



Feasibility of a Multiple Biofortified Food Intervention and its Potential Impact in the 1,000 Days Window of Opportunity: Proceedings of an Expert Consultation Meeting

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Facilitator:
Jonathan Gorstein

Rapporteurs:
Moira Donahue Angel and Alexandra Ruth

HarvestPlus leads a global effort to improve nutrition and public health by developing and deploying staple food crops that are rich in vitamins and minerals. We work with diverse partners in more than 40 countries. HarvestPlus is part of the CGIAR Research Program on Agriculture for Nutrition and Health (A4NH). CGIAR is a global agriculture research partnership for a food secure future. Its science is carried out by its 15 research centers in collaboration with hundreds of partner organizations. The HarvestPlus program is coordinated by two of these centers, the International Center for Tropical Agriculture (CIAT) and the International Food Policy Research Institute (IFPRI).



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INTRODUCTION

The HarvestPlus Nutrition Team convened a consultation meeting of experts in human nutrition and public health to discuss the potential feasibility of implementation and impact of a multiple biofortified-food efficacy trial throughout the entire 1,000 days window of opportunity. The envisioned trial would be the first of its kind to 1) test the impact of an agri-nutrition intervention within the context of Sustainable Development Goal No. 2 during these critical phases of human growth and development, and 2) study the impact of the *combination* of biofortified foods rich in pro-vitamin A carotenoids, iron and zinc on the nutrition and health status of women and their infants and young children. The goal of the meeting was for the experts to:

- Determine if there is sufficient evidence to support the hypothesis that multiple biofortified foods would have measurable nutritional impact during the 1,000 days window; and
- Recommend design elements of such an efficacy trial in order to maximize its potential for achieving impact.

In preparation for the consultative meeting, HarvestPlus commissioned GroundWork to conduct an extensive systematic review of the effect of interventions with low micronutrient doses on maternal and infant/child outcomes (1). The specific objective of the review was limited by available research and focused on the effects of low dose supplementation or fortification with vitamin A, zinc and iron during pregnancy and the first 2 years of life on child nutrition and health outcomes. The review was limited to interventions that used micronutrient dosages that are within the range of what can be achieved through currently available biofortified crops, given expected consumption patterns among different vulnerable groups.

RATIONALE

At present, HarvestPlus has moved from the delivery of single biofortified crops to deployment of multiple biofortified crops in several countries, with many more countries predicted to benefit from multiple biofortified crops in the years to come. Given the advantage of biofortification as a sustainable and cost-effective measure to enhance population micronutrient intake, it follows that a food basket of multiple biofortified foods also has the advantage of improving intake earlier in the lifecycle, especially pre-conception, and may have profound benefits during critical stages of human growth and development.

The rationale for expanding the target population from non-pregnant, non-lactating women and children 4-6 years of age to adolescent women, pregnant women and the fetus, and children during the first 2 years of life is based on encouraging results from over 12 years of research on the nutrient retention, nutrient bioavailability/bioconversion, and efficacy of HarvestPlus' target crops, which are biofortified with provitamin A, iron and zinc (2). During the early phases of discovery and development (2003-2014), HarvestPlus was cautious in defining its target beneficiary populations, because it was uncertain to what extent the younger children and pregnant women could benefit from the relatively small additional amounts of iron, zinc and vitamin A provided through biofortified crops, given the high physiological requirements associated with growth, pregnancy and lactation. Since then, results of bioavailability studies with children <3 years (3, 4) and women of child bearing age (5-8) point to important proportions of the Estimated Average Requirements for iron, zinc or vitamin A (RAE) being delivered by single biofortified crops. Further to these inputs, significant improvements in iron and vitamin A status of school children and women of reproductive age have been documented by randomized controlled efficacy trials with iron biofortified crops such as rice (9), beans (10) and pearl millet (11) and with provitamin-A biofortified crops including orange sweet potato (12), maize (13) and cassava (14). In addition, provitamin-A biofortified orange sweet potato has been shown to be an effective strategy for improving vitamin A status among children (15). To further expand the evidence base of single crops, HarvestPlus is currently conducting separate iron, zinc and provitamin-A crop efficacy trials with children <2 years in Mumbai, Bangalore and Delhi, and Zambia, respectively.

