore unknown.

While not all research requires epidemic preparedness, the experience of the FAQR team underscores the importance of forming strong partnerships with host country partners and being prepared to develop alternative research strategies when unexpected events occur. The COVID-19 pandemic is another example of an unforeseeable circumstance that has interrupted field research projects around the world. While some research simply cannot or should not continue during a global pandemic, it is possible that research may continue under the supervision of in-country partners. One option is to shift the existing resources to focus on continuing care for subjects already enrolled in a study, especially if the potential benefits to subjects outweigh the potential risks.³⁰ This approach is dependent on in-country circumstances, such as stay-at-home orders or risk due to political unrest. This shift may be outside the control of the individual study, but if it is, it should be decided by the PI and approved by the respective IRB institutions.

Challenges of shifting to remote research:

- The research team must rely heavily on in-country research partners to proceed with data collection and study management.
- The remote research team might only be able to receive data at the end of the collection process, thereby limiting their ability to address discrepancies.
- Shifting to remote research requires a transition period for the reestablishment of roles and responsibilities and communication methods, potentially losing time for data collection.
- For food assistance research, supply chains may be disrupted, which could impede the distribution of study foods and other essential supplies.

While continuing research remotely is possible, the change in the context likely affects the research study in many ways, and researchers must be prepared to suspend activities, if warranted or if required by the host country or the research institution. Public health emergencies, such as the COVID-19 pandemic, may insert bias into the study, given school closures, food price changes, and the stress on the health care system. The sample size may also significantly decrease due to attrition caused by the external factor. In the case of the FAQR [Four Foods Treatment Study](#) in Sierra Leone, we were able to resume the study once conditions had settled. However, the differences in context and study location meant that the 'resumption' was in fact treated as an entirely new study; data from the previous study were not incorporated. In any case, the safety of research team members and study participants comes first, an emergency exit strategy should be included in the study design.³¹ Finally, funders and all research partners should be made aware of impending changes.

IMPLEMENTATION PHASE TAKEAWAYS

<p>Defining and Adapting Roles and Responsibilities</p>	<ul style="list-style-type: none"> • Use role and responsibility assignment matrices (RAMs) to assure efficiency throughout the research process. • Sensitize staff to the possibility that roles and responsibilities may change over the course of study implementation. • Establish simple methods to update work orders as needed.
<p>Obtaining Ethics Committee Approvals for Research</p>	<ul style="list-style-type: none"> • It is helpful for local research partners to take the lead on the in-country ethics committee submission process when possible. It is best to explain the project in the local language and get clarity on the process up front.
<p>Collaborating with Local Implementing Partners</p>	<ul style="list-style-type: none"> • Establish expectations, roles and responsibilities, and decision-making authority prior to study start. • Conduct weekly meetings with all partners to discuss issues and develop mutual solutions. • Develop consistent, routine, and accessible methods to disseminate communications to all partners.
<p>Cultural Sensitivity to Ensure Equitable Partnerships</p>	<ul style="list-style-type: none"> • Strike a balance between humility, respect and deference to the local culture, and the authority and leadership needed to conduct the study. • Establish and continuously review expectations by creating opportunities for honest, bidirectional feedback. • Seek help from local partners to navigate differences in culture and communication styles with clarity and diplomacy.
<p>Training and Managing Research Staff in the Field</p>	<ul style="list-style-type: none"> • Establish a rigorous process for selecting enumerators invested in the research and train more individuals than the minimum needed to conduct the research. • Provide extensive training on anthropometric measurement procedures and standardize data collectors to a strict criterion of reliability and precision of each measurement. • Conduct periodic retraining on anthropometry, data collection instruments, and study objectives for research lasting more than two months.
<p>Recruiting Study Participants and Minimizing Attrition</p>	<ul style="list-style-type: none"> • Be prepared to adapt subject recruitment processes and retrain staff accordingly if recruitment plans fail to yield the required number of subjects. • If recruitment is an issue, revisit background data, inclusion/exclusion criteria, and other study-specific factors possibly inhibiting recruitment.

