

**LEGUME INNOVATION LAB FOR COLLABORATIVE RESEARCH
ON GRAIN LEGUMES**

FY 2014 – 2015 WORK PLAN
(April 1, 2014 – September 30, 2015)

Project Code and Title: Legumes and growth

Lead U.S. Principal Investigator (PI) and affiliated Lead U.S. University:

Mark Manary MD, Helene Roberson Professor of Pediatrics
Washington University School of Medicine in St. Louis

Host Country and U.S. Co-PIs and Institutions:

- Ken Maleta MBBS PhD, Professor in Community Health, University of Malawi College of Medicine
- Chrissie Thakwalakwa MS, Lecturer in Community Health, University of Malawi College of Medicine
- Indi Trehan MD, Assistant Professor of Pediatrics, Washington University School of Medicine in St. Louis

I. Project Problem Statement and Justification:

Each year millions of children in Africa die from malnutrition and even more are stunted due to nutritional and absorption deficiencies, interventions to help children affected and at risk are urgently needed to improve the lives of these children. Environmental enteropathy (EE), a pervasive chronic subclinical gut inflammatory condition is prevalent amongst these children and places them at high risk for stunting, malabsorption, and poor oral vaccine efficacy. EE is characterized by T-cell infiltration of the intestinal mucosa leading to a chronic inflammatory state with increased intestinal permeability, translocation of gut microbes, micro- and macronutrient malabsorption, poor weight gain, stunted physical and cognitive development, frequent enteric infections, and decreased response to enteric vaccines. EE often develops within the first three years of life, a high-risk period marked also by the transitions from exclusive breastfeeding to mixed feeding with complementary foods to the complete reliance on adult foods for sustenance. In traditional sub-Saharan African societies, complementary foods are dominated by protein-poor and micronutrient-poor starches such as maize, cassava, and sorghum. Alternative, yet culturally acceptable, complementary foods that could provide a better and more palatable balance of nutrients would potentially decrease in EE and improve growth amongst these at risk children. Legumes provide just such an opportunity, as their protein content is significantly higher than cereals, and they are rich in dietary fiber, starch, minerals, vitamins, and antioxidants.

II. Planned Project Activities for the Work plan Period (April 1, 2014 – Sept. 30, 2015)

We will prepare to conduct a randomized, controlled clinical trial to investigate the effect of cowpea or common bean consumption on infant growth and gut health.

Objective 1:

Develop a working Manual of Operations to conduct the research projects in the field.

Collaborators:

Malawi College of Medicine

Approaches and Methods:

Chrissie Thakwalakwa and the research team will develop a method of operations and standard operating procedures that will be followed through out the duration of the project. The study procedure guide will describe the mode of operations for all study related participant and community interactions, including clinic operations, patient and participant screening, participant consent, enrollment, and food distribution. The methodology will also provide guidelines for data collection, giving instructions on surveys, home visits, and anthropometric measurement guidelines including taking mid-upper arm circumference and collecting biological samples. We will also develop an events reporting procedure for any unexpected and adverse events that could occur during the duration of the project. The manual will provide the field work directives for the Malawian graduate students and the local research team. Ms. Thakwalakwa will lead the development of the operations manual.

Objective 2:

Develop and test the acceptability of two sets of 3-4 recipes that include either cow peas or common beans for use infants in the clinical trial.

Collaborators:

The Department of Food Science and Technology on the Bunda Campus of the Lilongwe University of Agriculture and Natural Resources (LUANAR): LUANAR, formerly known as the Bunda College of Agriculture.

Malawi College of Medicine

Approaches and Methods:

Using food development techniques used by the Washington University team and the resources of LUANAR, the research team will develop food recipes using cowpeas and common beans. The recipes will be developed in accordance with the WHO specifications: 200 kcal/d for children 6-9 months old and 300 kcal/d for children 9-11 months old. The candidate recipes will then undergo acceptability testing in 6-11-month-old Malawian infants over a 2-week period to select those to be used in the study, the acceptability studies will receive the support of the Malawi College of Medicine. Prior to initiating the acceptability trial, we will submit ethical approvals for both the Malawian College of Medicine and the Washington University Human Research Protection Office for approval. About 3-4 recipes will be selected for each of the target legumes (cowpea and common bean) to offer diversity and choice to the caretakers, as they will be asked to feed the food to their child daily for 6 months.

Objective 3:

Complete preparations to initiate study aim 1, including staff recruitment, training and community engagement and organization.

Approaches and Methods:

Working with our staff in Malawi and at the College of Medicine, the research team will be hired to initiate specific aim 1. A graduate student will be recruited by the College of Medicine in Malawi to take on the responsibilities of this project. Study staff including drivers, nurses and research assistants will undergo extensive training by the PI and his team in Clinical Good Practice techniques and in data collection methods to properly conduct all enrollment and data collection. The research team will visit Mitondo district clinics to mobilize and engage them in the upcoming research project.

The team will also conduct meetings with local community leaders and health centers. Concurrently, all ethical approvals will be initiated to conduct the study; approvals will be sought from the Malawi College of Medicine and Washington University Board of Ethics.