SUMMARY OF EVIDENCE FROM LOW-DOSE SUPPLEMENTATION AND FOOD-BASED TRIALS DURING PREGNANCY, INFANCY AND CHILDHOOD ON CHILDHOOD OUTCOMES

The systematic review and meta-analysis (1) investigated the effect of low-dose vitamin A, iron, zinc and multiple micronutrient interventions (delivering at least two out of the three micronutrients) during pregnancy, lactation and early childhood on young child outcomes. No single study that meets the inclusion criteria (low dose, age range, and frequency of micronutrient administration) spanned the entire 1,000 day window and also reported on child nutrition and health indicators. The key questions posed to the consultative group during the discussions of these results focused on how to interpret and extrapolate results from relevant fortification and supplementation interventions to a longer-term multiple biofortified food intervention. Results from the meta-analysis and key discussion points are summarized in this section.

Vitamin A

The body of evidence for an impact of low-dose vitamin A supplementation (up to 12 mg RAE for women and 3 mg RAE for infants/ children) during pregnancy and lactation on birth and child outcomes is small but consistent. Data suggest that there is a positive effect of pro-vitamin A/ preformed vitamin A given during pregnancy and lactation on cord blood retinol at birth and serum retinol up to 6 month of age, as well as on the vitamin A status of the mother and on breast milk retinol. However, no effect is seen on birth outcomes or child growth. Similarly, vitamin A interventions delivered to infants have a positive effect on their vitamin A status.

Discussion:

There is great potential of long-term impact from pro- vitamin A biofortified crops, perhaps more so than other biofortified crops because of the high pro- vitamin A concentration and frequency of (per capita) consumption. Important considerations raised are that serum retinol may not be as sensitive a biomarker to interventions with beta-carotene as serum beta-carotene in some populations; however, the functional relevance of serum beta-carotene is not well-understood. Evidence suggests that dark adaptometry (Palmer A, unpublished manuscript) and isotope dilution tests (12) are sensitive to small increases in the intake of pro-vitamin A foods, with the former being sensitive even under conditions of high prevalence of infection/inflammation. Furthermore, given that serum retinol is affected by inflammation, selecting a population that does not have malaria or HIV is necessary in order to interpret any study which aims to illustrate the impact of pro-vitamin A biofortified foods on vitamin A status.

Iron

The evidence of low-dose iron interventions during pregnancy consistently shows no effect on birth weight and prevalence of preterm birth. None of the eligible studies reported on child growth or child iron biomarker effects of iron administered during pregnancy. Low-dose iron interventions during infancy consistently show improvements in mean hemoglobin, mean serum ferritin as well as reductions in anemia (RR=0.59 [0.49 – 0.70]), iron deficiency (RR=0.22 [0.12 – 0.35]), and iron deficiency anemia (RR=0.20 [0.11 – 0.37]). Effects are small to moderate in trials administering a minimum dose of 6 – 8 mg per day and much larger in studies delivering 8 – 10 mg of iron per day. Supplementation had a larger effect than fortification, regardless of the dosage, presumably due to the negative effect of food per se on iron absorption. Baseline deficiency status and correction for inflammation were not accounted for in all studies, while subgroup analyses on iron deficiency (“low” or “adequate” iron status based on baseline mean serum ferritin) and inflammation (“corrected for inflammation” or “not corrected for inflammation”) did not yield any differences and did not explain heterogeneity of the results. In addition, the evidence suggests that low dose iron interventions have no impact on growth or morbidity outcomes (diarrhea, fever, respiratory infections). There is too little evidence on the potential impact on mental and psychomotor development in childhood associated with low-dose iron interventions to draw conclusions.

Discussion:

The significant impact of low-dose iron interventions on anemia and iron deficiency in infancy and early childhood is very compelling, although it may not be feasible to deliver 6 mg of additional iron through biofortified crops in this age

group. However, in thinking about the lifecycle, improving maternal status before and during pregnancy will pass on benefits to offspring, which may translate to important improvements in iron status even at very low levels.

Zinc

The evidence suggests that there is no significant effect of daily low-dose zinc of up to 21 mg during pregnancy on birth weight or on the probability of low birth weight. Limited or no data are available on the effect of zinc use during pregnancy and lactation on child growth, morbidity, zinc status as well as psychomotor and mental development. Providing up to 10mg additional zinc daily during infancy significantly increased serum/plasma zinc concentration by 2.03 $\mu\text{mol/L}$ ($p < 0.001$) and reduced the risk of zinc deficiency by 48% ($p < 0.001$) in infants 6-23 months of age. Subgroup analyses indicated that fortification had no effect on serum zinc levels, and that the strongest effect of supplementation on serum zinc is obtained when a daily dose of 7-10 mg is administered.

