



# KEY RESULTS TO DATE: iLiNS Project, March 2015

## BACKGROUND

- The first 1,000 days of life, from conception to age two, is considered to be a critical window because adequate nutrition during this period lays the foundation for healthy growth and development throughout childhood and into adulthood.
- Stunting by age two is an indicator of poor growth and is associated with adverse outcomes. The path to stunting is complex and can have an intergenerational dimension, including the interplay of poor diets and infection.
- Many women and young children in resource-poor settings do not receive sufficient nutrient-dense foods, which can have adverse consequences for maternal health, pregnancy outcomes, and child growth and development. Small-quantity lipid-based nutrient supplements (SQ-LNS) were designed to fill gaps between typical intakes and needs.

## THE iLiNS APPROACH

- The iLiNS Project explored the potential of SQ-LNS to support healthy growth and development. This potential was suggested in several earlier studies in Ghana and Malawi, but additional studies were needed.
- After developing several new formulations of SQ-LNS, the iLiNS Project conducted four randomized trials in Burkina Faso, Ghana and Malawi to evaluate the impact of providing SQ-LNS to pregnant and lactating women and infants and young children.
- The iLiNS Project also extends beyond efficacy trials to explore a range of economic issues, including cost-effectiveness, willingness to pay for the SQ-LNS products, and a range of possible product delivery systems.

## SELECTED HOUSEHOLD CHARACTERISTICS IN THE TRIAL SITES

- Food insecurity at the Burkina Faso and Malawi sites was moderate to high at baseline, and fell over time; levels of food insecurity and poverty in the Ghana site were low.
- At baseline, 79%, 93%, and 88%, respectively, of households in the Burkina Faso, first Malawi trial (iLiNS-DOSE) and second Malawi trial (iLiNS-DYAD-M) samples were below the World Bank poverty line.

## SUMMARY OF iLiNS TRIAL RESULTS

### Combined Pre-and Postnatal SQ-LNS: iLiNS-DYAD trials in Ghana and Malawi

#### OBJECTIVES

The main objective of the trials of combined pre- and postnatal home fortification with SQ-LNS for pregnant women and their children was to assess the impact of SQ-LNS on birth outcomes (birth weight, length and head circumference), as well as child growth and development outcomes at 18 months.

#### KEY FINDINGS

##### Birth outcomes:

When looking at combined results from Ghana and Malawi, infants born to mothers in the SQ-LNS group were heavier, longer and had larger head circumference at birth when compared to the group receiving iron and folic acid (control group). In Ghana, but not Malawi, SQ-LNS had a positive impact on the birth size of infants born to first-time mothers, when compared to both the control group and the multiple micronutrient group. This effect was not observed among mothers for whom it was not their first birth.

In both Ghana and Malawi, pregnant women with certain pre-existing risk factors for delivering a small infant were more likely to respond to LNS by having larger infants. In Ghana, these more “vulnerable” women included first-time mothers and in Malawi they included women with low education or pre-existing HIV or malaria infection.

##### Growth and development:

In Ghana, SQ-LNS provided through much of the “thousand days” was shown to have a positive impact on weight and length at 18 months of age when compared to the control group. Results suggest that the SQ-LNS intervention was able to reduce stunting in Ghana, where the prevalence of stunting in the study population at 18 months was about 12%. By contrast, in Malawi, researchers saw no significant effect of the intervention on child size at 18 months, where the prevalence of stunting in the study population at 18 months was 35%. There were no significant differences in child development outcomes at 18 months between intervention groups in either Ghana or Malawi. However, in both sites, the percentage of infants able to walk independently at 12 months of age was higher in the SQ-LNS group than in the control group.

#### INTERPRETATION

Findings suggest that prenatal SQ-LNS supplementation may help offset the influence of other risk factors for small birth size, such as malaria, HIV infection and low education levels.

The lack of response in less vulnerable women may suggest that there was limited potential for improvement and/or fetal growth is constrained by other factors.

These results suggest that the SQ-LNS intervention was able to reduce stunting in Ghana but not in Malawi. In Ghana, growth patterns among infants in all study groups were parallel after birth, which implies that most or all of the impact on child size at 18 months is attributable to the initial impact on birth size.

## Postnatal Trials: iLiNS-ZINC Trial (Burkina Faso) and iLiNS-DOSE Trial (Malawi)

### OBJECTIVES

The main objective of the iLiNS-ZINC trial was to determine the appropriate amount of zinc to include in SQ-LNS for infants and young children. Children in the intervention groups received 20g of SQ-LNS daily with various amounts of zinc, along with malaria and diarrhea surveillance and treatment (the “iLiNS-ZINC package”). As a second objective, children who received the iLiNS-ZINC package were compared with children who received neither SQ-LNS nor morbidity surveillance and treatment.

The main objective of the iLiNS-DOSE trial was to identify the most cost-effective growth-promoting daily dose and formulation of LNS. Intervention groups received varying doses of LNS containing milk powder or milk-free LNS.

