CHAPTER FOUR

Ethical and Sociocultural Considerations of Biofortified Crops: Ensuring Value and Sustainability for Public Health

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Contents

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1. INTRODUCTION

The purpose of this chapter is to examine the ethical and sociocultural issues of accessing, adopting, and mainstreaming biofortified crops into the global food system, with a special focus on nutritionally vulnerable populations with access to less diverse diets, who are susceptible to micronutrient deficiencies. This chapter will serve to objectives: (1) to highlight some ethical considerations related to biofortified crops and (2) to provide insights on how planned and implemented biofortification interventions can take into account sociocultural aspects of diets as part of integrated strategies to improve public health.

1.1 Biofortified Crops

Biofortified crops have become a potentially important food-based intervention to improve nutrition for the developing world. The investment and hopes of biofortified crops becoming a mainstay in the diets of many in low-income and poor-resource settings holds promise, as a "nutrition-sensitive agriculture" approach (Ruel et al., 2013). These approaches involve increasing access to diverse diets, fostering women's empowerment, and supporting livelihoods through agriculture-led growth. More research is needed to ascertain the effects on nutritional status.

Staple crops originate from cereals or starchy roots and tubers and are calorie dense, but often not sufficient in key micronutrients important for growth, health, and well-being. Since these predominant crops are considered to be affordable, hunger preventing foods in the diets of many populations (Dewey and Vitta, 2013; Hlaing et al., 2015), particularly low-income households, these starchy staples are the foods targeted for biofortification because they aim to improve micronutrient deficiencies for the general population. It is thought that biofortification can improve the nutritional content of the staple foods people already eat, providing a comparatively cost effective and sustainable means of providing more micronutrients in the food basket of the poor (Bouis et al., 2011). It is also thought to be a means to access more nutrient-rich foods for those populations who have insufficient access to a high quality and diverse diet or to commercially available supplements and other fortification mechanisms. Proponents of biofortification claim that the intervention should be seen as a food-based approach along with other interventions to improve dietary diversity and quality (Miller and Welch, 2013; Sundaram, 2014).

Biofortified crops are those in which a micronutrient dense trait is promoted in high-yielding varieties of staple crops such as corn, rice, potatoes, and wheat. Agricultural research centers supported by the Consultative Group on International Agricultural Research (CGIAR) including HarvestPlus, and by National Agricultural Research and Extension Systems (NARES) developed the biofortified crops and nongovernmental organizations and governments have largely promoted and disseminated these crops. It should be noted that not all biofortified crops incorporate genetic modification (GM). Most of the biofortified crops currently being researched, tested, and disseminated are bred through conventional mechanisms. The "headliner," politicized exception is Golden Rice, which is a GM crop still at the research stage (Hefferon, 2015). As it stands currently, GM crops are considered an intractable ethical controversy within the global food system. This chapter will not go into great detail on the ethical debate of GM foods, as that topic is worthy of its own landscape review. Table 1 shows the major biofortified crops that are being researched or have been disseminated in different regions of the world as of 2013 (Saltzman et al., 2013).

1.2 Ethical and Sociocultural Considerations

Ethics or moral philosophy is a branch of philosophy that involves systematizing, defending, and recommending concepts of right and wrong conduct. Ethics refers to standards of right and wrong that prescribe what humans ought to do, usually in terms of benefits to the society, doing no harm, rights and obligations and duties, fairness and equality, or specific values. By making a continuous effort to study our own moral beliefs and our moral conduct, we strive to ensure that we, and the institutions we work within, live up to standards that are reasonable and sound.

Food ethics examines how virtue, vice, rights, duties, benefits, and harms arise in connection with the way food is produced, processed, distributed, and consumed (Thompson, 2015). The ethical issues of biofortification are inherently intertwined with matters related to confidence in food safety, aesthetic preferences, food sovereignty, and protection of natural resources and localized food systems. Technological fixes to complex societal challenges are often controversial from an ethical standpoint. Arguments against pursuing technological fixes include: (1) the need to identify appropriate ways to assess and manage technologically induced risks; (2) the idea that agricultural biotechnology is incompatible with social justice; and (3) the importance of personal autonomy with respect to crop and food choice. If one is confident that

Table 1 Major Biofortified Crops in Development

Crop	Nutrient	Target Country	Lead Institutions	First Release Year
Banana/ Plantain	Provitamin A Carotenoids	Nigeria, Ivory Coast, Cameroon, Burundi, DR Congo	IITA, Bioversity	Unknown
	Provitamin A, Carotenoids, Iron*	Uganda	Queensland University of Technology, NARO	2019
Bean	Iron (Zinc)	Rwanda, DR Congo	CIAT, RAB, INERA	2012
		Brazil	Embrapa	2008
Cassava	Provitamin A	DR Congo	IITA, CIAT, INERA	2008
	Carotenoids	Nigeria	IITA, CIAT, NRCRI	2011
		Brazil	Embrapa	2009
	Provitamin A Carotenoids, Iron*	Nigeria, Kenya	Donald Danforth Plant Science Center	2017
Cowpea	Iron, Zinc	India	G.B. Plant University	2008
		Brazil	Embrapa	2008
Irish Potato	Iron	Rwanda, Ethiopia	CIP	Unknown
Lentil	Iron, Zinc	Nepal, Bangladesh, Ethiopia, India, Syria	ICARDA	2012
Maize	Provitamin A Carotenoids	Zambia	CIMMYT, IITA, ZARI	2012
		Nigeria	CIMMYT,IITA, IAR&T	2012
		Brazil	Embrapa	2013
		China	Institute of Crop Science, YAAS	2015
		India	DBT	Unknown
Pearl millet	Iron (Zinc)	India	ICRISAT	2012

Table 1 Major Biofortified Crops in Development—cont'd

Crop	Nutrient	Target Country	Lead Institutions	First Release Year
Pumpkin	Provitamin A Carotenoids	Brazil	Embrapa	2015
Rice	Zinc (Iron)	Bangladesh, India	IRRI, BRRI	2013
		Brazil	Embrapa	2014
	Provitamin A Carotenoids*	Philippines, Bangladesh, Indonesia, India	Golden Rice Network, IRRI	2013
	Iron*	Bangladesh, India	University of Melbourne, IRRI	2022
	Iron	China	Institute of Crop Science, CAAS	2010
Sorghum	Zinc, Iron	India	ICRISAT	2015
	Provitamin A Carotenoids*	Kenya, Burkina Faso, Nigeria	Africa Harvest, Pioneer Hi-Bred	2018
Sweet potato	Provitamin A Carotenoids	Uganda	CIP, NaCCRI	2007
		Mozambique	CIP	2002
		Brazil	Embrapa	2009
		China	Institute of Sweet Potato, CAAS	2010
Wheat	Zinc (Iron)	India, Pakistan	CIMMYT	2013
	Zinc (Iron)	China	Institute of Crop Science, CAAS	2011
	Zinc (Iron)	Brazil	Embrapa	2016

For projected releases, "first release year" refers to the first country listed; *Denotes transgenic variety; ( ) denotes secondary nutrient.