Discussion:

There is strong evidence that serum zinc is responsive to supplementation, but there is no evidence that zinc delivered as a fortificant results in changes of serum levels. The theory for this is that post-absorption metabolism of zinc is different when zinc is consumed with food, e.g. it may be delivered to the bone. It can be concluded from the evidence presented that food-based zinc interventions have no effect on serum zinc concentrations, at least for the doses administered during the duration of the studies included in the systematic review, namely 15 days to 12 months. However, other metabolic (and functional) indicators of zinc status are under development and hold promise at showing impact from zinc interventions.

SHOULD HARVESTPLUS EXPAND ITS TARGET POPULATION?

One of the key features of biofortification is that it reaches entire communities with the goal of improving the family diet. There are plausible benefits for other members of the household beyond the current HarvestPlus target populations, such as grandmothers, fathers, and especially adolescent girls.

However, the consensus of the technical experts was that the 1,000 days window may not be the right target for a food basket study. There are a number of logistical challenges with an exclusive focus on the potential contribution of biofortified foods on the 1,000 day window, including: (1) nutrient requirements among pregnant and lactating women are very high, (2) food consumption among infants (including potential biofortified crops) is very low, (3) and there is exposure to other interventions during this time period (i.e. iron supplementation during pregnancy, vitamin A supplementation in infancy) that should be taken into consideration.

Instead, the consultation concluded that the entire family or household may be more appropriate as the unit of intervention, and, if a basket of multiple biofortified foods is viable, shifts in micronutrient status among the entire population could be measured. However, if such a broad focus on the entire population is too ambitious or not feasible, adolescents or pre-adolescents would be a good target group for a food basket study. Adolescent girls have increased nutrient requirements due to rapid growth and physiological change; their food consumption is relatively large, and they represent an important target for improved nutrition and public health programs.

CONSIDERATIONS FOR AN EFFICACY TRIAL VS AN AGRICULTURAL INTERVENTION (EFFECTIVENESS STUDY)

The approach of HarvestPlus historically has been to establish efficacy of a single biofortified crop on micronutrient status before moving forward with effectiveness trials, crop delivery, and scaling up of programs. In the past, the scientific community and donors needed evidence that micronutrients provided from biofortified foods consumed at current levels of non-biofortified variants could be absorbed efficiently and sufficiently enough to improve the micronutrient status of populations. Moreover, efficacy data are often requested by stakeholders and in-country policymakers before making large investments in biofortification programs in their countries.

However, a multiple biofortified food basket study differs from single-crop studies and delivery programs in a few important ways. The food basket would likely deliver a more significant part of the household's diet than what is delivered in the single-crop studies. Thus, it is critical to understand the overall population consumption patterns under normal conditions and determine whether these amounts are sufficient enough to have impact on nutritional status if substituted with biofortified foods. In addition, the cultivation, harvesting, seasonality, and delivery mechanisms will likely vary for multiple biofortified foods in any given setting. Understanding these agricultural considerations will inform the feasibility and practicality of a multiple biofortified food basket and whether or not it will have meaningful impact on the diets and nutritional status of populations. The consultation concluded that preliminary investigative work on these aspects of feasibility, particularly those relevant to an agricultural intervention, would be required to properly inform whether any study of the biological impact, such as an efficacy trial, would be a worthwhile endeavor. In addition, the consultation also raised the broader question of whether an efficacy trial of multiple biofortified crops is needed when there is evidence from single biofortified crops.

WHAT OUTCOMES SHOULD BE CONSIDERED WHEN LOOKING AT A FOOD BASKET INTERVENTION OF BIOFORTIFIED FOODS?

