

**Feed the Future Innovation Lab for
Collaborative Research on Grain Legumes
(Legume Innovation Lab)**

**FY 2016 Annual Project Technical Progress Report
(October 1, 2015 – September 30, 2016)**

Project Code and Title: Legumes and growth

Lead U.S. Principal Investigator and University:

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

Collaborating Host Country and U.S. PIs and Institutions:

- Ken Maleta MBBS PhD, Professor in Community Health, University of Malawi College of Medicine
- Chrissie Thakwalakwa PhD, 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. Abstract of Research and Capacity Strengthening Achievements

In FY16, 100% enrollment in Study 1 and complete enrollment and sample collection for Study 2 was accomplished. Final sample collection for Study 1 will take place in December 2016 and samples will be sent to the University of California San Diego for sequencing and analysis. The local team implementing the clinical trial continues ongoing training in the principles of “Good Clinical Practice.” Two Malawian PhD students enrolled at the University of Malawi-College of Medicine were identified and began work on the project. The students are currently training at Washington University in lab techniques, attending classes and other training/seminars.

II. Project Problem Statement and Justification

Successful interventions to help prevent children from becoming malnourished and achieve their full growth potential remain lacking. EED, a pervasive chronic subclinical gut inflammatory condition, places rural children at high risk for malabsorption, stunting, and acute malnutrition. Minimizing EED is an essential step in improving the survival and growth of at-risk children. EED is characterized by T-cell infiltration of the intestinal mucosa leading to a chronic inflammatory state with increased intestinal permeability, translocation of microbes, nutrient malabsorption, poor weight gain, stunted physical and cognitive development, frequent enteric infections, and decreased response to enteric vaccines. EED often begins to develop shortly after the transition away from exclusive breastfeeding and increases progressively during the first several years of life, a high-risk period marked by 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 EED and improve growth amongst these at risk children. In this study, we are testing two different legume foods as complementary food products, given that their protein content is significantly higher than cereals, and they are rich in dietary fiber, starch, minerals, vitamins, and antioxidants. The active engagement of several Malawian graduate students as part of the capacity-building activities is essential to this work, as their local insights and knowledge of food systems and cultural feeding practices will help guide the optimal development and implementation of these bean flours at scale if they prove to be successful in reducing EED and stunting.

III. Technical Research Progress

Objective 1: *Develop a working Manual of Operations to conduct the research projects in the field.*

The Manual of Operation to conduct the research projects in the field was developed by Chrissie Thakwalakwa with input from the rest of the research team. The study procedure guide describes the mode of operations for all study related participants and community interactions, including clinic operations, patient and participant screening, participant consent, enrollment, and food distribution. The manual also provides guidelines for data collection, giving instructions on surveys, home visits, anthropometric techniques, the collection of biological samples, and event reporting procedures for any unexpected and adverse events. The manual provides the field work directives for the field team and continued to be utilized in FY16.

Objective 2: *Develop and test the acceptability of two sets of 3-4 recipes that include either cowpea or common bean for use infants in the clinical trial.*

The LUANAR graduate students developed food recipes using cowpeas and common beans. The recipes were developed in accordance with WHO specifications and the candidate recipes underwent acceptability testing in Malawian infants with the support of the Malawi College of Medicine. The acceptability data from these studies has been submitted for publication. The preferred flour recipes have been selected and are currently being used in the clinical trials during FY16.

Objective 3: *Complete preparations to initiate study aim 1, including staff recruitment, training and community engagement and organization.*

All ethical approvals were obtained from the institutional review boards at the University of Malawi College of Medicine and Washington University in St. Louis. The two PhD students recruited at the Malawi College of Medicine are currently in the United States at Washington University attending classes, learning lab techniques and attending other seminars/lectures/conferences to enhance their knowledge base. All local staff continues to undergo extensive training in Clinical Good Practice techniques and data collection methods to properly conduct all enrollment and data collection. The field teams continue to engage the district, local community leaders and health and health centers near Masenjere in Nsanje District and Limela in Machinga District in the current research project. 100% enrollment and over 50% of sample collection in Study 1 and 100% completion of sample collection for Study 2 was achieved in FY16.