### KEY FINDINGS

The children who received the iLiNS-ZINC package had significantly increased growth (weight and height) and reduced prevalence of stunting, wasting and anemia compared to children who did not receive SQ-LNS nor morbidity surveillance and treatment. These outcomes were not related to the amount of zinc provided. Children who were provided the iLiNS-ZINC package scored higher in motor, language and personal-social skills than children who did not receive the iLiNS-ZINC package.

There were no significant differences in growth or child development among the different study groups in the iLiNS DOSE trial. The prevalence of stunting increased in all groups during the study.

### INTERPRETATION

Children in Burkina Faso were thinner than children in Malawi from the outset and therefore, may have been more likely to respond to a nutritional supplement.

## Consensus points emerging from iLiNS socioeconomic research

### DEMAND FOR SQ-LNS

- Reported willingness-to-pay for SQ-LNS products was positive for nearly all respondents. Product-specific averages at baseline for a one-day supply ranged from US\$0.57 for SQ-LNS for pregnant and lactating women at the Ghana site to US\$0.15 for SQ-LNS for infants at the Malawi DOSE site.
- Provision of SQ-LNS during the trials did not generally influence reported willingness-to-pay.
- Willingness-to-pay revealed at auctions for SQ-LNS products was also positive for nearly all participants. Product-specific averages for a one-day supply were: US\$0.25 for SQ-LNS for women in Ghana and US\$0.12 for SQ-LNS for infants in Burkina Faso.
- A year-long, subsidized market trial for SQ-LNS was undertaken in Burkina Faso at the conclusion of the iLiNS-Zinc trial.
  - Caregivers purchased over 70,000 of sachets of SQ-LNS.
  - Initial demand was encouraging, but persistent demand dropped continually over the market trial, despite demand promotion activities.
  - Average consumption rates were well below one sachet/child/day.
  - Consumers, especially repeat-consumers, were highly sensitive to price.

## SUPPLYING SQ-LNS

- Average estimated production cost of SQ-LNS for infants (20g w/milk), produced in a new facility in Niger, is US\$0.14/sachet; at full capacity, the price drops to approximately US\$0.11/sachet.
- Identical products sourced from France and shipped to Niger cost approximately 20% more, under current import tax schemes.
- Production costs for milk-containing SQ-LNS are approximately 8% higher than for non-milk SQ-LNS.

## IMPLICATIONS OF SES RESULTS

- At the Burkina Faso site, measured demand for SQ-LNS is well below the daily consumption protocol tested in the trial. This pattern may be reflective of demand in other low-income settings, and its implications for household choices go beyond market-based distribution platforms.
- Local production of SQ-LNS likely will not dramatically reduce product costs.
- Many potential delivery platforms exist:
  - Choice of platforms will influence the public costs of providing SQ-LNS, SQ-LNS consumption patterns, and who pays what portions of total provision costs.
  - Choice of platforms will not influence the large proportion of product procurement/transportation costs in total cost.
  - Markets are ubiquitous and hence a tempting delivery platform, but in low-income settings, SQ- LNS consumption will likely be below trial-protocol levels.
  - Community-based and hybrid delivery platforms are currently ill-defined and untested.
  - Cross-community differences in nutritional needs and poverty suggest a need for spatial variation in the design/management of community-based SQ-LNS distribution platforms.
- There is a need for greater clarity among potential consumers and product promoters/vendors regarding SQ-LNS, and among researchers and practitioners regarding the benchmark(s) for effective demand for SQ-LNS, for children and for PLW.

### Implications for future policy and programming

- The potential for SQ-LNS to prevent malnutrition and improve health is only beginning to be understood. The positive results in children in Burkina Faso and during pregnancy in Ghana are encouraging, but the heterogeneity in response, evidenced by lack of response in Malawi, requires further investigation.
- These and other studies suggest that adequate access to health care and/or better sanitation and hygiene may be needed in combination with improved nutrition to achieve sustained responses in child growth and development.
- The findings in Ghana suggest that the prenatal component of the SQ-LNS intervention was more influential than the postnatal component in that setting, with respect to growth status at 18 months. However, the intervention package in Burkina Faso, which did not start until 9 months of age, reduced stunting at 18 months in that setting (where postnatal stunting was much more prevalent than in Ghana). This implies that both pre- and postnatal interventions can be effective, depending on the context and co-interventions.
- The impact of SQ-LNS should be tested more broadly in the context of programmatic initiatives that integrate nutrition into more comprehensive strategies; currently several research teams are working in partnership with implementers in on-going studies.
- If results from Burkina Faso and Ghana are replicated, interventions including SQ-LNS that generate similar stunting reductions have the potential to reduce the high public health and economic burdens currently resulting from early undernutrition in such countries.
- Policy makers will need to decide if this justifies the required investment.