

## 1. BACKGROUND

- Sub-optimal dietary intake during pregnancy can contribute to adverse pregnancy outcomes and poor child development<sup>1,2,3</sup>.
- Iron-folic acid (IFA) is recommended during pregnancy. Evidence suggests that multiple micronutrients (MMN) with energy and protein may better improve birth outcomes<sup>4,5</sup>.
- Lipid-based nutrient supplements (LNS), a nutritional product with both energy and micronutrients, are a promising new strategy to meet nutritional needs in pregnancy<sup>6</sup>.
- While evidence suggests that a 20-g LNS formulation was acceptable to pregnant women in Malawi and Ghana<sup>7,8</sup> no study has yet assessed acceptability and utilization of a 40-g LNS formulation among pregnant women.

## 2. OBJECTIVE

- To assess acceptability and utilization of a 40-g LNS (EPI-E) formulation with among pregnant women in rural Niger.

## 3. HYPOTHESIS

- Epi-E will be both acceptable and appropriately utilized among pregnant women in this setting.

## 4. MATERIALS & METHODS

### 4.1 Parent Trial

- This study is part of a nutrition-immunogenicity sub-study to test whether daily prenatal supplementation with LNS or MMN, compared to IFA, improves immune response to 3 doses of oral rotavirus vaccine.

### 4.2 Epi-E Formulation

- Developed with Nutriset SAS (Malaunay, France) to meet nutritional needs of pregnant women in Niger.
- 40-g dose with nearly 2 times the RDA of micronutrients for pregnant women.

### 4.3 Recruitment & Inclusion Criteria

- Recruitment occurred in Madarounfa, Niger at one health center in June (Ramadan) and September (non-Ramadan) 2014 among women presenting for routine antenatal care.
- Inclusion criteria:  $\geq 18$  years of age and pregnant.
- Exclusion criteria: intolerance to milk/peanuts; clinical status requiring inpatient referral.

### 4.4 Design & Procedures

- Data collection occurred at two time points: June (Ramadan) and September (non-Ramadan) using a two-part, multi-methods design with 26 – 28 women.
  - Part I** included two 50-g test meals at the health center (10-g EpiE + 40-g maize porridge).
  - Part II** included a 14-day home trial where women were given a two-week supply of Epi-E for home use.
- Open- and close-ended questions assessed organoleptic properties, acceptability, utilization, and willingness to pay.

## 5. RESULTS

### 5.1 Participant Characteristics (Table 1)

- Mean (SD) age was 29.5 (7.5) years in June (Ramadan) and 27.9 (7.9) in September (non-Ramadan).
- Mean  $>5.0$  previous pregnancies in both time periods.
- Few illness episodes reported in 24 hours before any test meal.
- All participants reported normal appetites before meals.

Table 1. Baseline characteristics and health of participants by day of test meal

Test day, (n)	June 2014 (Ramadan)		September 2014 (non-Ramadan)	
	Day 1 (26)	Day 2 (26)	Day 1 (28)	Day 2 (27)
<b>Participant characteristics</b>				
Age, Mean (SD)	29.5 (7.5)		27.9 (7.8)	27.7 (7.8)
Previous pregnancies, Mean (SD)	5.5 (2.9)		5.3 (3.2)	5.2 (3.1)
<b>Reported illness in previous 24 hours, n (%)</b>				
Runny nose	0 (0.0)	0 (0.0)	1 (3.6)	1 (3.7)
Cough	4 (15.4)	3 (11.5)	3 (10.7)	1 (3.7)
Difficulty breathing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fever	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting/nausea	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
Ear infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Other*	0 (0.0)	0 (0.0)	2 (7.1)	0 (0.0)
Normal appetite on test day, n (%)	26 (100.0)	26 (100.0)	28 (100.0)	27 (100.0)

\*Other illnesses reported on Day 1 (September 2014) were anemia (n = 1) and cold (n = 1)

### 5.2 Test Meal Results (Table 2)

- Very high acceptability with no important variation between periods (Ramadan vs non-Ramadan).
- $>90\%$  of the 50-g test meal consumed in under two minutes.
- Epi-E was rated highly (median '5 = like a lot') in terms of overall liking, color, taste, and smell.