Biofortified target crops and countries-release schedule. *BRRI*, Bangladesh Rice Research Institute; *CAAS*, Chinese Academy of Agricultural Sciences; *CIAT*, International Center for Tropical Agriculture; *CIMMYT*, International Maize and Wheat Improvement Center; *CIP*, International Potato Center; *DBT*, Department of Biotechnology; *IAR&T*, Institute of Agricultural Research and Training; *ICARDA*, International Center for Agricultural Research in the Dry Areas; *ICRISAT*, International Crops Research Institute for the Semi-Arid Tropics; *IITA*, International Institute of Tropical Agriculture; *INERA*, Institut National pour l'Etude et la Recherche Agronomiques; *IRRI*, International Rice Research Institute; *NaCRRI*, National Agricultural Crops Resources Research Institute; *NARO*, National Agricultural Research Organization; *NRCRI*, National Root Crops Research Institute; *RAB*, Rwanda Agriculture Board; *YAAS*, Yunnan Academy of Agricultural Sciences; *ZARI*, Zambia Agriculture Research Institute.

Source: Saltzman A., Birol, E., Bouis, H.E., et al. 2013. Biofortification: progress toward a more nourishing future. Global Food Sec. 2, 9–17.

biofortification will "do no harm" (or nonmaleficence), what values bear on society in promoting technologies that have the potential to help the poor and undernourished (Paarlberg, 2009; Singer, 1972)?

> *The fundamental problem of food ethics is an ethical problem because it complicates any effort to act on behalf of the poor. It therefore tests any proposal to specify the duties of the developed world, or better-off people. But it is also an ethical problem that bleeds rapidly into exceedingly complex social and economic issues. It is not a problem that suggests easy answers.*
>
> ***(Thompson, 2015)***

Sociocultural factors include the rules and behaviors of being human, such as how we determine who we are related to, how we make a living, how we organize the world, and our belief systems; thus they are inherently related to ethics (Staeck, 2001). Culture is the beliefs and customs that we learn as members of society and which bind members of any given society together. It is the social sharing of these beliefs and customs that allow people to relate to each other.

Culture is inherent in agriculture. Food is the product of agriculture and thus serves as a powerful lens to how we tie ourselves to the land and preserve our historic social traditions and culture (Counihan and Esterik, 2012). The types of foods we produce and consume, preparation and cooking practices, and the way we eat those foods and with whom and where, are repositories of tradition that embody the values of who we are and why we eat what we eat (Furst et al., 1996). Food systems are consistently shaping our culture and traditions and conversely, are being shaped by social norms (Denning and Fanzo, 2016). With the potential scale-up of biofortified foods, it is important to consider how biofortified crops shape, or change (if at all) local culture and traditions of foods and how they fit into societies.

Two notes of caution. First, tackling the ethical and sociocultural issues that potentially arise due to biofortification is complicated. While scientists widely agree on the general framework for nutrition (UNICEF, 1990), they frequently disagree about what are considered the "right" interventions for reasons that are not always clear but that often rely on divergent empirical predictions. The argument is often framed in terms of "doing the right thing," even when it is extremely difficult to discern what the right thing is through evidence-based decision making.

Second, nutrition has ethical implications that go beyond just food. By its very nature, nutrition comes into contact with multiple sectors and involves a range of stakeholders in order to reach the desired goal of improving the nutritional status of a population. The causes of chronic undernutrition, for example, are multidimensional, which should take into consideration maternal health, infant and young child feeding (IYCF) practices and knowledge, food security, access to health care, the environment, and the disease environment. There is no single root cause of chronic malnutrition, which creates challenges in finding solutions through policies and interventions.

By focusing only on food-related aspects of nutrition, such as biofortification, there are limits to what improvements can be made on the nutritional status of populations. This interpretation of food security (i.e., one would solve the nutrition problem if one addresses the food security problem) raises an ethical issue as to how to approach and address nutrition within its broader set of underlying contributors as well as the larger sustainable development context. The food that is produced and consumed needs to deliver both in terms of nutrition but also sustainability. This will be discussed in some detail as part of the second objective of Sections 3 and 4.

1.3 A Public Health Good

Part of the obligation of the public health and nutrition community is to improve the public's health in an equitable way (Kass, 2001). For this reason, it is important for the field of public health and nutrition to consider the ethical and sociocultural implications that a program, policy, or intervention may impose on society, with intended or unintended consequences.

There are key ethical considerations in how different population groups access a nutritious and sustainable diet that promotes health and well-being (Thompson, 2015). These considerations involve making societal decisions and defining values about food security that impact nutrition outcomes, and the ethical trade-offs between sustainability and ensuring that individual dietary and nutritional needs are met (Fanzo, 2015a, b). The role of biofortification and its influence on society is not immune to these considerations. Ethical questions that specifically relate to biofortification and its potential effects on public health include:

- What societal and cultural values are at stake when introducing biofortified crops into a community?
- How does biofortification respect the autonomy of a community[a] and contribute to local food sovereignty[b]?
- Are there any ethical concerns about scaling up and implementing biofortification as an intervention or program?

[a] Autonomy of a community means the right or condition of self-government or to be free from external control or influence.

[b] Food sovereignty is the right of peoples to healthy and culturally appropriate food produced through ecologically sound and sustainable methods, and their right to define their own food and agriculture systems.

- What ethical considerations are needed to guide the planning and introduction of biofortified foods into the world's nutritionally vulnerable populations?