Adapting to Unanticipated Events

- In some unforeseen circumstances, field research cannot or should not continue.
- When research is interrupted it may be possible to resume, though changes in context may influence the data.
- Shifting to remotely managed research requires strong in-country partners, excellent communication, and a reevaluation of the DMAP.

6: LEARNING PHASE

Translating study data into actionable results is the final stage of study execution. During this stage, the planning done in study conceptualization and design and implemented in data collection comes to fruition. Data analysis should be performed on an ongoing basis while data are being collected in order to fine tune analytic models and identify any inconsistencies or issues to be addressed while data collection is still ongoing. Final data analysis, though, is done once all data monitoring activities are completed in preparation for study closure, data managers have finalized data cleaning and have archived the data according to procedures outlined in the study DMAP. Analysis is done collaboratively, as specified in the study's roles and responsibilities documents; preliminary results of analysis should be shared with stakeholders for their feedback and insights. As final analysis progresses, results are reported in a range of formats and venues, including reports to funders, dissemination events, participation in conferences with presentations and posters. Partners, funders, recipient populations, and other stakeholders are debriefed on the results of the study, and planned research uptake activities are conducted to share the results with a policymakers and program implementers who will apply the results, as well as with the broader population. The recommendations arising from these studies are likely to be adopted to the extent that the study responds to concerns and needs of the organizations designing and implementing food aid programs for nutrition.

The strategy to ensure uptake of research results, which was integral to the FAQR field research dissemination, involved three steps, detailed below. For reference, reported materials from all FAQR field studies can be found at the [FAQR Research](#) page. The following steps were taken for all FAQR field studies after the completion of data collection:

- 6.1:** Analyzing the Data and Assessing Fidelity of Program Implementation;
- 6.2:** Debriefing Partners, Funders and Recipient Communities; and
- 6.3:** Research Dissemination

6.1: Analyzing the Data and Assessing Fidelity of Program Implementation

During this phase, data analysts familiar with the subject matter, outcomes, indicators, and context of the study follow the data analysis plan to answer the research questions established during study conceptualization. Analysts should pay close attention to account for any missing data, attrition, systematic errors, or possible confounders that might bias or otherwise affect the results. This is particularly important for quasi-experimental study designs that depart from strict RCT designs, which are commonly used in food aid and food assistance research. An example is the effectiveness and cost-effectiveness trial conducted in Burkina Faso, in which randomization was clustered, so that the comparability of study arms is dependent upon statistical controls.

In addition to analyzing data and presenting results, the study should be a learning opportunity for future studies: data collection tools and methods, realistic timelines, lessons learned about recruitment, training, supervision, and field work. This analysis of fidelity will include an assessment of whether the intervention was implemented as planned to determine whether any results are due to the intervention or to differences or failures of implementation (e.g., intermitting delivery of the study food, spoilage of one of the foods but not others). Fidelity evaluations might aim to:

- Gauge the degree to which partners adhered to terms of collaboration;
- Compare the achievements of the project to its intended aims;
- Assess the utility of data collection tools or other study technologies;
- Compare projected timelines with actual timelines; and
- Evaluate the sustainability of interventions used in the study.

These evaluations are a critical opportunity to show the practical and operational value of chosen implementation strategies to funders. Even in cases for which formal evaluations are not required by the funder, the learning and uptake phase of study execution offers the research team an opportunity to further debrief internally on their experiences from the study—strengths, challenges, strategies, next steps—with the aim to strengthen future research capacity.

6.2: Debriefing Partners, Funders and Recipient Communities

Research partners must be debriefed on the results and lessons derived from the study and for funded research, it is best practice to ensure that any reporting requirements outlined in the terms of agreement are included in the final report. In addition to reviewing strengths and challenges encountered during study execution, this phase constitutes an important opportunity to present results relevant to the specific stakeholder and get their feedback.

