International Lipid-Based Nutrient Supplements (iLiNS) Project

Project goal

To further develop the evidence base for the use of lipid-based nutrient supplements (LNS) to *prevent* under-nutrition in vulnerable populations.

Context

Tackling under-nutrition, including micronutrient deficiencies, is increasingly recognized as a high priority and high-return development investment. While attention has often focused on one or several individual micronutrients such as iron or vitamin A, poor quality diets are known to result in multiple deficiencies. Infants, young children and women of reproductive age are most vulnerable due to the high nutrient requirements of growth, pregnancy and lactation. For these groups, innovative and affordable approaches are needed to fill gaps in essential nutrients, and policy action may be required to develop and deliver them.

Summary

Lipid-based nutrient supplements (LNS) are a family of products designed to deliver nutrients to vulnerable people. They are considered "lipid-based" because the majority of the energy provided by these products is from lipids (fats). All LNS products provide a range of micronutrients, but unlike most other multiple micronutrient supplements LNS also provide energy, protein, and essential fatty acids (EFA). Like other essential nutrients, EFA cannot be produced within the body and must be consumed. High energy/high dose LNS products such as Plumpy'nut™ have emerged as a very effective option for treating severe acute malnutrition in children, and make it possible to do so via community-based programs. LNS products with a lower energy dose but a full complement of micronutrients were developed to enrich and not replace locally available foods. In early trials, they demonstrated potential to prevent child stunting and support normal motor development in Malawi and Ghana.

The iLiNS Project was designed to build on the earlier work by conducting additional efficacy trials in Malawi, Ghana, and Burkina Faso. The iLiNS Project trials aimed to confirm the potential of LNS for *prevention* of under-nutrition, and to identify product formulations that are improved with respect to nutrient content and energy dose, while keeping cost as low as possible. In addition to targeting children from 6 to 18 months of age, the iLiNS Project included two trials to evaluate the impact of LNS given to women during pregnancy and the first 6 months of lactation, as well as to their children from 6 to 18 months. The iLiNS Project also extended beyond efficacy trials to explore a range of economic issues, including costs, willingness to pay for the LNS products, and possible product delivery systems.

Objectives

iLiNS Project activities were structured around the following six objectives (study sites in parentheses):

1. Develop and test the acceptability of alternative LNS formulations for various target groups (all sites)

2. Evaluate the efficacy of reduced-cost formulations of LNS for infants and young children (Malawi)
3. Determine the optimal amount of zinc to include in LNS (Burkina Faso)
4. Evaluate the efficacy of LNS products for pregnant & lactating women (Malawi, Ghana)
5. Conduct socio-economic studies of LNS (demand, delivery systems, cost-effectiveness) (all sites)
6. Coordinate efforts, build capacity and use results to inform policies and programs

Efficacy study designs and outcomes

For objectives 2-4, we conducted four controlled intervention trials in which participants were randomly assigned to different study groups (see below). The trials used products developed and tested under Objective 1.

Objective 2: Malawi	**Objective 3: Burkina Faso**	**Objective 4: Malawi and Ghana**
1920 children	3200 children	~1300 women and their infants
LNS from 6 to 18 mo of age	LNS from 9 to 18 mo of age	LNS, multiple micronutrients or iron-folic acid tablets
6 study arms, varying dose & cost: • LNS with milk, 40 g/day • LNS no milk, 40 g/day • LNS with milk, 20 g/day • LNS no milk, 20 g/day • LNS with milk, 10 g/day • Delayed intervention	5 study arms, 20 g LNS/day, varying zinc: • LNS no zinc & placebo tablet* • LNS 5 mg zinc & placebo tablet* • LNS 10 mg zinc & placebo tablet* • LNS no zinc & 5 mg zinc tablet* • Delayed intervention *tablets given between meals	3 study arms, varying product and duration: • LNS 20 g/day, pregnancy, lactation to 6 mo & for child from 6 to 18 mo of age (comprehensive) • Multiple micronutrient tablet, pregnancy & lactation • Iron-folic acid tablet during pregnancy and placebo (low dose calcium) during first 6 mo lactation (standard care control)

Outcomes

- *Infants/children*: Anthropometric (growth) outcomes, anemia and micronutrient status, fatty acid status, morbidity, immune response, neuro-behavioral development, energy intake from complementary foods, infant and young child feeding practices, breastmilk intake, physical activity, adverse events.
- *Mothers*: Pregnancy weight gain and birth outcomes, anemia and micronutrient status, fatty acid status, salivary cortisol, breast milk composition (micronutrients and essential fatty acids), depressive symptoms, oral health, lipid profile.
- *Socioeconomic studies*: Estimates of willingness-to-pay (WTP) for LNS products, based on a) survey-based questionnaires, b) economic experiments with LNS auctions, and c) market tests of LNS products; estimates of the costs of alternative formulations and dosages of LNS.