Objective 4: *Increase the capacity, effectiveness and sustainability of agriculture research institutions which serve the bean and cowpea sectors in Malawi.*

The PI and the research team continue to promote sustainable research through relationships with the University of Malawi College of Medicine and with colleagues at LUANAR. In addition to the training of four graduate students, a junior faculty member, Chrissie Thakwalakwa at the College of Medicine, continues to be supported by this project and provide overall supervision of the field studies. The Agriculture Department at LUANAR was engaged in developing the formulations and recipes using cowpeas and common beans, and the Washington University team trained two student LUANAR food scientists on the development processes used in the Washington University food science lab. LUANAR masters students continue to be engaged in the clinical trial even after having developed the food recipes, supervising bean sourcing, flour production, preparation, and safety monitoring of the intervention foods. Two PhD students recruited at the Malawi College of Medicine are currently in the United States at Washington University attending classes, learning lab techniques and attending other seminars/lectures/conferences to enhance their knowledge base. Conducted Food Safety Seminar with speakers from Valid Nutrition Malawi, LUANAR, ICRISAT, MBS, CAMA, NASFAM and the University of Malawi-College of Medicine with 41 attendees from producers and private, government and civil sectors.

IV. Major Achievements

1. 100% enrollment in Study 1 and 100% sample collection in Study 2, requiring a large amount of effort and resources, including collaboration in the districts where the studies are being conducted. It also required ethics approval to be obtained, all staff to be hired and trained and food formulas to be developed and selected.
2. Successfully enrolled two Malawian PhD students in classes and taught them dPCR techniques.
3. Conducted a Food Safety Seminar with 10 speakers and 41 attendees from various sectors.

V. Research Capacity Strengthening

The PI and the research team continue to promote sustainable research through relationships with the Malawi College of Medicine and with colleagues at LUANAR. The training provided to the four Malawian graduate students continues and will help to develop them into investigators able to continue research on childhood malnutrition, especially in the use of grain legumes. Chrissie Thakwalakwa of the College of Medicine, with support from Drs. Manary, Trehan and Maleta, continues to supervise the field team, honing and improving her skills in conducting large collaborative clinical trials aimed at improving the nutritional status of impoverished rural children. The Agriculture Department at LUANAR was engaged in developing the formulations and recipes using cowpeas and common beans, and the Washington University team trained two student LUANAR food scientists on the development processes used in the Washington University food science lab. One of these students continues to be engaged in by supervising production and quality control of the flours using the food science and safety knowledge she obtained as part of her training. The two Malawian PhD students are

attending classes at Washington University that are not offered at the University of Malawi increasing their research knowledge base. These students have also been trained in dPCR lab techniques utilized in Dr. Manary's lab at Washington University.

VI. Human Resource and Institution Capacity Development

1. Short-Term Training: Staff Field Training

- i. *Purpose of Training:* Study research nurses, drivers, research assistants and staff received training in study guidelines, anthropometric data collection skills, biological sample collection methods and community engagement. Having a knowledgeable and capable staff is vital to conducting research.
- ii. *Type of Training:* Field Training for research activities
- iii. *Country Benefiting:* Malawi
- iv. *Location and dates of training:* Malawi, 2016
- v. *Number receiving training (by gender):* 6 female nurses, 4 male drivers, 15 village health workers (11 male, 4 female)
- vi. *Home institution(s) (if applicable):* Nurses and drivers are from the University of Malawi College of Medicine; village health workers are employed by the Ministry of Health
- vii. *Institution providing training or mechanism:* University of Malawi College of Medicine

2. Short-Term Training: Food Safety

- i. *Purpose of Training:* A 1 week training course on food safety, where the key threats to legumes and other Malawian crops are emphasized across the value chain.
- ii. *Type of Training:* Food Training
- iii. *Country Benefiting:* Malawi
- iv. *Location and dates of training:* Malawi, 2016
- v. *Number receiving training (by gender):* 22 males and 19 females.
- vi. *Home institution(s) (if applicable):*
- vii. *Institution providing training or mechanism:* University of Malawi College of Medicine