If the preliminary investigative work indicates that a multiple biofortified food intervention is feasible, the primary outcome of an intervention is increased nutrient intake in order to determine the potential contribution of multiple-biofortified crops to meeting dietary requirements. In addition to intake, effects on the diet's nutrient density and diversity should also be considered. However, there was no clear consensus on whether biological and functional outcomes should be measured. Some experts believed that it would be difficult to demonstrate measurable effects on status and functional indicators in real-life settings and it may not be necessary to do so as showing improvement in micronutrient intake is compelling enough evidence on its own. Others believed that there is a good chance that the prevalence of micronutrient deficiency in the target population would shift and could be detected with current measurement tools. Moreover, showing biological impact may still be important to stakeholders and policymakers.

If it is decided that biological and functional outcomes will be measured in an efficacy study, the standard measures for vitamin A and iron status should be collected. New tools to evaluate the efficacy of iron interventions, such as the isotope dilution method, could be helpful. Given that there are no sensitive zinc biomarkers for food based interventions, it is recommended that biological samples be stored with the knowledge that new zinc biomarkers are on the horizon. Other outcomes to measure, depending on the target population, are dark adaptometry, breast milk retinol, gut microbiome, and measures of infection/inflammation.

THE WAY FORWARD: DEFINING A RESEARCH AGENDA

Moving forward, two phases of research were identified. The first phase is a feasibility assessment to determine if a biofortified food basket would be suitable and feasible in a particular area and whether the multiple biofortified basket could improve dietary intake. If the initial phase of work is deemed successful and viable, a second phase would be to design a study to determine the impact of a multiple biofortified food basket on nutritional outcomes in an area where a food basket approach has already been proven to be a feasible intervention.

Additional recommendations which emerged from the consultation regarding these two phases are described in greater detail below:

Phase 1: The purpose of this research is to determine the feasibility of filling multiple nutrient gaps through food baskets containing multiple biofortified crops. This will require profiling populations and existing dietary patterns in areas that are likely to benefit from a multiple biofortified food basket. This phase will also explore the mechanisms of how these foods will be deployed and introduced to communities, whether the most vulnerable demographic groups will adopt them, and predict if the food basket can improve their nutritional intake if the foods are consumed at current levels of the non-biofortified varieties. This assessment of the potential contribution of the multiple biofortified foods to the diet will be done through the adoption of linear programming tools, modelling exercises, and field work.

Key research questions:

Feasibility of the intervention

1. Is it possible from an agricultural point of view to combine multiple biofortified foods into an “existing food basket”? How will this vary by population group, demographics and setting?
2. How do delivery mechanisms and agricultural factors affect the feasibility of a biofortified food basket? Will multiple biofortified crops be grown on a farmer’s plot? If so, do planting and harvest seasons affect whether or not multiple biofortified foods appear on the consumer plate at the same time? If not, will a farmer purchase them in the market where there is significant competition from non-biofortified varieties?
3. How will the food basket be defined? Will the food basket of two or more biofortified crops be combined to increase intake of a single or multiple micronutrients? Will the food basket replace non-biofortified foods at levels currently consumed or will a food basket re-proportion the foods to have the greatest impact on population status?

Assessing the feasibility of the intervention

1. What are the candidate countries, or regions within countries, that could demonstrate the feasibility of a basket of biofortified foods, considering the current consumption levels of multiple crops, delivery mechanisms and adoption challenges? How will this vary by population group, demographics and setting? And are these populations deficient in multiple micronutrients that could be addressed by a biofortified food basket?
2. How are food basket items distributed among family members in the household and how do intakes of food basket items vary by household member?
3. Are the crops that are likely to be grown or purchased in a given environment combinable from a dietary and cultural point of view?
4. Would the food basket lead to improved intake at levels currently eaten? Would the nutrient density in diets of communities change after biofortified foods are introduced? Is there an optimal dietary pattern including local and biofortified foods that would further improve micronutrient intake in these populations?
5. What are the marginal gains when one includes biofortified foods as part of a package of interventions, such as in complement with improvements in water, sanitation and hygiene?

Phase 2: The purpose of this research is to test the impact of a multiple biofortified food basket agricultural intervention on narrowing multiple micronutrient intake gaps and improving specific outcomes in a target population with a high prevalence of micronutrient deficiencies through a cluster randomized effectiveness trial with a nested efficacy trial.