This chapter does not focus on just one ethical issue associated with the role of biofortified foods in the context of achieving improved nutritional status. Instead, it provides an overview of some of the pressing ethical and sociocultural considerations of biofortification that ultimately affect rural, poor, and nutritionally vulnerable populations through policy, action, and accountability in the nutrition field. Considerations such as protection of vulnerable populations, individual autonomy, respect for culture, liberty and self-determination, and food justice issues are touched upon. In doing so, an established and applied ethical framework for public health was used as a tool to assess biofortification strategies.

2. MATERIALS AND METHODS

In order to better understand the ethical and sociocultural issues of biofortified foods, two approaches were taken: (1) a review of relevant literature to gather empirical evidence and (2) a normative analysis of ethical implications using a public health ethical framework tool (Kass, 2001). This framework served as a tool in outlining the moral importance of biofortification in advancing public health benefits and promoting social justice while minimizing threats to liberty, privacy, and social and physical harms.

To further hone the analysis, the literature review was focused and ethical analysis to the biofortified crops shown in Table 1. While these crops are at different stages of research (breeding, efficacy, or effectiveness trials) and development (piloting or full dissemination) crops listed in Table 1 were referred to as "biofortified crops" or "biofortification" or "biofortified foods" in the literature review. Moreover, rather than focusing on the entire impact pathway of biofortified crops from discovery to delivery (Fig. 1), studies examining the discovery stage of these crops were omitted.

2.1 Literature Review for Empirical Evidence Analysis

To begin understanding the ethical and sociocultural issues of biofortification, a literature search of empirical evidence was done using a series of combination keywords. These searches were not systematic, nor were they intended to be. Seminal research studies and reviews were identified that presented evidence related to the two overarching objectives or that were identified as being critical to link biofortification with its potential ethical issues.

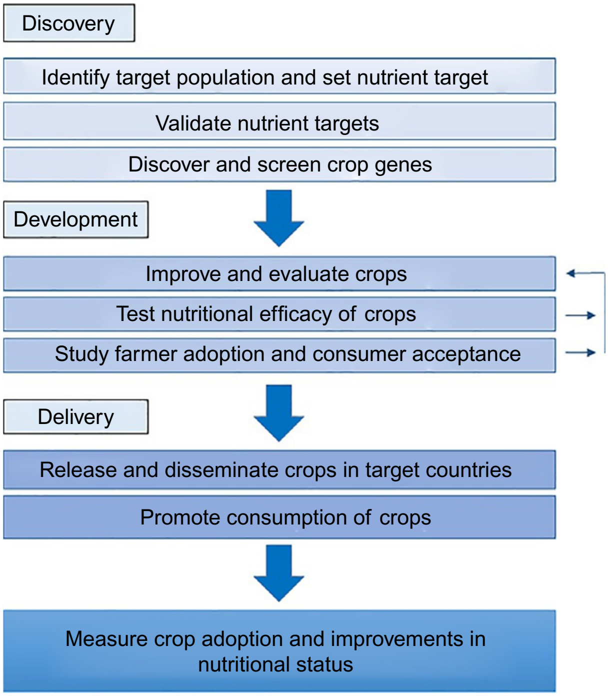

Fig. 1 Impact pathway of biofortified crops. *Source: Saltzman A., Birol, E., Bouis, H.E., et al. 2013. Biofortification: progress toward a more nourishing future. Global Food Sec. 2, 9–17.*

The following databases were searched across the two main objectives of the study with a specific emphasis on ethical and sociocultural aspects: PubMed, Web of Science (WOS), Social Science Research Network (SSRN), and Google Scholar. A snowball process, whereby the reference lists of appropriate studies were scanned to discover further potentially relevant studies, was used to identify additional studies. No differentiation was made between studies obtained by the initial search and those identified by snowballing. The snowball process was also used to identify gray literature. Studies were only considered if they had been published between 1960 and the present and were written in English. Google Scholar searches were further restricted from 1990 to the present due to the high number of non-relevant entries.

Table 2 shows the key search terms and database results from specific search dates. Two primary search terms were initially used: biofortification and biofortified crops. Thereafter, secondary search terms were then paired with the primary terms. Google Scholar did not provide productive

Table 2 Terms and Results From Literature Search

First Search Term	Second Search Terms (Search Date)	PubMed Result	WOS Result	SSRN Result
Biofortification	None (11/12/15)	390	1005	6
	Ethics (11/12/15)	0	0	0
	Consumer acceptability (11/23/15)	2	0	0
	Traditional foods (10/16/15)	17	38	1
	Dietary diversity (10/16/15)	4	15	0
	Consumer willingness to pay (11/25/15)	1	11	0
	Decision making (11/23/15)	2	3	0
	Tradition food consumption (11/12/15)	0	0	0
	Cultural beliefs (11/23/15)	17	1	0
	Farmer perceptions (11/13/15)	0	0	1
Biofortified crops	None (11/16/15)	97	106	0
	Ethics (11/16/15)	0	0	0
	Staple (11/16/15)	46	0	0
	Cash crop (11/16/15)	0	0	0
	Promoting (11/23/15)	5	15	0
	Marketing (11/23/15)	1	1	0
	Markets (11/23/15)	1	1	0
	Consumption (11/13/15)	21	0	0
	Diet patterns (11/13/15) *note only used biofortified	4	8	0

searches because ethical review processes were included as part of the search results. Thus, the review of published papers included PubMed, WOS, and SSRN results with some relevant articles found in Google Scholar. Because searches for ethics and sociocultural aspects of studies were so limited, papers were scoured for aspects that touched or addressed ethical and socio-cultural issues.

2.2 Framework for Normative Analysis

Utilizing the empirical evidence stemming from the biofortification literature, an "Ethics Framework for Public Health," (Kass, 2001) developed by the ethicist Nancy Kass was adopted, which serves as a tool to help stakeholders consider the ethics implications of biofortification interventions. Fig. 2 shows the six components of the framework that highlight ethical implications needing to be considered when adopting biofortification strategies. The use of this framework is not intended to answer all the ethical and sociocultural questions that may arise with biofortification because the field and its evidence base are still evolving.

