

Impact of Legumes vs. Corn-Soy Flour on *Environmental Enteric Dysfunction* and *Stunting* in Rural Malawian Children

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Stunting

- Stunting is referred to as being short for age
- Causes:
 - Inadequate infant and young child feeding
 - Clinical and subclinical infections
- Consequences of stunting:
 - Premature deaths
 - Long-term cognitive defects
 - Lower adult economic productivity
 - High health cost
 - For girls: increased risk of stunted children.

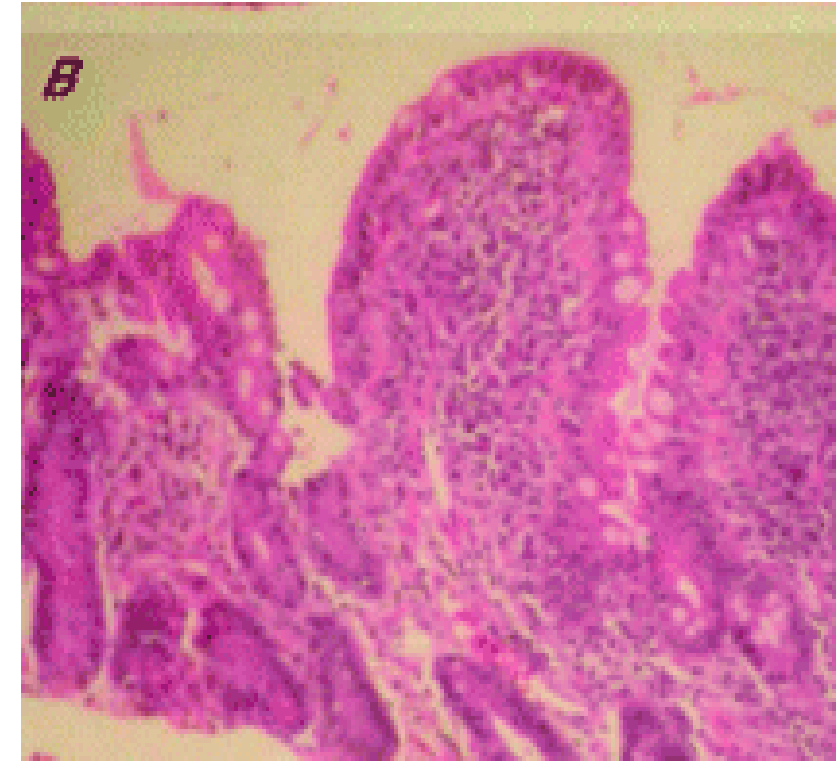
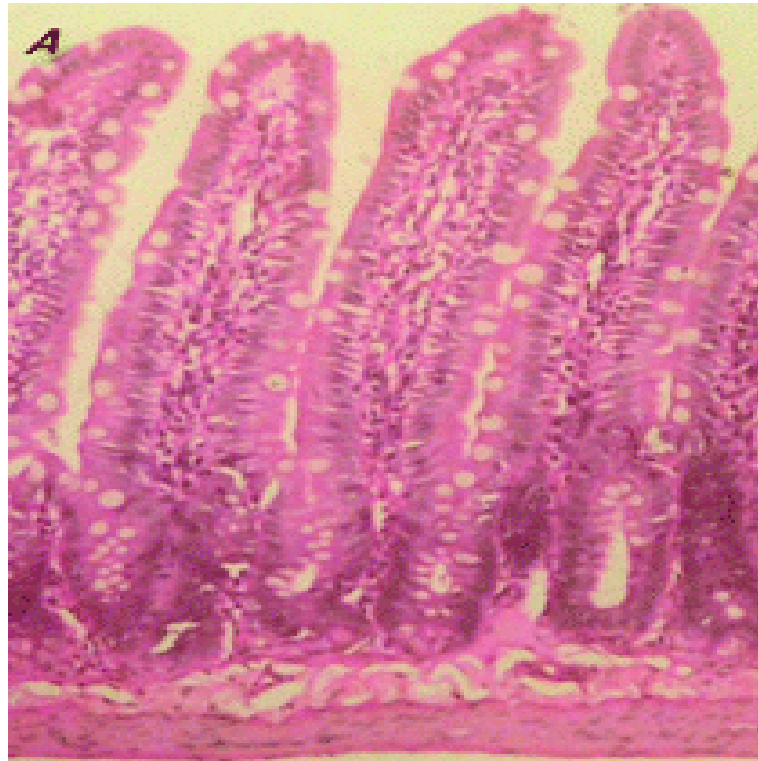