If roles, responsibilities, and expectations were explicitly outlined prior to study execution, this debrief can serve the dual function of a research update and a mutual performance review of the partnership. Funders will similarly have an opportunity to assess whether research teams consistently adhered to the terms of their partnership and met specified reporting requirements. Funders and other stakeholders may also be interested in preliminary results prior to full data analysis and dissemination. In this case, research teams can prepare and present a preliminary analysis, with the caveat that further data cleaning and analyses are needed to confirm final results. When presenting preliminary findings, research partners might also update funders and other partners on final analysis and dissemination timelines and work collaboratively to organize joint research uptake activities. These discussions may naturally yield opportunities to identify future research questions and possibilities for future partnerships.

6.3: Research Dissemination

Plans for sharing study results and promoting research uptake should be discussed and established during the concept phase and revisited several times prior to study closure.³² By devising an uptake strategy early and identifying both local and non-local strategic partnerships to realize that strategy, research staff can work to ensure that all relevant stakeholders stay engaged with the study throughout its duration and that the target audience for the research is reached. To achieve this aim, final products outlined in the research uptake strategy must be drafted, disseminated, and publicized with the help of strategic partners. Research teams must also consider whether or not published results will be open-access or for a restricted audience. **Table 4. Developing a Research Uptake Strategy Outline** depicts the key outputs and dissemination planning for food assistance for nutrition research.

Table 4. Developing a Research Uptake Strategy Outline			
<p>Author Lindsey Ellis Green, FAQR Project Manager</p> <p>CHALLENGE The key outputs of any field study are the findings and their interpretation based on the collection and analysis of data. Planning for the dissemination of these findings is a key activity of the research team. It is wise to develop a research uptake strategy at study outset to ensure that there is intentional consideration of how findings will be packaged and communicated as a direct response to the programmatic questions addressed in the study. Funders themselves may have specific requirements for dissemination of research results that will be part of the uptake strategy.</p>	<p>BACKGROUND The focus areas of FAQR were strengthened by research outputs and categorized into these workstreams:</p> <ul style="list-style-type: none"> • Programming • Cost effectiveness • Processes: food safety, supply chain, industry standards • Evidence and research agenda • Food aid products: innovations, ingredients, matrices, packaging • Influencing policy: interagency harmonization 		
<p><i>The following elements should be considered when putting together a strategy to ensure uptake of the research results:</i></p>			
Output Development	The form(s) in which research results are disseminated.		
Support for Communication	Strategies by which outputs are shared and capacity is built to translate outputs into policy and practice.		
Stakeholder Engagement	Defining relevant stakeholders for each output and tailoring output sharing to specific stakeholder groups to ensure maximum research uptake.		
Monitoring and Impact Assessment	Tracking the success of output dissemination, supporting communication and stakeholder engagement to support research uptake and sustained engagement with FAQR research outputs.		
<p>OUTPUT DEVELOPMENT <i>What form will the output take?</i></p> <table style="width: 100%; border: none;"> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> • Report • Protocol/Guidance Document • Publication (e.g., published journal article/manuscript) </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> • Tool/Model • Workshop/Meeting presentation • Summary Document (fact sheet, infographic) </td> </tr> </table>		<ul style="list-style-type: none"> • Report • Protocol/Guidance Document • Publication (e.g., published journal article/manuscript) 	<ul style="list-style-type: none"> • Tool/Model • Workshop/Meeting presentation • Summary Document (fact sheet, infographic)
<ul style="list-style-type: none"> • Report • Protocol/Guidance Document • Publication (e.g., published journal article/manuscript) 	<ul style="list-style-type: none"> • Tool/Model • Workshop/Meeting presentation • Summary Document (fact sheet, infographic) 		

SUPPORTING COMMUNICATION

What communications tools will be used to share and promote the output?