Objective 4:

Increase the capacity, effectiveness and sustainability of agriculture research institutions which serve the bean and cowpea sectors in Malawi.

Approaches and Methods:

While initiating Study Aim 1, the PI and his research team will promote sustainable research through relationships with the Malawi College of Medicine and with colleagues at LUANAR. The research team recognizes how integral it is that local Malawi institutions be equipped to initiate and conduct operational health, nutrition and agriculture studies to improve the health and wellness of its population, and extensive training and support will be offered. Chrissie Thakwalakwa of the College of Medicine will be charged with developing the study procedures, guidelines and materials for the study, she will be under the guidance of the PI and his research team. The Agriculture Department at LUANAR, led by Vernon Kambambe, will be engaged developing formulations and recipes using cowpeas and common beans, the PI and his team will train two student LUANAR food scientists on the development processes used in the Washington University food science labs.

Trainees

- Chrissie Thakwalakwa – PhD Candidate, Malawi College of Medicine
- 2 students from LUANAR to develop recipes
- 1 COM PhD student to conduct the research project

III. Contribution of Project to USAID Feed the Future Performance Indicators:

This project supports the US Government's Feed the Future commitment to a multifaceted approach to nutrition and sustainably reducing global poverty and hunger. EE is estimated to cause about one third of the child stunting seen worldwide and the causes of EE are multifactorial. Our project aligns with these goals: developing a dietary intervention for children at risk for malnutrition and enteropathy using legumes, a local and common Malawian crop, is an opportunity to harness a local crop to resolve widespread condition afflicting children across the developing world. In the first year of the project we will set forth the methodology and training to develop a food that can treat this condition, and also train local universities and students on the methods to conduct this kind of research.

IV. Outputs:

- Manual of Operations for Field Work
- Recipe development report on lab development of cowpea and common bean interventions

V. Engagement of USAID Field Mission(s)

Continued communication, engagement and collaboration are planned with Cybill Sigler and John Edgar from the FTF team at the USAID mission in Lilongwe, Malawi. They will take on an associate role in this project. The PI and his team will remain in communication with their team and look for the potential of future engagements.

VI. Partnering and Networking Activities:

The PI and his team will work with the Program Manager for the Soil Health Consortium of Malawi about spreading the word about the projects development. The main role of the consortium is to encourage stakeholders to disseminate knowledge on Integrated Soil Fertility Management (ISFM), which includes legume rotation. The consortium holds ISFM symposia, travel workshops, and annual meetings, producing technical and policy briefs after these various consultations. Our research team will communicate with their group about relevant advances and technologies in the legume sector. All project outputs will be shared with these groups and the research team will seek out opportunities for synergy and collaboration.

VII. Leveraging of CRSP Resources:

VIII. Timeline for Achievement of Milestones of Technical Progress:

See attached

Training/Capacity Building Work plan for FY 2014 - 2015

Degree Training:

First and Other Given Names: Chrissie

Last Name: Thakwalakwa

Citizenship: Malawi

Gender: Female

Training Institution: Malawi College of Medicine

Supervising CRSP PI: Ken Maleta and Mark Manary

Degree Program for training: Public Health Nutrition

Program Areas or Discipline: Public Health

If enrolled at a US university, will Trainee be a "Participant Trainee" as defined by USAID? No

Host Country Institution to Benefit from Training: Malawi College of Medicine

Thesis Title/Research Area: Public Health Nutrition

Training status: Active

Type of CRSP Support (full, partial or indirect) g for training activity

Short-term Training: Recipe Development

Type of training: Recipe development for dietary interventions

Description of training activity: Develop recipes based on WHO recommendations for dietary interventions using cowpeas and common beans

Location: LUANAR

Duration: 2 months

When will it occur? Spetember 2015

Participants/Beneficiaries of Training Activity: Graduate students and researchers at LUANAR
anticipated numbers of Beneficiaries (male and female): 2

PI/Collaborator responsible for this training activity: Mark Manary

List other funding sources that will be sought (if any): None

Training justification: By engaging students and faculty at LUANAR, the development of appropriate recipes for our chosen legume varieties will also be culturally sensitive and feasible in the village setting, and the interventions that are successful are more likely to be implemented for the long term. Students will also be trained by the Washington University research team, a

group that has successfully developed over 50 recipes in prior studies that have been accepted by the Malawian general population.

Short-term Training: Staff Field Training

Type of training: Field training for research activities

Description of training activity: Training study research nurses, drivers, research assistants and staff on the field study guidelines. Trainees will receive training in “Good Clinical Practice” guidelines, anthropometric data collection skills, biological sample collection methods and community engagement.

Location: Malawi College of Medicine

Duration: 1 week

When will it occur? Aug 2015

Participants/Beneficiaries of Training Activity: Research team

Anticipated numbers of Beneficiaries (male and female): 10

PI/Collaborator responsible for this training activity: Indi Trehan and Ken Maleta

List other funding sources that will be sought (if any): None

Training justification: this training is necessary to conduct the research projects, having a knowledgeable and capable staff is imperative to conducting this research.

Equipment (costing >\$5,000):

-80C freezer