Environmental Enteric Dysfunction (EED)

- Chronic inflammatory state of the gut
- Has non-specific cause
 - Linked unsanitary living conditions
- Asymptomatic
- Is virtually ubiquitous among people living in rural areas
- First three years of life is a high risk period

What happens in EED

- In EED there are abnormal changes in ***Structure*** and ***Function*** of the small intestine



Structural change	Functional change
Flattening of villous	Reduced nutrient absorption
Inflamed and permeable	Microbial translocation

Measuring EED

- Most commonly measured by dual sugar absorption tests
 - Drink non-metabolized sugars of different sizes (Lactulose and Mannitol)
 - Collect urine produced over a 4 hour period
 - measure relative concentrations of the sugars in urine
 - higher ratios indicative of increased intestinal permeability

Why Legumes?

- Diets enriched in legumes decrease markers of inflammation
- May serve as a major source of protein and micronutrients
 - carbohydrate consumption often predominates in complementary feeding
- Accessible and cheap
 - grows well in Africa
 - are culturally accepted
 - drought-tolerant crop

Hypothesis and outcomes

Hypothesis:

- legume supplement in children will improve their height and L:M ratios compared to those on standard food supplements.

Intervention:

- Cowpeas,
- Common beans,
- Corn Soy blend (control)

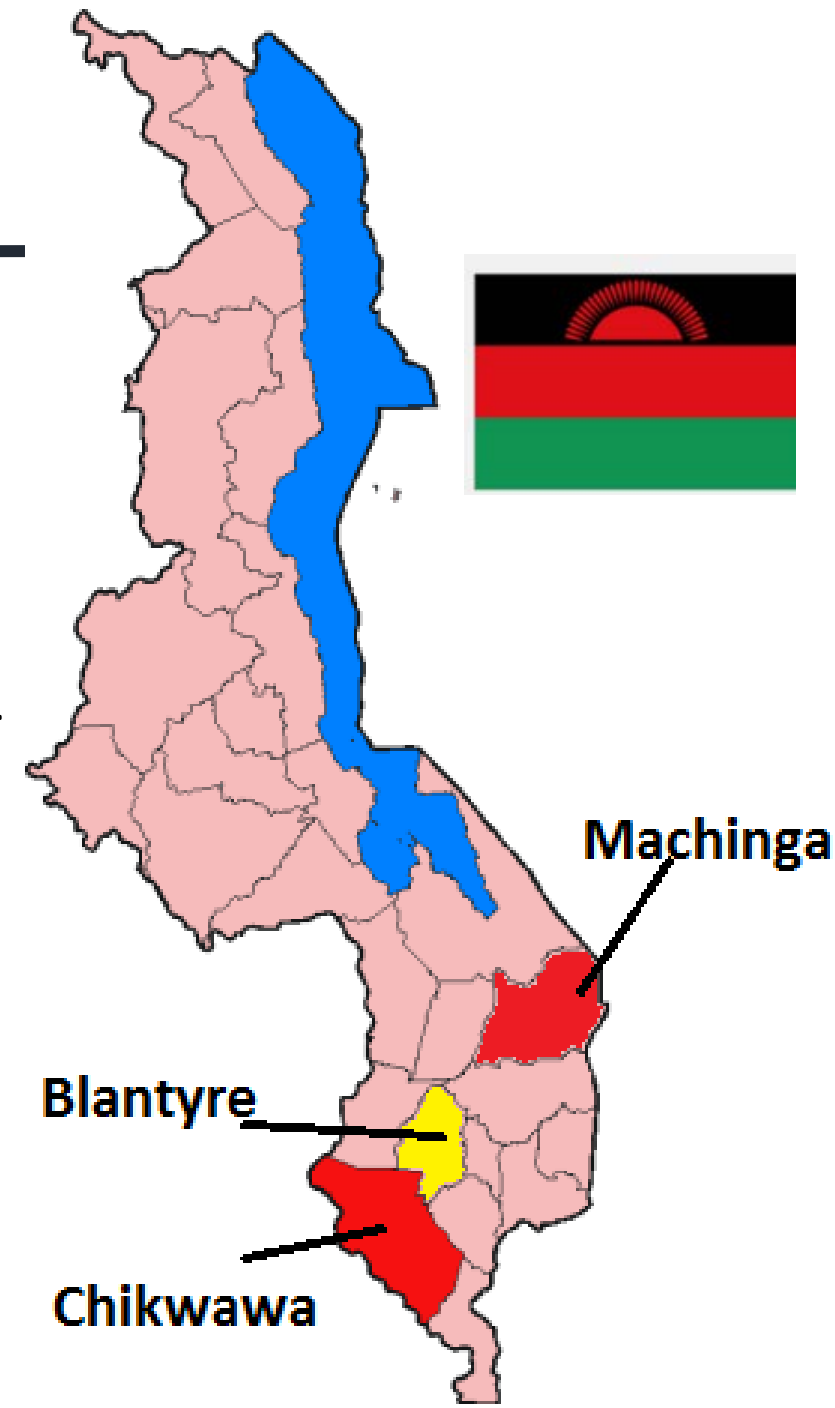
Outcomes:

- Change in height
- Change in L:M ratios

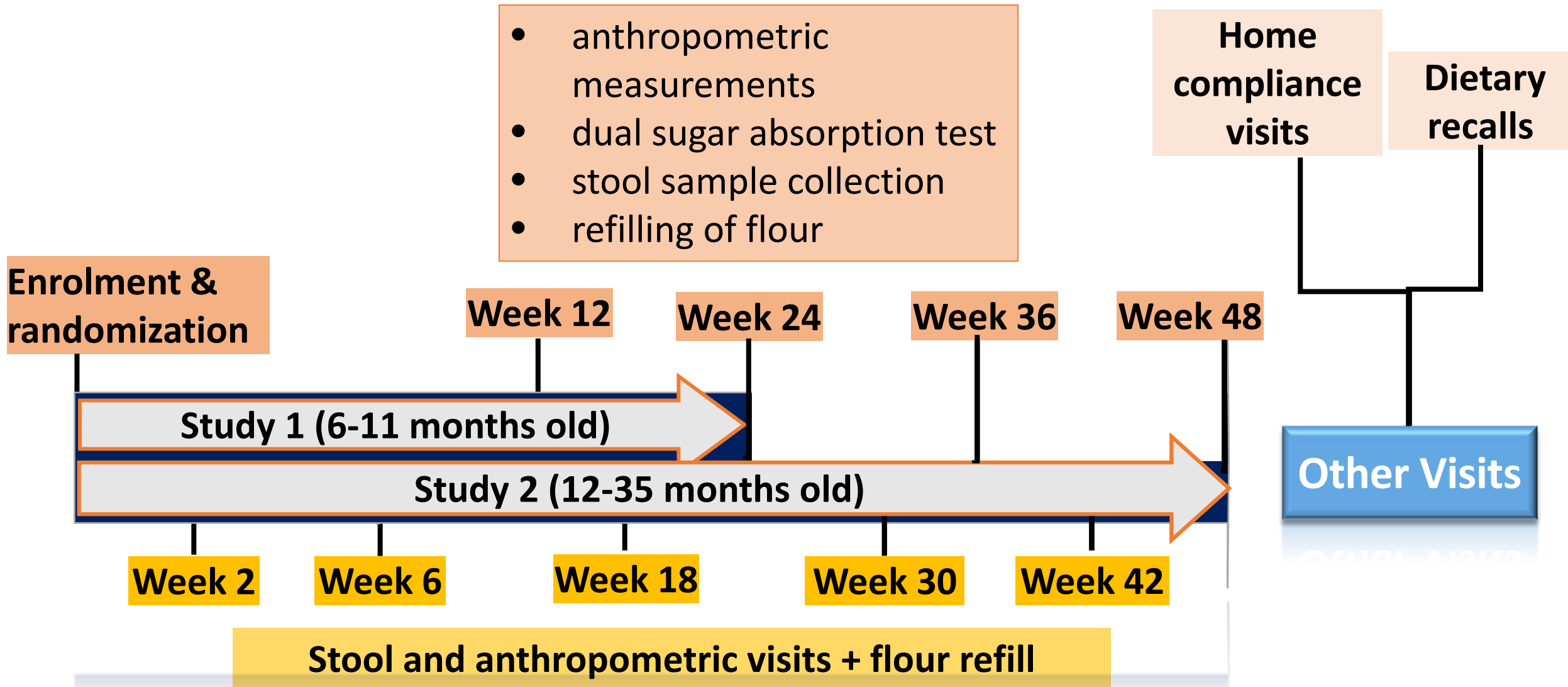


Trial Setting

- Healthy children aged 6 to 23 months
- Limeria and Nthenda, in southern Malawi
- Randomised to cowpea, common beans, or corn-soy blend



Trial Procedures



Trial profile

Study 1 Exclusions (n=56)

- 33 MAM
- 3 SAM
- 2 medical condition
- 16 over age
- 1 moved
- 1 refused

Study 1: 304 approached
Study 2: 400 approached

Study 2 Exclusions (n=30)

- 14 MAM
- 11 over age
- 5 sample size saturated

Study 1: 248 enrolled
Study 2: 370 enrolled

Group A

Study 1: n=91
Study 2: n=139

Group B

Study 1: n=93
Study 2: n=114

Group C

Study 1: n=96
Study 2: n=139

Study 1: 9 lost to follow up
Study 2: 7 lost to follow up

Study 1: 12 lost to follow up
Study 2: 9 lost to follow up

Study 1: 11 lost to follow up
Study 2: 6 lost to follow up

Study 1: 64 in cohort, 18 completed
Study 2: 132 in cohort

Study 1: 64 in cohort, 17 completed
Study 2: 105 in cohort

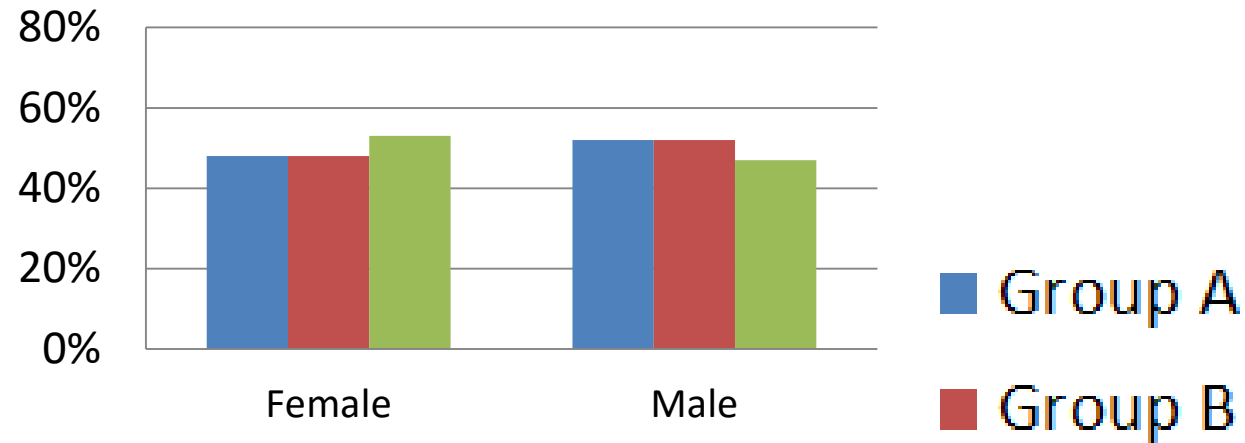
Study 1: 67 in cohort, 18 completed
Study 2: 133 in cohort