Key research questions:

1. What are the characteristics of adopters of multiple crops (i.e. modality of delivery of multiple crops, socioeconomic status, etc.), and what are the barriers to uptake?
2. What is adherence and acceptability to multiple biofortified crops?
3. What is the household distribution of the food basket? Is there equitable distribution among family members, particularly among girls?
4. Does a multiple biofortified food basket improve micronutrient intake and close nutrient gaps, and how does this vary by age/physiological group?
5. What is the change in density in diets of communities after biofortified foods are introduced? And over the long-term?
6. Will a behavioral intervention that optimizes dietary patterns containing local and biofortified foods improve micronutrient intake?

An additional nested efficacy trial was proposed, which would test the nutritional impact of a food basket intervention among pre/adolescent girls or a group that Phase 1 identifies as being most likely to respond to the intervention:

1. What is the impact of a food basket on micronutrient intake, micronutrient status and functional outcomes?
2. Does the impact on micronutrient intake, micronutrient status and functional outcomes vary by baseline deficiency in one or all three micronutrients?
3. Does the impact on micronutrient intake, micronutrient status and functional outcomes further improve from a behavioral intervention that optimizes dietary patterns containing local and biofortified foods?

NEXT STEPS

The guidance and recommendations from the group of experts have generated a clear mission for the Nutrition Unit at HarvestPlus. As a next step, the Nutrition Unit will produce a concept note that incorporates the social, cultural, dietary and agronomic feasibility assessment and family nutrition framework as detailed in these proceedings. The concept note will be shared internally at HarvestPlus and with a small committee of experts in the second quarter of 2016. Seed money for Phase 1 research has been secured, and the feasibility assessment will begin in the second half of 2016.

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ANNEX: Meeting participants

Meeting organizers/presenters

Jonathan Gorstein (facilitator), Department of Global Health, University of Washington, Seattle, WA and Executive Director, Iodine Global Network

Erick Boy, HarvestPlus/International Food Policy Research Institute, Washington, DC

Mourad Moursi, HarvestPlus/International Food Policy Research Institute, Washington, DC

Moirá Donahue Angel, HarvestPlus/International Food Policy Research Institute, Washington, DC

Alexandra Ruth, HarvestPlus/International Food Policy Research Institute, Washington, DC

Fabian Rohner, Groundwork, Crans-près-Céligny, Switzerland

Nicolai Petry, Groundwork, Crans-près-Céligny, Switzerland

Ibironke Olofin, Harvard School of Public Health, Boston, MA

Participants

Kenneth Brown, Bill and Melinda Gates Foundation, Seattle, WA

Colin Cercamondi, Laboratory for Human Nutrition, Swiss Federal Institute of Technology Zürich, Zurich, Switzerland

Parul Christian, Bill and Melinda Gates Foundation, Seattle, WA

Ian Darnton-Hill, Tufts University Friedman School of Nutrition Science and Policy and the University of Sydney Boden Institute of Obesity, Nutrition, and Exercise, New York, NY

Omar Dary, United States Agency for International Development (USAID), Washington, DC

Luz-Maria De Regil, Micronutrient Initiative, Ottawa, CA

Kathryn Dewey, Department of Nutrition, University of California Davis, Davis, CA

Julia Finkelstein, Division of Nutritional Sciences, Cornell University and St. John's Research Institute, Bangalore, India

Rafael Flores-Ayala, International Micronutrient Malnutrition Prevention and Control Program, Nutrition Branch, Division of Nutrition, Physical Activity and Obesity, US Centers for Disease Control and Prevention, Atlanta, GA

Maria Nieves Garcia-Casal, Evidence and Programme Guidance, Department of Nutrition for Health and Development, World Health Organization, Geneva, Switzerland

Marjorie Haskell, Program in International and Community Nutrition, Department of Nutrition, University of California Davis, Davis, CA

Richard Hurrell, Swiss Federal Institute of Technology Zürich, Zurich, Switzerland

Janet King, Children's Hospital Oakland Research Institute, Oakland, CA, and the University of California at Berkeley and Davis

Nancy Krebs, University of Colorado School of Medicine, Aurora, CO

Saurabh Mehta, Cornell University, Ithaca, NY

Amanda Palmer, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Andrew Prentice, MRC Unit The Gambia and MRC International Nutrition Group, London School of Hygiene & Tropical Medicine, London, United Kingdom

Marie Ruel, Poverty, Health and Nutrition Division, International Food Policy Research Institute

Hans Verhoef, MRC Unit The Gambia and MRC International Nutrition Group, London School of Hygiene & Tropical Medicine, London, United Kingdom

Keith West, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD