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CHAPTER 13

BUILDING THE CASE FOR BIOFORTIFICATION: MEASURING AND MAXIMIZING IMPACT IN THE HARVESTPLUS PROGRAM

Johnson N[1*], Asare-Marfo D[2], Zeller M[3] and E Birol[2]

*Corresponding author email: Nancy.Johnson@fao.org

[1]CGIAR Research Program on Agriculture for Nutrition and Health, International Food Policy Research Institute, Washington, DC

[2]HarvestPlus, International Food Policy Research Institute, Washington, DC

[3]University of Hohenheim, Stuttgart, Germany

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ABSTRACT

This paper describes the research and related activities that HarvestPlus undertook at each stage of the research process—discovery, proof of concept, delivery at scale—to establish and continuously strengthen the evidence base for program impact. Structured around the program's theory of change, the evidence base includes estimates of the magnitude of potential impacts on key development outcomes as well as support for key assumptions that underlie outcomes along the impact pathway from release of biofortified varieties through adoption by farmers, consumption by consumers, and ultimately, to improved nutritional status. The HarvestPlus experience has important lessons for research for development (R4D) programs, many of which struggle to demonstrate progress towards outcomes and impacts throughout the research process.

Key words: Research for Development (R4D), Impact Assessment, Theory of Change, Micronutrient Deficiencies, Crop Varietal Improvement

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INTRODUCTION

Development investments are expected to impact development outcomes. Estimating the impact is particularly challenging for investments in research for development (R4D), not only due to the long time lags between investment and impact, but also to the fact that large segments of the impact pathway are outside the control of researchers. To meet this challenge, HarvestPlus took a multi-pronged approach to building its case for impact, informed by its theory of change (Figure 13.1). In addition to rigorously estimating potential impact on key development outcomes, the program explained *how* impact was expected to happen by articulating a plausible pathway from research outputs to outcomes to impacts. Key causal assumptions behind the links in the impact pathway—what must happen for the causal linkages to occur—were identified. Testing these assumptions was built into the program research agenda.

While outcomes were expected to occur during and after the research process, work to estimate the potential size of impact on outcomes and to validate key underlying assumptions along the impact pathways started well in advance of when outcomes were expected to occur (Figure 13.1). The following sections describe examples of the kinds of research and evaluative studies that were done at each stage of the research process--Discovery, Proof of concept, and Delivery at scale[1]--to build the case for, and to maximize the probability of, program impact.

In addition to making the case for impact, HarvestPlus used the information and evidence generated to improve program performance, to engage key stakeholders, and to build intellectual, financial, and policy support for an innovative R4D agenda. HarvestPlus' systematic approach to building an evidence base for impact offers lessons for other R4D programs, and their stakeholders, about how to monitor progress towards outcomes and impacts throughout the research process [1].

[1] The phases of biofortification research defined below reflect overall research progression, however, the pace of work on a particular crop and/or country may have been faster or slower.

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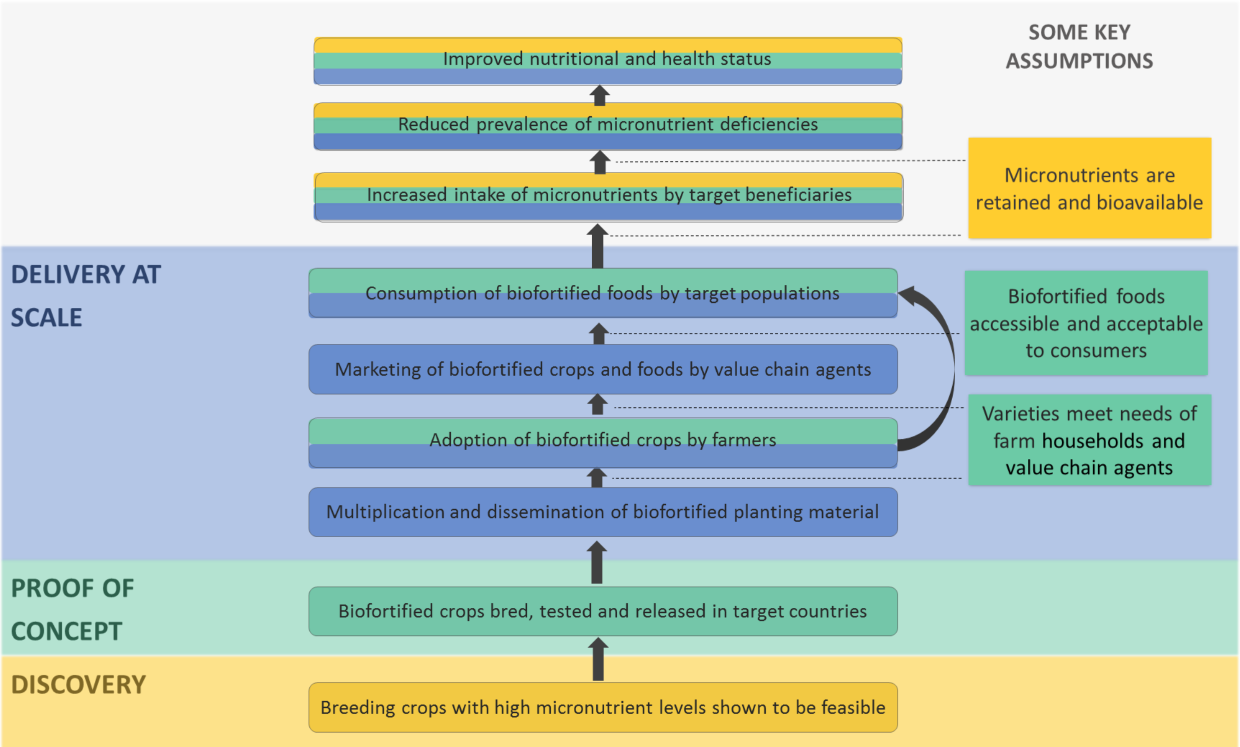

Figure 13.1: Biofortification theory of change and stage(s) of research at which impact evidence was generated

DISCOVERY PHASE (≈1995 TO 2008)

In 1995, CGIAR scientists began exploring the possibility of using conventional breeding techniques to breed micronutrient-rich staple crops. By 2000, they had evidence from six crops that "biofortification" was feasible[2]. At the same time, economists and nutritionists explored the potential impact, efficacy, and cost-effectiveness of biofortification. While it was recognized early on that breeding for high-levels of micronutrients had the potential to improve overall crop growth and productivity, proponents of biofortification were clear that its effectiveness must be judged in terms of its public health rather than agricultural impact. Only by showing a potential contribution to improving micronutrient status and reducing the associated human health burdens could investment in biofortfication, especially by the public health community, be justified. Proponents laid out a convincing narrative about how the one-time, up-front investment in breeding the crops would yield benefits for many years with little additional cost, comparing favorably with the recurring and thus accumulating costs of fortification and supplementation. The narrative was supported with initial estimates of how biofortification might increase micronutrient intakes at scale based on national data, and examples of how it might affect specific measures of micronutrient deficiency using available data from pilot studies where available [2].

[2] Proceedings of an international conference that reviewed the findings of the CGIAR Micronutrients Project are published in the *Food and Nutrition Bulletin*, Vol. 21, No. 4, December 2000.

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Even at this early stage, before the formation of HarvestPlus, it was clear that researchers had an impact pathway in mind and were aware of specific threats to the realization of large-scale, sustainable impact, including low adoption by farmers, depletion of micronutrients in the soil, lack of consumer acceptance, poor bioavailability, and possible micronutrient toxicity in humans. Notably, these risks reflected concerns from different sectors and disciplines, underscoring the need to engage and convince a diverse set of stakeholders that biofortification could work in terms of both agronomics and nutrition. During the discovery stage, research on the role of agro-food-value chains for biofortified seeds and food was not emphasized.

When biofortification became a CGIAR Challenge Program in 2004, a significant investment was made to rigorously estimate global impact and cost-effectiveness using Disability Adjusted Life Years (DALYs), a standard metric for assessing the impact of public health interventions. Economists and nutritionists worked together to develop a framework for systematically assessing the impact of consumption of biofortified crops on functional health outcomes [3] and used data from breeding programs, national statistics, and other sources to estimate the potential impacts and cost effectiveness (cost per DALY saved) for a range of crops and countries under different scenarios [4, 5, 6]. In the analysis, care was taken to provide transparent and plausible estimates of how much of the crop would be consumed, how it would be consumed (to take into account processing losses), and how much of the micronutrients would be absorbed by the body. Diet and health factors that could serve to promote or inhibit micronutrient absorption were also considered. The results showed that on average biofortification was a cost effective intervention, though the cost per DALY saved varied by crop and country (see Chapter 14 for additional detail). The findings of these studies provided important evidence on the potential of biofortification, and justification for increased investment.

PROOF OF CONCEPT PHASE (≈2008-2013)

Once the feasibility and potential cost effectiveness of biofortification was established, the challenge became demonstrating that biofortified varieties could be bred that were both nutritionally efficacious and attractive to farmers and consumers [7, 8, 9]. While official release of varieties is not generally considered part of proof of concept, in this case official release was necessary in order to be able to conduct effectiveness studies, as discussed below.

During proof of concept, new promising lines developed by the CGIAR centers during the discovery stage were tested by national research partners in target countries to select varieties with superior agronomic and nutrition traits compared to existing varieties [10]. HarvestPlus and its national research partners sought farmers' participation in multi-location trials (for example through demonstration plots and farmers' field days) to obtain information from female and male farmers on their preferences for agronomic and consumption traits of new varieties (see Chapter 5 for additional detail). This work was designed to ensure that assumptions about farmer adoption would hold, and at the same time provided valuable information to crop breeders about current popular varieties, preferred agronomic and consumption traits, and informed planning for crop delivery by

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providing information about the current structure of seed and food markets and farmers' access to seed as well as farmers' crop sales.

During this phase, HarvestPlus also launched a series of consumer acceptance studies that addressed a key question about the validity of the impact pathway —will consumers be willing to consume biofortified varieties, especially if they look and taste different from current varieties? Using accepted food science methods such as sensory evaluation and hedonic trait analysis, consumers' evaluation with respect to color, taste, texture, aroma, cooking, and storage characteristics of biofortified crop varieties were compared to conventional varieties by male and female consumers. In addition, various preference elicitation methods (including experimental auctions, revealed choice experiments, and stated choice experiments) adapted from the experimental economics literature quantified consumers' valuation of biofortified food compared to conventional food. Such research was conducted for vitamin A (orange) sweet potato in Uganda in 2006 [11]), for vitamin A maize in Zambia in 2007 [12] and in Ghana in 2008 [13], for vitamin A cassava in Nigeria in 2011 [14], for iron pearl millet in India in 2013 [15], and for high iron beans in Rwanda [16] and Guatemala in 2013 [17].

These studies also tested the impact of various levers on consumers' evaluation and valuation for biofortified foods. For example, nutrition information was given in different intensity and through different information channels to inform future delivery strategies on seed and food marketing. Other levers included different branding options and the nature (national or international) of the agency that is endorsing or delivering the biofortified staple food. Overall the studies show that biofortified foods are liked by target consumers, sometimes even in the absence of information about their nutritional benefits [18]. The results of the consumer acceptance studies helped allay concerns about whether biofortified varieties would be accepted and consumed [19] and generated important insights that country programs now use in the design of their advocacy and information campaigns, seed and food labelling and branding strategies, and nutrition education about biofortified varieties.

As varieties with sufficiently high target or near-target levels of micronutrients became available, efficacy studies were conducted to definitively assess whether consumption of biofortified foods could improve nutritional status. Data from six efficacy trials show that regular consumption of biofortified staple crops can significantly improve vitamin A and iron status and reduce the burden of micronutrient deficiencies in targeted populations living in South Asia, Sub-Saharan Africa, and Latin America [20]. Efficacy trials were carried out for vitamin A (sweet potato in South Africa, maize in Zambia) and iron (rice in Philippines, beans in Mexico and Rwanda, pearl millet in India) crops, but efficacy evidence for zinc rice and wheat is still being investigated.

While efficacy trials provide evidence under highly-controlled conditions (similar to medical research), effectiveness studies seek to assess impacts under more realistic conditions in farming communities. In effectiveness studies, biofortified crops are made available to farmers but the decisions about whether and how much to grow and/or consume are made not by researchers but by households and individuals within them. These studies, implemented as cluster randomized controlled trials, focus on a much larger portion of the impact pathway and provide even stronger evidence that biofortification can work. They require, however, certain conditions to be met in order to justify the significant investment. These conditions include completed efficacy studies and officially released biofortified varieties with full target micronutrient levels.

During the development phase, two such studies were conducted, both with orange sweet potato, in Uganda [21] and Mozambique [22]. The research showed that orange sweet potato production and consumption significantly increased, as did vitamin A intakes among children and women belonging to farm households that were randomly assigned to the treatment group that received biofortified planting material. In addition, the research tested two models for delivery of planting material to farmers. The less expensive, less intensive delivery model was found to be as effective as the more intensive and hence more expensive delivery [23]. These effectiveness trials helped to shape the delivery strategy for Uganda, Mozambique, and other countries. The cost per DALY averted was found to range between $15–20 for the least expensive delivery model, indicating a highly cost effective public health intervention. A recent study published in the Lancet stated, “The feasibility and effectiveness of biofortified vitamin A-rich orange sweet potato for increasing maternal and child vitamin A intake and status has been shown,” though the authors noted that similar evidence is needed for other crops and micronutrients [24]. Additional effectiveness studies for iron and zinc crops are planned.

Even though the program during this phase was not yet in a position to observe or document progress at scale in terms of reaching farmers or consumers, it generated a convincing body of evidence that biofortification was efficacious and likely to be cost-effective in practice. This evidence was useful for program management and helping with the design of delivery strategies, and it was also critical for engaging and maintaining stakeholder commitment to biofortification. HarvestPlus sponsored a symposium at the International Congress of Nutrition (ICN) in 2013 entitled “Biofortification: From Discovery to Impact.” Impact evidence played a crucial role in the transition from development to delivery at scale, both in terms of building the case for broad support (for example, session on evidence led by DFID at the Second Global Conference on Biofortification in Kigali in 2014) and investment in delivery in specific countries (for example, USAID in Uganda).

DELIVERY AT SCALE (≈2014-2018)

At the “delivery at scale” stage of the research cycle, research outputs should be available to support widespread dissemination. And indeed, in the case of HarvestPlus, evidence from research has been incorporated into the program’s delivery and scaling up strategies. While many crop improvement programs and projects end after proof of concept, HarvestPlus is funded to engage in delivery as part of the learning process. Therefore, the program is in a position to document outcomes along the pathway through both monitoring and evaluative research. Monitoring activities in HarvestPlus are carried out by its Monitoring, Learning and Action (MLA) unit and capture key indicators of program reach, such as the quantity of biofortified crop planting material produced and delivered and the number of farm households adopting and consuming biofortified crops.

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This information is collected regularly by country-level MLA teams using standardized protocols [25] and is the basis for learning within and across the country-programs, and for regular updating of the theories of change.

In addition to its accountability function, the MLA team, together with the economics and nutrition research teams, is tasked with helping the program learn from the delivery experience about what is working, where and why, and how strategies can be improved and ultimately sustained and scaled up within and beyond the target countries. Learning from country-level delivery experiences requires a more detailed and contextualized Theory of Change (ToC) than the relatively generic one that guided the program during discovery and proof of concept. A significant amount of detail is needed to reflect the specific crop and country contexts and the specific actions of delivery partners, such as seed companies, extension services, non-governmental organizations (NGOs), marketing departments, and public relations agencies, as they design and implement interventions targeted at specific geographical areas, retailers, and farmer and consumer groups.

In 2013, detailed delivery-stage ToCs were developed as examples for three HarvestPlus crop-country combinations, and the evidence base to support them was assessed [26]. Figure 13.2 shows the results for one crop-country combination, orange maize in Zambia. Given the significant investment in building an evidence base for the potential impact of HarvestPlus during the earlier phases of the program, there was good evidence available for most parts of the ToCs. Key gaps, included the role of input and output market in providing incentives to producers and in making biofortified crops available to consumers, and in the role of gender in achieving production and consumption outcomes[3]. Age and sex-disaggregation were fully integrated into nutrition-related aspects of HarvestPlus but gender was not as systematically considered in all aspects of the agricultural and value chain research.

[3] In response to the need to better account for gender in research and in impact pathways, HarvestPlus undertook a strategic gender assessment in 2013. http://a4nh.cgiar.org/2014/10/06/harvestplus-strategic-gender-assessment/.

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Research questions and likelihood of occurrence	**Assumptions**	**Strength of evidence# that the key assumption holds true**
Will target farmers be aware and convinced of the benefits of orange maize? ***Likelihood: medium to high***	Farmer awareness Farmer acceptance	Strong Medium
Will target farmers grow orange maize? ***Likelihood: medium***	Access to seed Varieties perform as expected	Weak Strong
Will processors and traders buy and use orange maize? ***Likelihood: medium to high***	Traders and processors reached with information about orange maize	Medium to strong
Will target consumers be aware of and willing to eat orange maize? ***Likelihood: medium to high***	Consumer acceptance Consumer awareness	Strong Medium
Will target consumers eat orange maize? ***Likelihood: medium***	Availability and accessibility	Medium
Will target consumers' consumption of orange maize reduce the prevalence of inadequate vitamin A intakes? ***Likelihood: medium to high***	Accurate targeting of consumers Retention and bioavailability of vitamin A No adverse changes in diet	Medium Strong Strong

Figure 13.2: Impact pathway example: status of evidence for provitamin A orange maize in Zambia
Source: adapted [26], p. 15.

To better understand potential constraints to seed availability and access among target households and to inform delivery strategies, HarvestPlus conducted studies to learn from past experience with improved varieties in target countries, including pearl millet in India [27, 28]; cassava in Nigeria [29] and beans in Rwanda [30].

One important source of information that will complement monitoring data and test the ToC will be impact assessment surveys. Given that significant delivery of first wave varieties (that is less than full target level of micronutrient) has taken place in several countries, crop-producing households are randomly surveyed to measure adoption, diffusion, disadoption rates, consumption vs sales patterns, and also to compare the crop and micronutrient intakes of adopting and non-adopting households. These studies are also expected to shed light on the household, community, market, agro-ecological and other factors that affect adoption, diffusion, disadoption and consumption, and to generate useful information for the country plans as they continue developing and delivering biofortified planting material. Data from adoption studies can also generate important information about the "middle" part of the impact pathway. Because adoption studies measure uptake at scale, they provide an important complement to the effectiveness studies. The results of the impact assessment studies provide more precise estimates of uptake, including for specific categories of beneficiaries, and can be used to assess how well delivery strategies are working.

While adoption studies can't go as far as measuring change in nutritional status, their results can be used to refine ex ante impact assessments [31, 32], portfolio analyses, and tools such as the Biofortification Prioritization Index (BPI) [33] that are used to identify suitable investment options and sites for introduction and expansion of biofortification (See chapter 14 for more detail).

A nationally-representative impact assessment study was recently carried out in Rwanda where high iron beans have been released and disseminated since 2010. Preliminary results suggest that roughly 28% of Rwandan households have grown at least one high iron bean variety since dissemination began [34]. Six adopter-type categories were created to represent a household's iron bean growing history. The highest proportion of adopters are continuous growers while the smallest proportion are discontinued growers. A report based on data from the main survey is expected in late 2016.

DISCUSSION

This paper describes the HarvestPlus program's systematic efforts to measure and to maximize impact, guided by their impact pathways and ToC. This was crucial for ensuring that program investment in impact-related research was appropriately focused, and for communicating with and engaging the broad range of stakeholders needed to ensure long term success. HarvestPlus program provides an example of how a research program can demonstrate progress towards outcomes and impacts, starting in the early stages of research and continuing through proof of concept to delivery at scale. Generating an evidence base for impact was built into the program's research agenda as well as its monitoring and evaluation activities.

In retrospect, there are several areas related to markets and gender where more research could have been conducted at an earlier stage to strengthen the evidence base for impact. Given that these issues are especially relevant in the "middle" of the impact pathway, they are likely to be overlooked in agricultural programs that seek to contribute to nutrition outcomes, so care should be taken in future programs to ensure that they are considered early on. Identifying and prioritizing gaps in the evidence base for impact is an important responsibility of program management, as is ensuring that findings are shared and used within the program as well as by external stakeholders.

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