Study 1 Baseline characteristics

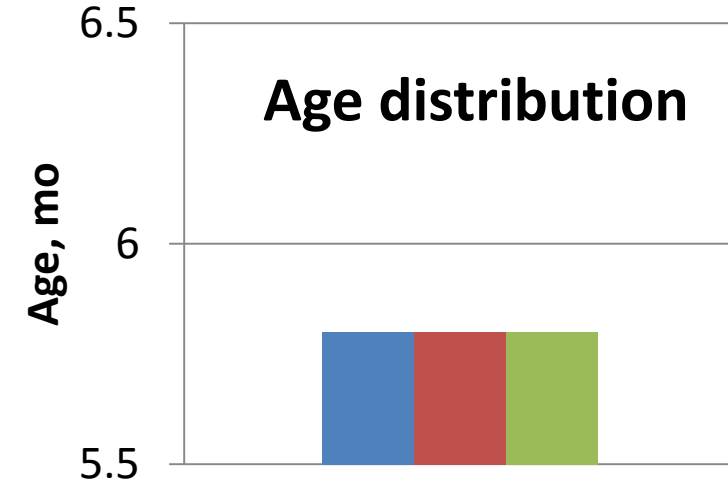
Characteristics	Study 1 (6-11 months old)
	Overall (n=246)
Female, %	48
Age, months	5.8 ±0.26
Length, cm	63.7±2.48
Weight, kg	7.1±0.74
Weight-for-height, z score	0.4±0.89
Weight-for-age, z score	-0.6±0.86
Height-for-age, z score	-1.2±1.04
Children stunted (height-for-age <-2), %	24