- Webinar/Seminar
- Conference presentation (oral or poster presentation)
- Meeting and dissemination event
- Posting to FAQR website, listservs, communities of practice, and social media
- Announcement and press release

STAKEHOLDER ENGAGEMENT

Which stakeholder groups are the targets of this output?

Policymakers & Funders

- Includes United States and international government entities (USAID, USDA, WFP, WHO) that fund, facilitate, and design policies around food aid. FAQR activities and research results can provide insight into the impact of existing food aid programs, means for improving impact or cost-effectiveness, influence agenda and priority setting, and offer best practices for programs.

Researchers

- Includes organizations that engage in the research and studies of food aid policies, products, and processes, which can benefit from the results of FAQR activities and research findings in their studies.

Industry

- Includes private sector actors who supply, develop and transport food aid products. They can refer to FAQR research on product formulation, innovations and optimization of food aid processes.

Practitioners & Implementers

- Includes organizations that manage and deliver food aid programs during humanitarian emergencies and as part of development projects. FAQR activities and research findings can influence programmatic decision-making,

MONITORING AND IMPACT ASSESSMENT

How does this research continue to be relevant and impact the future of food assistance for nutrition?

Efficiency Gains

- Use of tools to support decision-making, program or operational changes, improvements to USAID/FFP systems and processes

Evidence Generation

- Application of new knowledge, information dissemination, policy change

Enhanced Collaboration

- Capacity-building, public-private partnerships, adapting industry standards

RECOMMENDATIONS

For the FAQR team it was useful to apply key topics to each planned output in order to ensure that the ways outputs fit together or were reinforced were clearly considered.

Note that as the FAQR project encompassed research beyond the field studies referenced in this document, the project's Research Uptake and Sustainability Strategy (RUSS) encompassed more than 15 outputs from 9 different research workstreams.

The RUSS was compiled during project implementation, but it is recommended to begin construction of a research uptake strategy at the beginning of study conceptualization so that resource needs (pictures, data, information) for the RUSS are met during study implementation and to ensure communication with potential research stakeholders is initiated as soon as possible.

LEARNING PHASE TAKEAWAYS

Analyzing the Data and Fidelity of Program Implementation	<ul style="list-style-type: none">• Formulate analysis plan prior to data collection and initiate the analysis before data collection is complete to test methods.• Pay attention to confounders that may bias results and include these in study limitations. Use statistical controls to account for variables that may influence comparability of study arms, especially for non-experimental and quasi-experimental study designs.• Conduct process evaluations to allow for attribution of study results by assessing whether the program being studied was implemented as expected.• Use informal evaluations among study team members to distill lessons learned and improve future research capacity.
Debriefing Partners, Funders and Recipient Communities	<ul style="list-style-type: none">• External study debriefs following study closure serve the purpose of a preliminary research update, an evaluation of the overall research partnership, and an opportunity to discuss and plan future research activities.
Research Dissemination	<ul style="list-style-type: none">• Research uptake strategies developed earlier in the study are applied after final analysis to achieve maximum impact.• The intended outcome of research uptake activities is to ensure that research outcomes inform future programs and policy.

7: KEY TAKEAWAYS

The FAQR team credits its success to a balanced ability to plan carefully and adapt strategically. By distilling and disseminating our field-based lessons learned alongside best practices in research, we hope to contribute to the research community's aim to respond more efficiently and effectively to global food assistance efforts. The key considerations described in this report are summarized below:

1. Invest ample time in crafting clear research questions that can be translated into validated, measurable variables and a rigorous study design.
2. Conduct landscape reviews and formative research, including scoping trips, to refine the study approach and assess feasibility of implementation.
3. Establish realistic timelines and resources.
4. Design the study to support the analysis. Incorporate realities of the field research and programmatic constraints into those decisions.
5. As decisions are made during the study, keep the vision and fundamental aims of the research at top of mind.
6. Make cultural awareness and equitable partnerships a cornerstone of the research team and actively seek feedback about cultural appropriateness of activities and behaviors.
7. Involve local communities by making them aware that the study is occurring to enhance their cooperation and increase the likelihood of smooth study implementation.
8. Focus on strong collaboration among research and implementation partners, and establish clear and specific roles, responsibilities, and expectations for all team members.
9. Invest in developing a strong, clear and comprehensive data management plan, including clear allocation of responsibilities.
10. Staff field teams with well-trained, subject matter experts familiar with the geography and local language(s); include a rigorous selection process with adequate training and retraining and regular supervision.
11. Study team members must develop a shared sense of accountability for collecting quality data. The success of the study depends on the quality of the data collected.
12. Communicate team accomplishments and challenges regularly. Systematize feedback mechanisms between field and remote teams.
13. Revisit, review, and come to agreement on evolving roles and responsibilities of team members.
14. Develop and implement a research uptake strategy for communication of results to organizations that can potentially use them.
15. Reflect on study processes, partnerships, challenges, and successes to inform future research programs design and collaborations.

ACKNOWLEDGEMENTS

This report would not be possible without the qualitative interviews provided by Lindsey Ellis Green, Ilana Cliffer, Stacy Griswold, Breanne Langlois, Ye Shen, Devika Suri, Shelley Walton, Beatrice Rogers, and Patrick Webb. The time and support offered to the Food Aid Quality Review by the Implementing Partners, volunteers, and local partners involved in the three field studies conducted by the FAQR team were invaluable, not only for a successful implementation of the studies, but also for informing this report.

REFERENCES

1. REFINE Nutrition, <https://refinenutrition.org/about-us>. Accessed July 6, 2020.
2. Webb, P; Rogers, B; Walton, S; Boiteau, J; Schlossman, N; Johnson, Q; Koepfel, L; Suri, D; Langlois, B; Vosti, S; Rosenberg, I. 2016. [Food Aid Quality Review Phase II Close-Out Report, Report to USAID from the Food Aid Quality Review](#). Boston, MA: Tufts University.
3. Babbie, E. "The Practice of Social Research". 13th, Int. ed. Cengage Learning. Ch 3 (2012).
4. Vastine, A., Gittelsohn, J., Ethelbah, B., Anliker, J. and Caballero, B., 2005. [Formative research and stakeholder participation in intervention development](#). *American journal of health behavior*, 29(1), pp.57-69.
5. Action Against Hunger "[Designing and Managing Research Projects: A Practical Guide for Fieldworkers](#)" (2016)
6. Bhutta, Z.A., Das, J.K., Rizvi, A., Gaffey, M.F., Walker, N., Horton, S., Webb, P., Lartey, A., Black, R.E., Group, T.L.N.I.R. and Maternal and Child Nutrition Study Group, 2013. [Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost?](#) *The lancet*, 382(9890), pp.452-477
7. de Pee, S., Grais, R., Fenn, B., Brown, R., Briend, A., Frize, J., Shoham, J. and Kiess, L., 2015. [Prevention of acute malnutrition: distribution of special nutritious foods and cash, and addressing underlying causes—what to recommend when, where, for whom, and how](#). *Food and nutrition bulletin*, 36(1_suppl1), pp.S24-S29.
8. Martineau, T. (2016). [USAID Food For Peace FY 2016 Food Assistance Tables](#). USDA, & USAID. (2015). U.S. International Food Assistance Report, 58.
9. Webb, P., Rogers, B., Rosenberg, I., Schlossman, N., Wanke, C., Bagriansky, J., Sadler, K., Johnson, Q., Tilahun, J., Masterson, A.R. and Narayan, A., 2011. [Delivering improved nutrition: recommendations for changes to US food aid products and programs](#). Boston, MA: Tufts University.
10. Stukel, D., and M. Deitchler., 2012. [Addendum to FANTA Sampling Guide by Robert Magnani \(1991\): Correction to Section 3.3. I Determining the number of households that need to be contacted](#). Washington, DC: FHI 360
11. Villanova University, 2019. Project Management: [How to Streamline Roles and Promote Team Collaboration with an Effective RACI Chart](#). Accessed January 2021.
12. Melnic, A.S. and Puiu, T., 2011. [The management of human resources within projects: the structures of the project team, the responsibility assignment matrix](#). *Economy Transdisciplinarity Cognition*, 14(1), p.476.
13. Council for International Organizations of Medical Sciences, 2002. [International ethical guidelines for biomedical research involving human subjects](#). *Bulletin of medical ethics*, (182), pp.17-23.
14. Tufts University. Office of the Vice Provost for Research. [HS IRB International Research Guide](#). Accessed December 2020.
15. Tindana, P.O., Singh, J.A., Tracy, C.S., Upshur, R.E., Daar, A.S., Singer, P.A., Frohlich, J. and Lavery, J.V., 2007. [Grand challenges in global health: community engagement in research in developing countries](#). *PLoS Med*, 4(9), p.e273.
16. The World Bank. [Training Guidelines: Content and Structure](#). DIME Wiki, The World Bank Group. Published 2019. Accessed May 30, 2019.
17. Food and Agriculture Organization of the United Nations. FAO Statistical Development

- Series No. 6 [Conducting Agricultural Censuses and Surveys](#). Published 1996. Accessed May 30, 2019.
18. Alex, J.L., Miller, E.A., Platt, R.E., Rachal, J.R. and Gammill, D.M., 2007. [Making the invisible visible: A model for delivery systems in adult education](#). *Journal of Adult Education*, 36(2), pp.13-22.
 19. World Food Programme. [Purchase for Progress Enumerator Training Manual](#). Rome; 2010.
 20. Croome A, Mager F. [Doing Research with Enumerators](#).; 2018. doi:10.21201/2018.3576.
 21. Keyser, M.W., 2000. [Active learning and cooperative learning: understanding the difference and using both styles effectively](#). *Research strategies*, 17(1), pp.35-44.
 22. The World Bank. [Enumerator Training](#). DIME Wiki, The World Bank Group. Published 2018. Accessed May 30, 2019
 23. Gillwald, A., 2018. [ICT HH and Business Survey Field Manual](#).
 24. Croome A, Mager F. [Doing Research with Enumerators](#).; 2018. doi:10.21201/2018.3576.
 25. The World Bank. [Enumerator Training](#). DIME Wiki, The World Bank Group. Published 2018. Accessed May 30, 2019
 26. Croome A, Mager F. [Doing Research with Enumerators](#).; 2018. doi:10.21201/2018.3576.
 27. Kopper, S. & Parry, K. [Survey Design](#). Abdul Latif Jameel Poverty Action Lab. Accessed July 2020.
 28. Stukel, D., and M. Deitchler., 2012. [Addendum to FANTA Sampling Guide by Robert Magnani \(1991\): Correction to Section 3.3. I Determining the number of households that need to be contacted](#). Washington, DC: FHI 360
 29. Koroma, A., Manary, M., Marron, B., Green, J., Rogers, B., Walton, S., Chui, K.H.K., Suri, D., Langlois, B. and Jayson, L., 2015. [Comparison of four supplementary foods in treating moderate acute malnutrition in Sierra Leone: an Ebola-constrained cluster-randomized, controlled clinic-based effectiveness trial](#). A report from the Food Aid Quality Review to USAID. Boston, MA: USAID.
 30. Mourad, M., Bousleiman, S., Wapner, R. and Gyamfi-Bannerman, C., 2020, November. [Conducting research during the COVID-19 pandemic](#). In *Seminars in perinatology* (Vol. 44, No. 7, p. 151287). WB Saunders.
 31. Gardner, A., Greenblott, K. and Joubert, E., 2005. [What we know about exit strategies: practical guidance for developing exit strategies in the field](#). Lusaka, Zambia.
 32. McCormack, R and Yakowenko, E. 2016. [Designing and managing research projects](#). *Action Against Hunger*