The Kass ethical framework was created "to provide practical guidance for public health professionals and to highlight the defining values of public health, values that differ in morally relevant ways from values that define clinical practice and research" (Kass, 2001). Because public health has a societal approach to promote and protect health through social actions, biofortification, which inherently aims to improve well-being (in the form of increased access to micronutrients) of a larger population or community, warrants a careful analysis of ethical implications. The framework thus serves as a tool to help public health practitioners consider the ethical implications

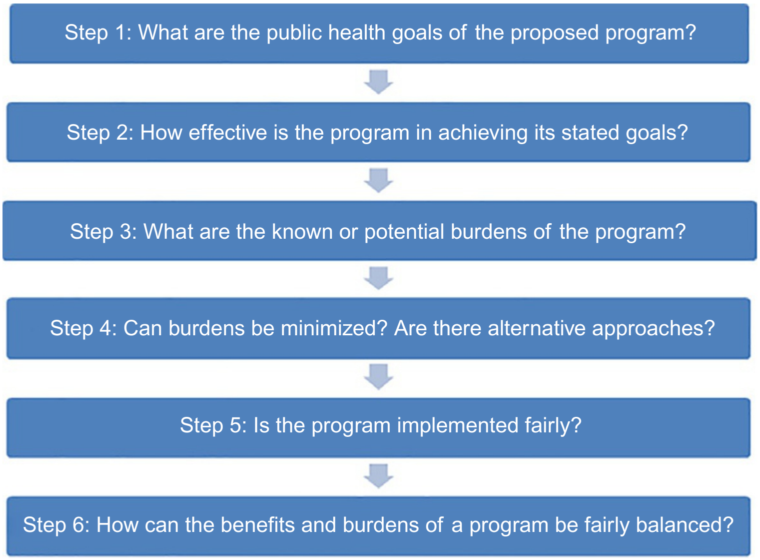

Fig. 2 Ethics framework for public health. *Source: Kass, N.E., 2001. An ethics framework for public health. Am. J. Public Health 91 (11), 1776–1782.*

of programs, policy proposals, research initiatives, and proposed interventions associated with biofortification (Kass, 2001; Kass et al., 2014).

2.3 Limitations

There were limitations to this study. First, there is very little written about the ethics and sociocultural issues of biofortification, most likely because biofortification is still mainly in efficacy and effectiveness trials, with some crops still in early research and development phases. At the present time, only orange-fleshed sweet potato (OFSP) is being taken to scale in 14 sub-Saharan countries, under the umbrella of the Sweetpotato for Profit and Health Initiative led by the International Potato Center (Low, 2011). More time is needed to determine the societal impacts of such crops. Second, the authors noted that the bulk of research published on the topic has been coordinated and/or commissioned by one main group of researchers, that being HarvestPlus. HarvestPlus, a CGIAR supported program, is the forefront leader in developing and disseminating biofortified crops. HarvestPlus has disciplinary specialists who identify researchers from major academic institutions or CGIAR centers to undertake the efficacy and effectiveness research and publishing results. Although it is assumed that all research is vetted and unbiased, this poses an inherent conflict of interest, and it is not necessarily in their vested interest to examine potential ethical concerns over such crops. Third, because searches for ethics and sociocultural aspects of studies were so limited, a formal systematic review of the topic was not possible.

3. RESULTS

This chapter attempts to highlight disagreements about what values should be taken into account, what trade-offs between values are justifiable, and what strategies are ethically and socioculturally acceptable with biofortification strategies for improved public health outcomes. While not intended to bring about concrete answers to these issues, it is hoped that tangible progress on ethical and sociocultural issues and disagreements is possible even in the absence of consensus about agreed values.

For this chapter, the literature searches yielded articles that were empirically examined for potential ethical and sociocultural challenges and benefits to address objectives 1 and 2. The literature review results were then structured and analyzed using the six-step ethical framework developed by Kass (2001) to address both objectives. While there is very little in the published scientific literature on biofortification-related ethics and societal issues, some information can be garnered to at least highlight possible issues and areas to be more mindful of when moving forward with the scale-up of such interventions.

Objective 1: Review Ethical and Sociocultural Considerations of Biofortification

3.1 Step 1: What Are the Public Health Goals of Biofortification?

Understanding what the goals of biofortification are and for whom is the first step in assessing ethical considerations. According to Kass (2001), the answer to this first question should be expressed in terms of public health improvement and status. In most public health programs, mortality and morbidity reductions are the outcomes in which most programs should be assessed. In the case of biofortification, the goal is to reduce the prevalence of micronutrient deficiencies (particularly vitamin A, zinc, and iron) in a population and potentially reduce morbidity and mortality related to the said micronutrient deficiencies.

An early CGIAR report clearly stated the goals of biofortification as follows:

> *The ultimate goal of the biofortification strategy is to reduce mortality and morbidity rates related to micronutrient malnutrition and to increase food security, productivity, and the quality of life for poor populations of developing countries by breeding staple crops that provide, at low cost, improved levels of bioavailable micronutrients in a fashion sustainable over time.*
>
> ***(CIAT and IFPRI, 2002)***

The overall goals of biofortification are well aligned with public health goals, and there are potentially other social benefits that can accrue from biofortification programs.

Also relevant to public health goals is to whom the benefit will accrue; the goals should be designed to provide a public good or protect individuals from themselves. Although sometimes thought of as paternalistic, biofortification does not impose any issues of "restricting" liberties to protect others. Instead, it provides a public good benefit for improving individuals' ability to protect their own health through a food-based approach to improve diets and potentially, nutritional status. Overall, the goals of biofortification have been well defined.

3.2 Step 2: How Effective Is Biofortification in Achieving Its Stated Goals?

The second step of the framework requires identifying if a program is effective in reaching its goals and provides beneficence or acting to benefit other (Beauchamp and Childress, 2013). In order to do this, it is essential to understand the assumptions that lead us to believe biofortification will achieve its goals and identify the data necessary to back those assumptions. This also helps to avoid speculation of effectiveness. Linking food-based approaches to "hard," biological health outcomes, such as mortality, can be difficult because the impact pathway is not always direct and solely causative, and instead is considered long, and multifaceted. For the purposes of this chapter, several assumptions are highlighted to evaluate the effectiveness of biofortification in achieving its goals based on the literature available, but should be considered steps toward that ultimate goal. The assumptions are:

1. Biofortified crops grow well in the target settings or regions.
2. The local food basket available to certain populations is insufficient to meet nutrient requirements.
3. There is a prevalence of micronutrient deficiency(ies) in the population.
4. Consuming biofortified crops will improve micronutrient status.

These assumptions provide answers to assess the larger public health goal, but also allow for some realism in where the research for development of biofortified crops stands at the moment. It should be noted that for some assumptions, there is sufficient data, however in some cases, the information reflecting these assumptions is scant. This is not meant to be an exhaustive list but an instrument to shed light on the ethical dimensions at stake and point to the areas where more research may be needed.