Study 2 Baseline characteristics by study arm

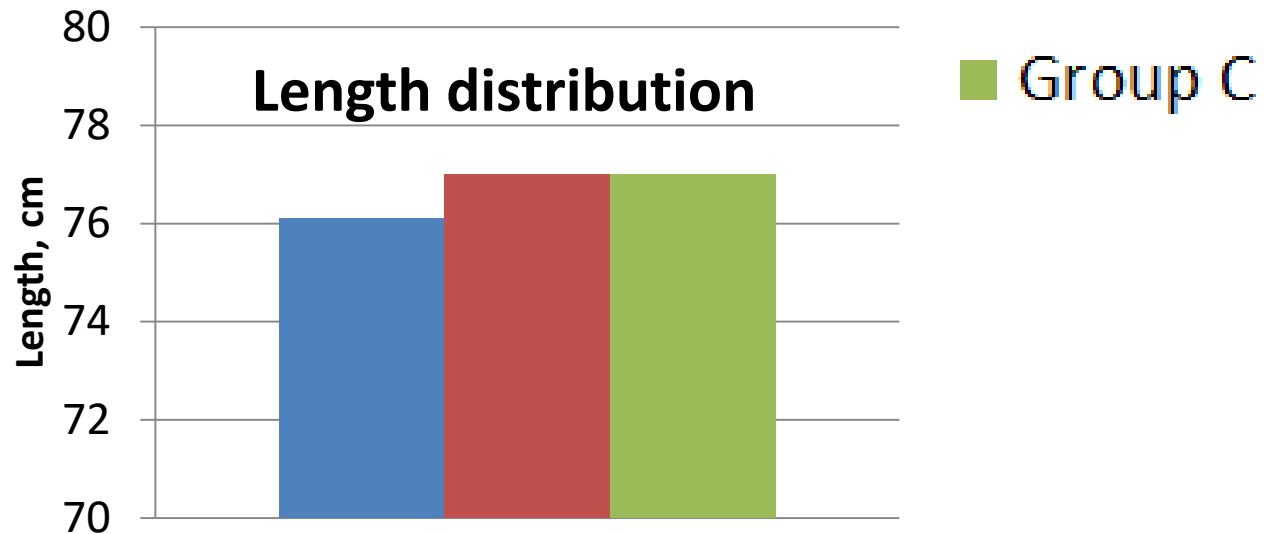
Sex distribution



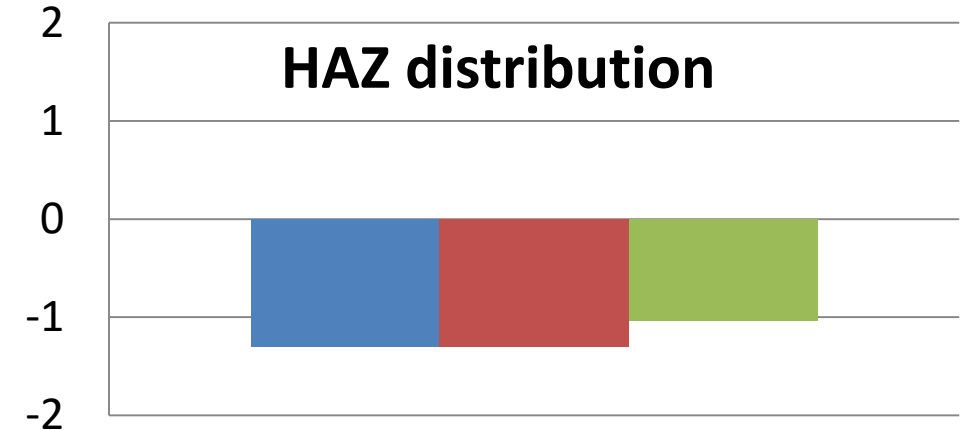
Age distribution



Length distribution



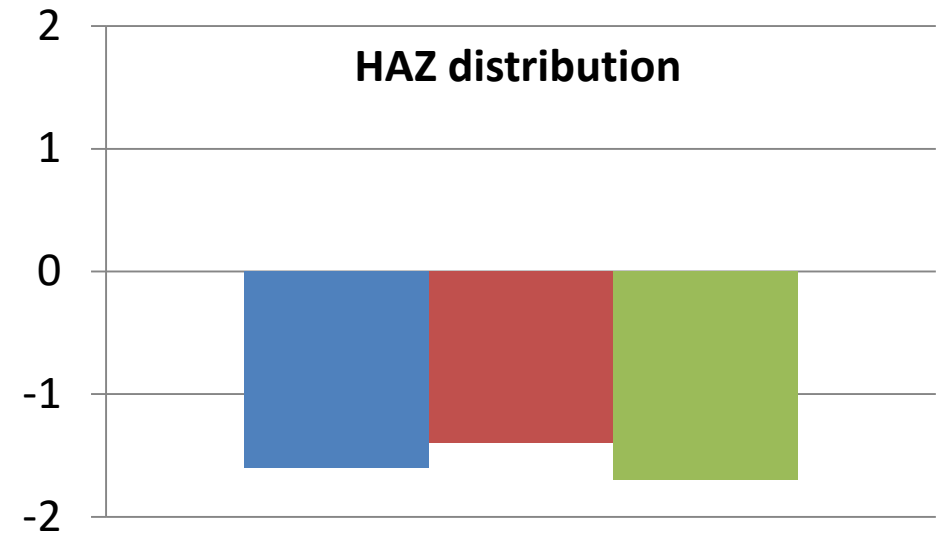