Table 2. Consumption behaviors and attitudes toward Epi-E from test meal

No. of participants, (n)	June 2014 (Ramadan)		September 2014 (non-Ramadan)	
	Day 1 (26)	Day 2 (26)	Day 1 (28)	Day 2 (27)
<b>Consumption of 50g Epi-E/maize porridge mixture</b>				
Grams of serving consumed, Mean (SD)	48.56 (1.50)	47.60 (2.18)	45.64 (1.83)	45.78 (1.99)
Average amount consumed of total serving, (%)	97.12	95.20	91.28	91.56
Time (min) taken to consume, Mean (SD)	1.73 (0.96)	1.08 (0.39)	1.54 (0.88)	1.00 (0.68)
<b>Hedonic scale scores of Epi-E, median (min, max)*</b>				
Overall liking	5 (5, 5)	5 (5, 5)	5 (4, 5)	5 (5, 5)
Color	5 (5, 5)	5 (5, 5)	5 (4, 5)	5 (5, 5)
Taste	5 (5, 5)	5 (5, 5)	5 (4, 5)	5 (5, 5)
Smell	5 (5, 5)	5 (5, 5)	5 (4, 5)	5 (5, 5)
<b>Interviewer perceptions, n (%)</b>				
Interviewer believes participant liked Epi-E	26 (100.0)	26 (100.0)	27 (96.42)	27 (100.0)

\*Response values ranged from 1 (Dislike a lot) to 5 (Like a lot)

### 5.3 Home-Feeding Trial Results (Tables 3 – 4)

- Only two reported side effects (fever, change in urine color).
- No sachet went unused; none was traded/sold.
- Preference for consumption directly from sachet rather than as a mixture, due to "convenience" and "flavor."
- During Ramadan, Epi-E was eaten in morning and evening, whereas consumed in morning or midday during Ramadan.
- All women reported positive feelings toward Epi-E, claiming "have begun to feel energy" and "gained strength."
- Nearly all women said they would purchase Epi-E if sold and would be willing to pay more for it than for both their prescribed micronutrient and for their favorite snack food.

Table 3. Epi-E consumption during 2-week home trial

	June 2014 (Ramadan)	September 2014 (non-Ramadan)
No. of participants, (n)	25	23
<b>Sachet utilization at home</b>		
No. sachets received at start of trial period, (n)	16	14
No. of total sachets consumed by participant, Mean (SD)	14.0 (0.3)	14.0 (0.2)
No. of sachets consumed by participant per day, Mean (SD)	1.7 (0.5)	1.1 (0.3)
No. sachets consumed by others, Mean (SD)	2.0 (0.3)	0.0 (0.2)
Any sachets sold or traded, n (%)	0 (0.0)	0 (0.0)
<b>Usual amount of Epi-E eaten each time consumed, n (%)</b>		
Half sachet	18 (72.0)	2 (8.7)
Full sachet	7 (28.0)	20 (87.0)
More than a full sachet	0 (0.0)	1 (4.3)
<b>Time(s) of day consumed Epi-E*, n (%)</b>		
Morning	21 (84.0)	18 (60.0)
Midday or Afternoon	2 (8.0)	12 (40.0)
Dinner or Evening	19 (76.0)	0 (0.0)
<b>How usually consumed Epi-E, n (%)</b>		
Mixed with food	1 (4.0)	0 (0.0)
Directly from sachet	24 (96.0)	23 (100.0)

\*Times of day consumed Epi-E\* was calculated as the sum of total reported feeding episodes.