3.2.1 Assumption 1: Biofortified Crop Grows Well in Targeted Settings or Regions

From a technical standpoint, some challenges are ever present when introducing a new crop to a target setting or region. First, the timing to get a product to the field is lengthy and complex. Breeding, testing, and release processes can take 4–10 years to complete (Saltzman et al., 2013). Because the timeframe is considerable, there should be some consideration of other alternative and more immediate approaches to bringing vital nutrients to vulnerable populations. Other options have been widely considered and implemented among the nutrition community. Vitamin A supplementation is one such example (Mason et al., 2015; West et al., 2015). While biofortification is largely thought to be "one tool in the toolbox" of interventions, the nutrition and agriculture communities have focused mainly on biofortification as the most promising nutrition-sensitive agriculture intervention with very few other options (with the exception of home gardens) presented (Bouis et al., 2013; Haddad, 2013; Jaenicke and Virchow, 2013; Ruel et al., 2013; van den Bold et al., 2015).

Second is an issue of production. Understanding the variability and unpredictability across different soil characteristics, agroecosystems, and climatic conditions will remain a challenge with biofortified crops (Masset et al., 2011). More impact evaluations are needed to assess their effectiveness under different situations, stresses, and contexts. Limited studies have demonstrated that biofortified crops are at least as productive (both in terms of yields and in terms of their economic value) as traditional ones (Low et al., 2007b). One study showed that micronutrient-rich seeds are associated with greater seedling vigor and yield (Bouis, 2003). These seeds also provide benefits to the soil in that the soil is able to take up mineral micronutrients that confer disease resistance (Bouis, 2003; Masset et al., 2011). Studies have further shown that biofortified crops do not result in lower yields and instead are considered to be high yielding (Masset et al., 2011).

Third, seasonality limits the availability of these foods and can influence farmer adoption of crops; so new methods of processing and storing need to be a part of an intervention, or the development or promotion of micronutrient-rich crops year round (Jenkins et al., 2015). There is little known about the continued adoption of crops after the initial planting season. Seasonality also has significant impacts on child growth and nutritional status (Thomson et al., 2015). Thus, it will be important to consider equitable and consistent access to biofortified interventions during all times of the year if this approach was to be promoted, sustained, and scaled.

3.2.2 Assumption 2: The Food Basket Available to Certain Populations Is Insufficient to Meet Nutrient Requirements

Bouis et al. (2013) states, "Breeding staple foods is considered a low-cost sustainable strategy compared to a permanent solution to substantially improve diet quality (i.e. higher consumption of pulses, fruits, vegetables, fish and animal products)." Has there been enough evidence to suggest this? The less intensive integrated agriculture-nutrition model using OFSP biofortification intervention and delivery platform tested cost $15–20 per disability-adjusted life year (DALY) averted, which, according to the authors, is considered a cost-effective strategy (De Moura et al., 2014).

While it is clear that biofortification is a promising strategy for delivering micronutrients where potential access to a diverse diet is impossible, more empirical evidence is needed to assess other sustainable scenarios that harness dietary diversity of foods systems, which include, but are not limited to solely promoting biofortification (Burchi et al., 2011; Johns and Eyzaguirre, 2007). A future hypothesized risk is that these foods begin to dominate the food basket with less focus on expanding the diet to include other sources of nutrient-rich foods outside staple grains. There is also a risk of displacing some traditional varieties that may be more nutrient rich and adaptive to the local environment (DeFries et al., 2016). The ideal situation would be to include biofortified crops as part of a diverse food environment (Herforth and Ahmed, 2015), even in the context of increasing homogeneity of the food supply (Khoury et al., 2014). Careful oversight is necessary to ensure no harm is done and minimize burdens so that communities have additional options to obtain sources of micronutrient-rich foods.

But what are these options? Unfortunately, there is little information on what types, and the distributions of food intake people consume and overall dietary patterns (Nugent et al., 2015). Few systematically assessed dietary intake data are available on a global scale, however some databases are in the pipeline (Del Gobbo et al., 2015; Micha et al., 2015). Availability and expenditure estimates from FAO data are what is currently used by researchers, however these data do not accurately reflect individual dietary intakes and differences within populations in local contexts (Micha et al., 2015). Without having accurate intake data of micronutrients and the foods consumed to obtain those nutrients, it is increasingly difficult to justify the need for biofortification as the most relevant strategy to invest in from a country or political perspective. Should poor data collection be an excuse to take no action? For many working on these complex problems of poverty, undernutrition, and weak food systems, the problem is clear and obligatory beneficence may outweigh inaction.

3.2.3 Assumption 3: There Is a Prevalence of Micronutrient Deficiency in the Population

Micronutrient deficiencies are prevalent across the globe (Black et al., 2013) and deficiencies such as iron, iodine, vitamin A, folate, vitamin D, and zinc can have devastating health consequences. At least half of children worldwide ages 6 months to 5 years suffer from one or more micronutrient deficiency, and globally more than 2 billion people are affected (Micronutrient Initiative, 2009). However, it is still difficult to understand the magnitude of those deficiencies because prevalence data are scarce (Von Grebmer et al., 2014).

> *Obtaining accurate data is a challenge. Time lags, data gaps, and lack of disaggregation are common problems…many important micronutrients lack prevalence data, because related biomarkers have not yet been identified for a nutrient deficit. As long as these gaps in data persist, it will be difficult to describe the full contours of hidden hunger.*
>
> **(Von Grebmer et al., 2014)**

Significant and multiple micronutrient deficiencies exist due to inadequate local diets, poor sanitation and hygiene, and broken public health systems. However, there is currently no systematized way of measuring micronutrients on a timely, cost effective, regular basis among potentially deficient populations.

Biofortification could serve as a blanket approach to potentially capture major micronutrient deficiencies in poor populations with high consumption of nutrient-poor staple crops. The international community has often problem-solved micronutrient deficiencies in this way, suggesting that if malnutrition is due to overreliance on a single low-nutrition food, substituting that food for one with a higher nutrient content is a rational solution (McDonell, 2015). Yet not all researchers are suggesting biofortified crops be viewed in this way. Low et al. (2007b) stress:

> *In this model, OFSP is not a "magic bullet" but an easily exploitable resource to enable resource-poor households to improve their ability to provide adequate nutrition to their most vulnerable household members. OFSP provides an entry point for change agents to empower poor caregivers to change behaviors concerning dietary practices. (Low et al., 2007a).*

Asare-Marfo et al. (2013) suggest that country-level data, with its limitations, be used to determine where biofortification interventions should be targeted. There are also limitations of data recorded in international and national statistics that do not reflect the diverse foods that are consumed in a region, however these data are currently being used to determine which areas to target for biofortification (Heywood, 2011).

3.2.4 Assumption 4: Consuming Biofortified Crop Will Improve Micronutrient Status

Utilization of micronutrients is a complex metabolic process; meal composition and many environmental factors affect rates of absorption of these nutrients. More research is being done to better understand the relationship of intake and utilization of nutrients, particularly as it relates to the microbiome (Nicholson et al., 2012; Von Grebmer et al., 2014). Without addressing bioavailability, along with other multisectoral interventions (i.e., sanitation and hygiene) that address other causes of malnutrition, the effects of biofortification could be less effective (Masset et al., 2012). With that said, effectiveness trials in Uganda and Mozambique have shown increased intake of vitamin A enriched OFSP by children improved vitamin A status (Hotz et al., 2012a, b). Moreover, children under the age of five in Mozambique that consumed OFSP experienced reduced diarrhea prevalence and duration by 11.4%, and by 18.9% in children under the age three (Jones and Brauw, 2015).

Part of improving nutrition status through consumption means that the biofortified crop retains its nutrients during processing. There have been some issues in retention of nutrients within the crops during production, processing, and cooking. Retention varies by crop and by heat levels. In general, OFSP has high levels of beta-carotene, so that even with average losses of 20%–25% during cooking the amount of beta-carotene remains high. In contrast, in Nigeria, there are different preparations of their main staple crop, cassava. Gari involves intensive drying whereas fufu is made from fresh roots and does not store as long as gari. Consideration needs to be paid to the retention of vitamin A in these different methods of processing and storing of yellow cassava (the biofortified crop); as the processing and storage of yellow cassava has been shown to degrade provitamin A by as much as 65%–80% (Johnson et al., 2015).

An ex ante study estimated the costs and potential benefits of biofortification of food crops with provitamin A, iron, and zinc for 12 countries in sub-Saharan Africa, Asia, and Latin America. The authors concluded that biofortification has a significant impact on the burden of micronutrient deficiencies in the developing world in a highly cost-effective manner using DALYs as an outcome. Of course, the impact differs depending on the crop, the micronutrient, and the country, but the results are encouraging (Meenakshi et al., 2010).

3.2.5 Summary of Step 2

In the case of biofortification, there are gaps in the data across all four assumptions. Based on the data at hand, should biofortification be implemented at scale with gaps in sound evidence? Can success be guaranteed? How much data are enough? In terms of cost, effects on micronutrient status, and targeting of vulnerable populations, there is evidence to suggest that biofortification thus far, with its limited crop testing, has positive effects. The constraint on liberties with regard to ensuring a diverse food system, and limits with regard to agronomic potential need to be further explored and researched. Some argue that the rise of micronutrient deficiencies in the international discourse has led to dominance of supplements, fortification, and biofortification as the "quick fix" solutions to the problem (although the authors would argue that the development of biofortified crops is not a quick fix). However, this approach has its critics which suggest that this approach is a "nutritionism"—one that sees food as a vehicle for delivering "supernutrients" in the most effective way possible—thus the problem is a technical one, not a societal one (Kimura, 2013; Scrinis, 2008; Von Grebmer et al., 2014). In considering these four assumptions, if no data exist that demonstrate the validity of an intervention or program's assumptions, ethically, the program should not be implemented. However, good data alone do not justify the program; it allows us to move to consider step 3.

3.3 Step 3: What Are the Known or Potential Burdens of Biofortification?

If the data suggest that the program or intervention is found to be effective at achieving its goals, the next step is to identify the potential burdens or harms of the program or nonmaleficence. With nonmaleficence, there are intended and foreseen effects (Beauchamp and Childress, 2013). In most interventions mainstreamed in international development, any harms that are caused are usually unintended and not foreseen. As Kass explains, identifying the burdens generally falls into three broad categories: (1) risks to privacy and confidentiality, (2) risks to liberty and self-determination, and (3) risks to justice. We focused on the latter two since privacy and confidentiality do not pose to be a burden in the context of biofortification interventions.

One could also ask what are the potential harms if we do not biofortify crops? For decades, the agriculture sector has focused on breeding technologies with the sole purpose of improving yields of staple crops, and downstream, potentially improving incomes. With scientific transformation and lower costs to improve the nutritional quality of those crops, is it moral to ignore the technology that could improve the quality of the crops that much of the world consumes?

3.3.1 Risks to Liberty and Self-Determination

Self-determination is the process in which a person controls his/her own life. For a country, it is the process by which a country determines its own statehood and forms its own allegiances and government. Each country has the right to freely choose its sovereignty. In the context of biofortification, choice plays a pivotal role (even in the context where choices are limited due to poverty or social exclusion) and the ability to make those choices without forced influence or burden is essential.

3.3.1.1 Dietary Choices

The food environment alters how dietary choices are made and how we produce, access, prepare, and consume food as a society (Herforth and Ahmed, 2015). Taste, health, social status, cost, and resources are all influencers of what foods are chosen to eat, but culture and tradition are also key factors (Fieldhouse, 2013). Events also influence production and consumption: social events and gatherings, holiday traditions, special occasions, and religious or ritual observances that call for special foods (Meyer-Rochow, 2009). For some, food choice can be deeply personal and often hinge on our ideals, sense of identity, and habits (Pelto and Backstrand, 2003).

Food itself is central to our sense of identity, often showing the geography, diversity, and hierarchy of a certain culture. Johns et al. (2013) states: "Cultural criteria often define value. Markets for varieties of cereals, legumes, fruits, vegetables or other foods associated with particular cuisines or recipes connect producers with increasingly urban consumers who share cultural values and history." For others who live in poverty and with food insecurity, food choices are limited.

Should food be considered an exceptionality similar to water? Some consider food distinct from other human needs and should have special treatment due to its importance in human survival (Fanzo, 2015a, b; Thompson, 2010, 2015). Many resource-poor communities are often largely consuming staple crops to meet their caloric needs. Biofortification programs are mainly targeting these communities as a first priority. One could argue that more food choices are being offered. However, it should be noted within those imposed limited choices, culture, and tradition of food and its practices run deep and should not be undermined or deprioritized with the introduction of new foods.

To date, there is very little mention in the biofortification literature about the cultural or religious relevance (if any) of the crops chosen for biofortification. Vandana Shiva, an advocate for local foods, argues that in India, banana plants are "sacred" and adorn all social and religious functions, and all auspicious occasions. She has criticized the use of genetically engineered biofortification of iron or vitamin A-rich bananas for two reasons: (1) the sacred aspects of bananas and (2) there are other affordable, accessible, and safe options to meet nutrition needs for iron (Shiva, 2014).

The behavior of others in our social environment also strongly influences our own decisions and actions (Burger and Shelton, 2011). Healthy and unhealthy social norms have been found to be positively associated with healthy and unhealthy food intake (Lally et al., 2011) and can affect intentions to consume healthy foods. That does not mean that these social norms cannot change. One study randomized children to either consume a diet made up of biofortified yellow maize (intervention) or white maize (traditional). Children were receptive to the new biofortified food.

There have been studies showing that introducing new foods to children early can break stigmatizing social norms around food (Coulthard et al., 2009; Vereecken et al., 2004). It will be important for the biofortification research community to understand how this change in children's behavior would translate into adults adopting and eating the biofortified food as well. Or will these foods be seen as different and cause issues of sustainability or adoptability? How can social norms be shifted so the entire community accepts the biofortified version and what potential interference does this have on traditions? Thus far, there has been little published on the impact of consumption of biofortified foods on traditional dietary patterns (Masset et al., 2011).

3.3.1.2 Production Choices

For farmers, there are many factors that determine what crops to grow. For example, in Zimbabwe, farmers prefer to grow white maize, not yellow (vitamin A-rich maize) due to its agronomic properties (Nuss et al., 2012). Other aspects include social norms related to agrarian societies, which are influenced by many complicated historical, political, and socioeconomic factors, such as education, income, family and community traditions and customs. In Kenya, yellow maize has associations with food aid and animal feed that make it less appealing to certain social classes (Nuss et al., 2012). Moreover, consumer preferences influence market prices, which also influence farmer decision making (Qaim et al., 2007).

Making decisions on what to grow is a critical decision among risk-adverse farmers with limited options and one where liberty and self-determination are crucial. A cash crop is an agricultural crop that is grown for sale to return a profit. Cash crops have significant impacts on the livelihoods of farmers, and for smallholder farmers, cash crops are vital. Thus, there are a few issues to consider with biofortified crops. First, farmers' livelihoods are dependent on natural, among other, resources. It is important to understand if biofortified crops impact those natural resources and potential yields of biofortified crops. Second, it is important to understand if farmers can afford to propagate biofortified crops. Third, it is important to know if there is a market for these biofortified foods and if farmers can get a good price at local markets. More research needs to be done to ensure that biofortified crops do not distort local markets for agricultural commodities in recipient countries, and in turn, have adverse effects on local farmers from these countries (Thompson, 2010).

3.3.2 Risks to Food Justice

Food justice ensures the benefits and risks of where, what, and how food is grown, produced, transported, distributed, accessed, and eaten are shared fairly (Gottlieb and Joshi, 2010). When populations are targeted to be part of biofortification strategies, it is necessary to examine the potential risks to justice this may pose and find ways to minimize inequalities.

3.3.2.1 Acceptance of Crops

There is considerable published research on acceptability of biofortified foods, including biofortified cassava, vitamin A maize, OFSP, iron beans, and iron pearl millet, and acceptability of the food depends on appearance, texture, odor, and taste (Birol et al., 2015; Talsma et al., 2013). A systematic review by Talsma et al. (2015) found that from a sensory perspective, yellow maize, orange maize, high iron beans, and nontraditional foods prepared with orange sweet potato are generally accepted in study populations.

One example, Golden Bread, made of OFSP, is a bread product made by interested women farmers and existing bakers. After piloting the bread, consumers preferred the OFSP Golden Bread compared to the traditional pure wheat flour bread (Low et al., 2007b). The golden color and heavier texture of the OFSP bread was more appealing than the pale color and light texture of the traditional bread.

> *Marketability requires the existence of markets as well as acceptance of the crops by consumers (whereby farmers themselves are also consumers). Mineral biofortification through conventional breeding represents an "invisible" trait that neither requires consumers to change their behavior nor induces sensory changes, so it is unlikely to cause acceptance problems. However, biofortification may result in changes in crop color, taste, or dry matter content. In these cases, consumer acceptance hinges on consumers' awareness of the nutritional properties of the crops and on the degree to which they are affected by micronutrient deficiencies; that is, it depends on consumers' awareness of the benefits the crops have for themselves and their families.*
>
> ***(Stein, 2015)***

The communities' acceptance of GM (or transgenic) technology should be weighed as well. While most biofortified crops are not GM at the moment, there are still public misconceptions. Views held by a society may determine if a conventionally bred crop verses a GM crop would be viable as an approach. Research has shown that access to media, trust in government and geography may influence these views. In Northeastern Brazil, access to mass media increased the probability of acceptance of GM crops (Gonzalez et al., 2009). This may be explained by media coverage of such technology generally being positive which is thought to have influence on public perceptions. In China, GM technology is seen as positive due to the influence by the government control over media (Gonzalez et al., 2009). In contrast, India media reports are negative around GM technology and consumers have lower acceptance of GM technology (Gonzalez et al., 2009).

3.3.2.2 Adoption of Crops

Regarding acceptability, not only is this key for consumers, but consumer acceptability will also influence farmer adoption decisions. If there is low acceptance, market prices will be low for farmers (Qaim et al., 2007), coming back to the old adage of where there is demand, supply will answer to that demand. In Uganda, OFSP has been promoted within communities through the engagement of women's groups, but were other food-based options also presented in which communities could take their pick? For example, in Timor Leste farmers taste tested 10 different varieties of sweet potatoes. When given the choice, most chose the white-fleshed sweet potatoes because the taste, texture, and growing conditions had similar characteristics to the traditionally consumed tuber cassava (Fanzo and Curran, 2013).

It is still too early to know if biofortified crops will have an effect on farmer livelihoods and if these foods will ever be considered major cash crops in some rural economies. Although the research has shown mixed impacts of cash crops on nutrition and dietary diversity outcomes (DeWalt and DeWalt, 1987; Kennedy et al., 1992), this is one area where more data could be useful. Less research has been done to better understand farmers' acceptance of biofortified crops and the impact of yields of other crops including cash crops, and farm profits (Masset et al., 2011).