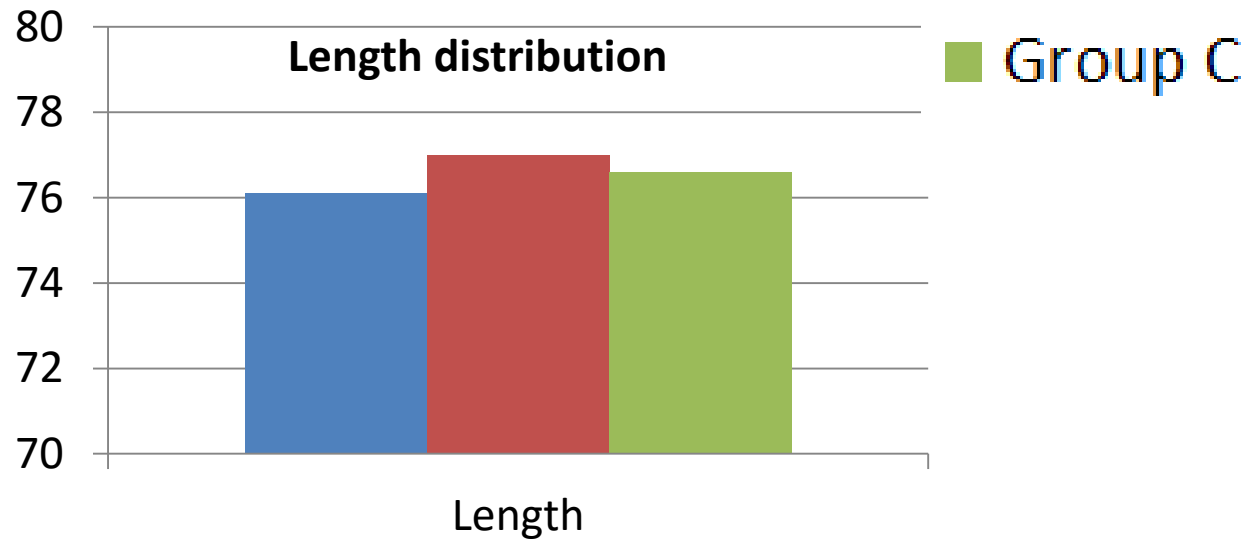
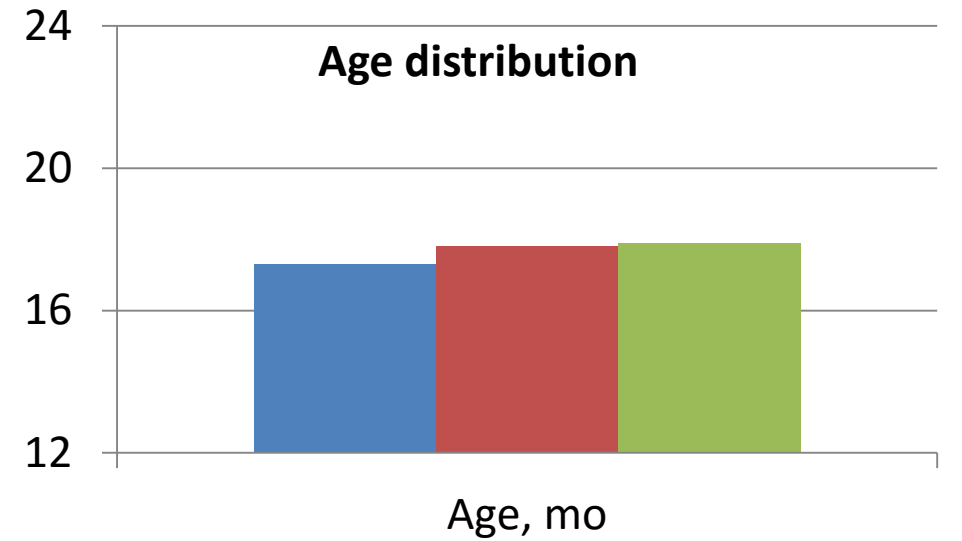
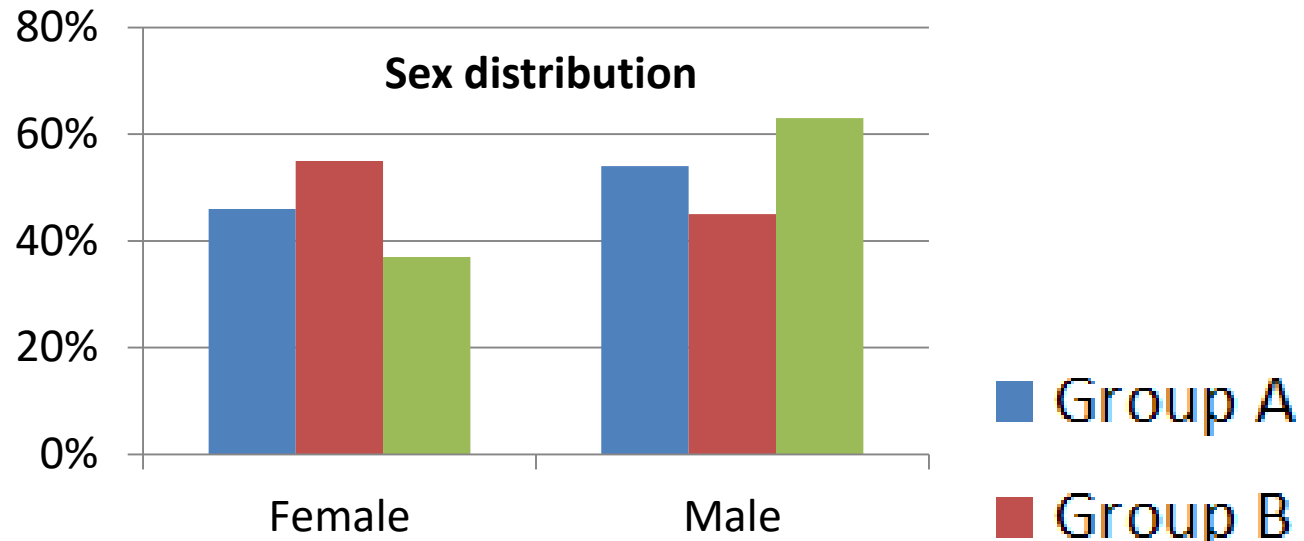
HAZ distribution