Table 4. Participant perceptions after 2-wk home trial

	September 2014 (non-Ramadan)
No. of participants, (n)	23
<b>Hedonic scale scores of Epi-E*, median (min, max)</b>	
Overall liking	5 (5, 5)
Color	5 (5, 5)
Taste	5 (5, 5)
Smell	5 (5, 5)
<b>Interviewer's perception, n (%)</b>	
Interviewer believes participant was enthusiastic about Epi-E	23 (100.0)
Willingness to eat Epi-E again, n (%)	23 (100.0)
Willingness to purchase Epi-E, n (%)	22 (95.70)
<b>Willingness to pay for Epi-E, Mean (SD)</b>	
Amount willing to pay per daily sachet of Epi-E*	\$0.31 (0.29)
Amount last paid for daily prenatal micronutrient	\$0.05 (0.05)
Amount last paid for 1 serving of favorite snack food	\$0.31 (0.19)
Willing to pay more for Epi-E than prenatal micronutrient, n (%)	23 (100.0)
Willing to pay more for Epi-E than favorite snack, n (%)	15 (65.21)

\*All monetary values reported in USD and based on mid-market exchange rate (1 USD = 516.95 CFA Franc) during month of study (September 2014) [www.xe.com](http://www.xe.com)

## 6. CONCLUSIONS

- First study to assess acceptability and utilization of a 40-g LNS formulation among pregnant women in Niger.
- Despite its novel formulation with nearly 2 times the typical micronutrient profile, acceptability was high.
- Given the positive results, Epi-E has been introduced in a larger ongoing clinical effectiveness trial.

## 7. ACKNOWLEDGEMENTS

- We would like to acknowledge and extend our gratitude to Kathryn G. Dewey and Mary Arimond for sharing their materials and procedures from iLiNS work in Ghana.

## 8. REFERENCES

- Black, R. E., Victora, C. G., Walker, S. P., Bhutta, Z. A., Christian, P., De Onis, M., . . . Martorell, R. (2013). Maternal and child undernutrition and overweight in low-income and middle-income countries. *The Lancet*, 382(9890), 427-451
- Hoddinott, J., Behrman, J. R., Maluccio, J. A., Melgar, P., Quesada, A. R., Ramirez-Zea, M., . . . Martorell, R. (2013). Adult consequences of growth failure in early childhood. *The American Journal of Clinical Nutrition*, 97(6), 1593-1600
- McClure, E. M., Goldenberg, R. L., Dent, A. E., & Meshnick, S. R. (2013). A systematic review of the impact of malaria prevention in pregnancy on low birth weight and maternal anemia. *International Journal of Gynecology & Obstetrics*, 121(2), 103-109
- Huybregts, L., Roberfroid, D., Lanou, H., Menten, J., Meda, N., Van Camp, J., & Kolsteren, P. (2009). Prenatal food supplementation fortified with multiple micronutrients increases birth length: a randomized controlled trial in rural Burkina Faso. *American Journal of Clinical Nutrition*, 90(6), 1593-1600
- Mridha, M. K., Matias, S. L., Chaparro, C. M., Paul, R. R., Hussain, S., Vosti, S. A., . . . Saha, S. L. (2016). Lipid-based nutrient supplements for pregnant women reduce newborn stunting in a cluster-randomized controlled effectiveness trial in Bangladesh. *AJCN*, 103(1), 236-249
- Dewey, K. G., & Arimond, M. (2012). Lipid-based nutrient supplements: how can they combat child malnutrition. *PLoS Med*, 9(9), e1001314
- Adu-Afarwah, S., Lartey, A., Zeilani, M., & Dewey, K. G. (2011). Acceptability of lipid-based nutrient supplements (LNS) among Ghanaian infants and pregnant or lactating women. *Maternal & Child Nutrition*, 7(4), 344-356
- Ashorn, U., Alho, L., Arimond, M., Dewey, K. G., Ashorn, P. (2015). Malawian mothers consider lipid-based nutrient supplements acceptable for children throughout a 1-year intervention, but deviation from user recommendations is common. *Journal of Nutrition*, 145, 1588 - 1595