3. Degree Training

- i. *Name of trainee:* Lucy Bollinger
- ii. *Country of Citizenship:* USA
- iii. *Gender:* Female
- iv. *Host Country Institution Benefitting from Training:* University of Malawi College of Medicine
- v. *Institution providing training:* Washington University
- vi. *Supervising CRSP PI:* Mark Manary and Indi Trehan
- vii. *Degree Program:* Masters
- viii. *Field or Discipline:* Biological Sciences
- ix. *Research Project Title (if applicable)*
- x. *Start Date:* May 2015
- xi. *Projected Completion Date:* May 2016

- xii. *Is trainee a USAID Participant Trainee and registered on TraiNet?* No
- xiii. *Training status (Active, Completed, Pending, Discontinued, or Delayed):*
Completed

4. Degree Training

- i. *Name of trainee:* William Cheng
- ii. *Country of Citizenship:* USA
- iii. *Gender:* Male
- iv. *Host Country Institution Benefitting from Training:* Washington University
- v. *Institution providing training:* Washington University
- vi. *Supervising CRSP PI:* Mark Manary and Indi Trehan
- vii. *Degree Program:* Masters
- viii. *Field or Discipline:* Biological Sciences
- ix. *Research Project Title (if applicable)*
- x. *Start Date:* May 2016
- xi. *Projected Completion Date:* May 2017
- xii. *Is trainee a USAID Participant Trainee and registered on TraiNet?* No
- xiii. *Training status (Active, Completed, Pending, Discontinued, or Delayed):*
Active

5. Degree Training

- i. *Name of trainee:* Oscar Divala
- ii. *Country of Citizenship:* Malawi
- iii. *Gender:* Male
- iv. *Host Country Institution Benefitting from Training:* University of Malawi College of Medicine
- v. *Institution providing training:* University of Malawi College of Medicine
- vi. *Supervising CRSP PI:* Mark Manary, Ken Maleta, Indi Trehan
- vii. *Degree Program:* PhD
- viii. *Field or Discipline:* Epidemiology
- ix. *Research Project Title:* N/A
- x. *Start Date:* August 2015
- xi. *Projected Completion Date:* July 2017
- xii. *Is trainee a USAID Participant Trainee and registered on TraiNet?:* No
- xiii. *Training status (Active, completed, pending, discontinued or delayed):*
Active

6. Degree Training

(Provide the following information for each person in degree training with full or partial financial support from the project.)

- i. *Name of trainee:* Yankho Kaimila
- ii. *Country of Citizenship:* Malawi
- iii. *Gender:* Female
- iv. *Host Country Institution Benefitting from Training:* University of Malawi College of Medicine

- v. *Institution providing training:* University of Malawi College of Medicine
- vi. *Supervising CRSP PI:* Ken Maleta
- vii. *Degree Program:* PhD
- viii. *Field or Discipline:* Epidemiology
- ix. *Research Project Title:* N/A
- x. *Start Date:* August 2015
- xi. *Projected Completion Date:* July 2017
- xii. *Is trainee a USAID Participant Trainee and registered on TraiNet?:* No
- xiii. *Training status (Active, completed, pending, discontinued or delayed):*
Active

7. Degree Training

- i. *Name of trainee:* Chrissie Thakwalakwa
- ii. *Country of Citizenship:* Malawi
- iii. *Gender:* Female
- iv. *Host Country Institution Benefitting from Training:* University of Malawi
College of Medicine
- v. *Institution providing training:* Tampere University in Finland
- vi. *Supervising CRSP PI:* Ken Maleta
- vii. *Degree Program:* PhD
- viii. *Field or Discipline:* Community Health
- ix. *Research Project Title:* N/A
- x. *Start Date:* August 2015
- xi. *Projected Completion Date:* July 2017
- xii. *Is trainee a USAID Participant Trainee and registered on TraiNet?:* No
- xiii. *Training status (Active, completed, pending, discontinued or delayed):*
Active

8. Degree Training

- i. *Name of trainee :* Theresa Ngoma
- ii. *Country of Citizenship:* Malawi
- iii. *Gender:* Female
- iv. *Host Country Institution Benefitting from Training:* The Lilongwe
University of Agriculture and Natural Resources (LUNAR)
- v. *Institution providing training:* LUNAR
- vi. *Supervising CRSP PI:* Mark Manary, Indi Trehan, Ken Maleta
- vii. *Degree Program:* Masters
- viii. *Field or Discipline:* Food Science and Technology
- ix. *Research Project Title:* N/A
- x. *Start Date:* January 2015
- xi. *Projected Completion Date:* December 2015
- xii. *Is trainee a USAID Participant Trainee and registered on TraiNet?* No

- xiii. *Training status (Active, completed, pending, discontinued or delayed):*
Active

9. Degree Training

- i. *Name of trainee:* Ulemu Chimimba
- ii. *Country of Citizenship:* Malawi
- iii. *Gender:* Female
- iv. *Host Country Institution Benefitting from Training:* LUNAR
- v. *Institution providing training:* LUNAR
- vi. *Supervising CRSP PI:* Mark Manary, Indi Trehan, Ken Maleta
- vii. *Degree Program:* Masters
- viii. *Field or Discipline:* Food Science and Technology
- ix. *Research Project Title:* N/A
- x. *Start Date:* January 2015
- xi. *Projected Completion Date:* December 2015
- xii. *Is trainee a USAID Participant Trainee and registered on TraiNet?:* No
- xiii. *Training status (Active, completed, pending, discontinued or delayed):*
Complete

VII. Achievement of Gender Equity Goals

Beneficial findings and knowledge gained from these studies will benefit both women and men in these societies, including parents and children. Farming work is generally carried out by both men and women in this agrarian culture, so this will benefit both genders. Improvements in child health are most likely to benefit women in Malawi, as they have the primary role in childrearing. Health improvements that lead to improved survival and intellectual development of girls will also likely translate into improved school performance and capacity for careers. Demonstrating achievement of such goals is beyond the scope of the current project.

In terms of training future scientists, all but one of our Malawian graduate students is female. Both American graduate students are female. One of our non-degree American students is female.

Particular care was extended to women for inclusion in the Food Safety training course. With approximately 46% of attendees being female.

VIII. Explanation for Changes

We have no significant changes or delays to report.

IX. Self-Evaluation and Lessons-Learned

Project SO3.1 has proceeded very well. Two out of our four Malawian graduate students have successfully completed their training and have graduated. The other two are currently in St. Louis, Missouri, studying at Washington University and receiving laboratory training. Our large number of village health workers have also received significant training in the identification and management of malnutrition, skills that they report they have taken back to their communities to improve nutritional counselling of

children, agricultural practices, and the clinical identification of malnourished children.

The clinical trial itself is nearing completion before the end of 2016 with successful recruitment and retention of more than our anticipated sample size. No significant challenges have been encountered during the course of the study; no significant adverse events have occurred and the mothers of children in the trial report great happiness with being involved in such a lengthy study aimed at improving the growth and gut health of their children. Nearly all of the clinical samples have been returned to the United States and analysis of the dual-sugar and microbiome results has begun on a blinded basis. After the clinical trial finishes in December 2016, the study's growth data will be unblinded to see if the legume interventions had any benefit on growth rates.

The collaboration with the University of Malawi and LUANAR has continued successfully and has brought all of our institutions closer together, especially with the recent Food Safety Seminar held in Blantyre. We look forward to nurturing this relationship in the future to work on other projects aimed at improving food security, agricultural output, and the health of women and children in Malawi.

X. Scholarly Accomplishments

1. Trehan I, et al. "Common beans and cowpeas as complementary foods to reduce environmental enteric dysfunction and stunting in Malawian children: study protocol for two randomized controlled trials. *Trials* (2015) 16:520

XI. Progress in Implementing Impact Pathway Action Plan

We remain on track with the Impact Pathway developed during the project planning and workplan stage. Both Goal 1 (capacity building) and Goal 2 (clinical trial decreasing stunting and EED) are being carried out as planned. The measurements of success (Steps 3 and 4) are still several years away from completion, as originally planned.

ANNEXES

Annex 1. Tables, Figures, and Photos Cited in the Report

Annex 2. Literature Cited

(List all literature cited in the body of the technical progress report in full bibliographic form.)