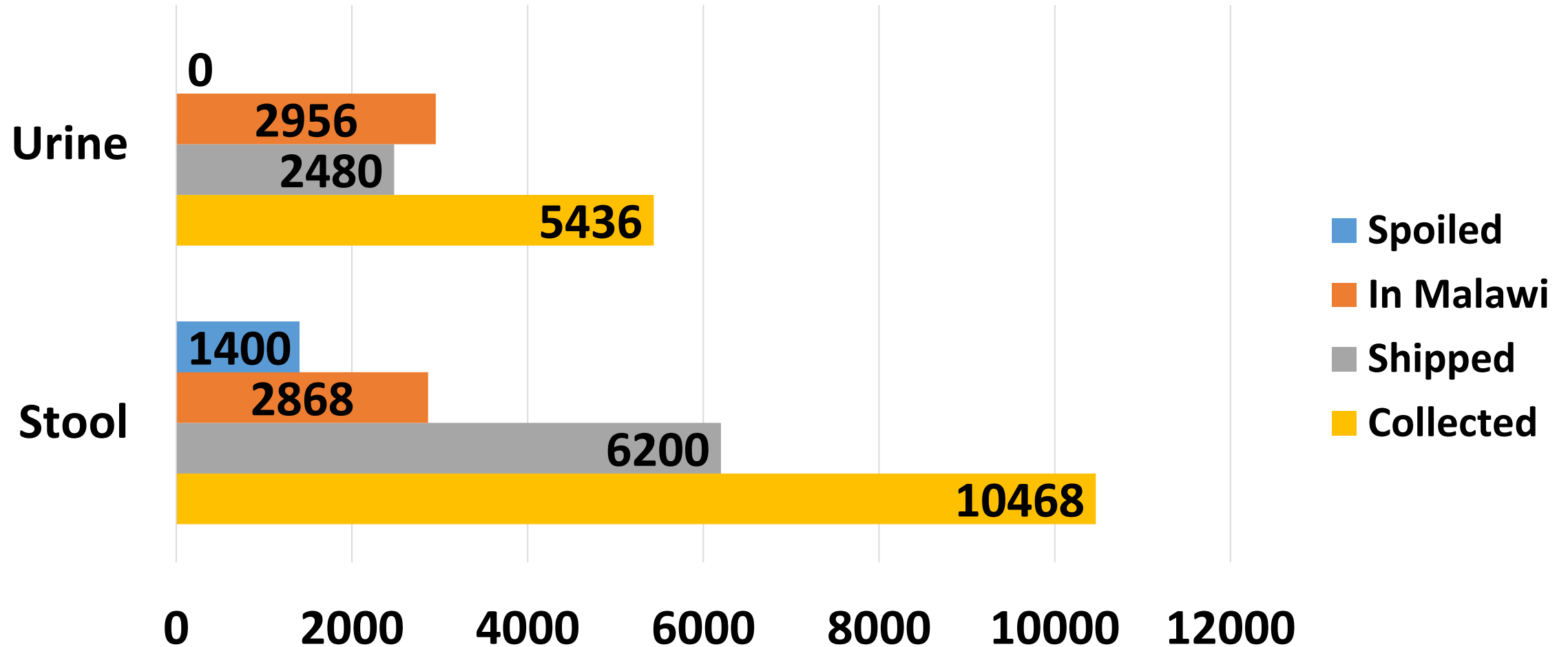
Study 2 Baseline characteristics

Characteristics	Study 2 (12-23 months old)
	Overall (n=356)
Female, %	45
Age, months	17.7±3.7
Length, cm	76.5±4.85
Weight, kg	9.6±1.30
Weight-for-height, z score	-0.1±0.90
Weight-for-age, z score	-0.8±0.96
Height-for-age, z score	-1.6±1.15
Children stunted (height-for-age <-2), %	36

Study 2 Baseline characteristics by study arm



Stored biological samples (15,904 vials)



Trial progress

- Study 1:
 - 62 (21%) follow up completed
 - 52 to be enrolled
- Study 2:
 - enrollment completed
 - majority now between week 24 and week 30 of follow up
- Projected end date: Dec 2016

Acknowledgements



USAID
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Legume Innovation Lab