Whatever the results, it is imperative to consider that biofortified crops do not completely replace other high-value crops that have the potential to reach domestic and international niche markets. The economies of scale also need to be examined when promoting these crops to farmers. In general, smaller farms achieve lower rates of return than larger farms thus careful consideration should be paid to what is being grown, what reaches markets and provides a sustainable livelihood for farmers while addressing nutritional needs of farmer households. Stein (2015) argues that the exploitation of such economies of scale can make genetic biofortification a very cost-effective intervention.

3.3.2.3 Accessibility of Crops to the Producer = Consumer

Korthals (2015) argues that current biofortification programing is one-sided—it neglects the roles and needs of farmers (who are also consumers). Farmers who are considered "target" populations of biofortification programs often live in conditions of scarce natural (i.e., water) and infrastructure capitals (i.e., markets). Perhaps biofortified crops are not seen as a priority in meeting their own needs.

One example of this is beta-carotene-rich maize in Zambia. Johnson and colleagues (Johnson et al., 2015) indicated that the most marginalized farmers are unable to buy the orange maize seeds due to the cost. Even the Zambian government's Farmer Input Support Program (FISP) tends to reach farmers of greater wealth and land (Smale and Birol, 2013). Furthermore, most of the subsistence farmers do not regularly sell maize but instead sell small surpluses of other crops (Zulu et al., 2007). This reinforces biofortified maize's ability to improve vitamin A intakes in smallholder households.

It will be important for the CGIAR, HarvestPlus, and others to consider market solutions along with dissemination that consider not only quantity, quality, and safety, but also sustainability as well. In Mozambique, while the OFSP was preferred, low purchasing power served as a significant constraint in its reach (Jenkins et al., 2015).

The research thus far is generally positive and there is clearly a market demand for biofortified foods. Masset et al. (2012) indicated that consumers, overall, are willing to pay a premium for food with higher micronutrient content and Low et al. (2007b) have demonstrated that OFSP was the cheapest source of vitamin A on the market in rural Mozambique. Rural households in Uganda had an increased willingness to pay for OFSP as opposed to other varieties. Overall, willingness to pay studies show that "populations are willing to pay a (small) premium for biofortified crops, especially after information on health benefits is given" (Chowdhury et al., 2011).

3.3.3 Summary of Step 3

Biofortification programs should limit the constraint on meaningful liberties, minimize the risks of harm or burdens, and avoid inadvertent negative effects such as stigma or threats to dignity. With regard to self-determination and liberties, there is no evidence to suggest that biofortification poses harm or burden. However this may be due to limited research to assess the issue. On food justice issues, the evidence is mixed regarding support and adoption of biofortified crops and acceptance and access to biofortified foods. As these crops are rolled out, more implementation and/or operations research need to be done to see the effects of crops on farmer choice, in the milieu of other crop choices, and the impact on livelihoods. This will lead to more research on markets. How do biofortified crops get sold on markets, what is their price point and consumer purchasing power? Having a potentially powerful tool that mitigates nutrition deficiencies but remains unaffordable, inaccessible, or unacceptable to vulnerable populations is a waste of resources and effort and could potentially present moral dilemmas in the face of limited research in these areas. This points us to step 4 to evaluate how burdens can be minimized.

3.4 Step 4: Can Burdens Be Minimized? Are There Alternative Approaches?

With the burdens outlined earlier, efforts should be taken to decide if these burdens can be minimized and determine if there are alternative approaches. With any biofortification strategy, involving the community, producers, and women early in efficacy and effectiveness research can minimize burdens (World Bank, 2013). Alternative approaches to alleviating micronutrient deficiencies exist, so understanding what strategies are already in place and how biofortification can complement those existing activities in the local context is vital. Each of these considerations is discussed below.

3.4.1 Community and Producer Involvement

The freedom of choice[c] is an essential component when intervening in communities. Beyond just the *need* for these foods, and establishing justification to communities that there is a need, do farmers and consumers play a role in deciding whether or not these nutritionally enhanced foods are a priority for them (Johns and Eyzaguirre, 2007)? There are examples, using food-based interventions, where this works. Through keyhole and double-dug gardens, implementers engaged stakeholders through a participatory approach from the beginning, to enhance livelihoods of intended beneficiaries and ownership of the intervention as a part of capacity building, which resulted in effective implementation (Aphane et al., 2011).

Korthals (2015) takes a deontological[d] position, suggesting biofortification should engage communities early in a rights based, pragmatic approach that brings together all the stakeholders from the beginning and find out where the root causes of malnutrition lie. Instead of focusing solely on producing more of these foods, "there is a need for prevention of leakage

[c] Freedom of choice is the right of individuals to determine their own actions.

[d] Deontological ethics is the normative ethical position that judges the morality of an action based on the action's adherence to a rule or rules.

of nutrients in particular in the postharvest period and during food preparation and cooking. Education may be important as well as health improvements." Going even further, some argue that addressing food problems by exclusively targeting its nutritional aspects "obscures structural inequalities and power asymmetries by recasting the food problem as a primarily technical matter" (McDonell, 2015). Perhaps looking beyond just the deficiency is critical to address the underlying societal and development issues as to why communities suffer from deficiencies.

3.4.2 Women Involvement

In the food sovereignty[e] movement, gender equality is a priority (Patel, 2012). Evidence shows that when women are able to access resources to improve food security, household, and child health greatly improve (Smith et al., 2003). Women are also some of the most nutritionally vulnerable. Haddad argues that for biofortification programs to be successful, one needs to reduce gender asymmetries with respect to decision making around agriculture—traits, crops, technology, information, time use, storage, and consumption properties—thus food production will map more closely into food consumption needs. Development practitioners and governments should focus on strengthening institutions that can help women articulate voice, promote accountability to those voices, and be responsive to those voices (Haddad, 2013).

OFSP campaigns have targeted women as their main vehicle in distribution of vines and consuming the product at the household level (Jones et al., 2015). One study found that plots that are jointly controlled by both men and women, where the woman has primary control over decision making, are more likely to have OFSP; plots that are controlled solely by men are least likely to contain OFSP (Gilligan et al., 2014). However, marketing of biofortified crops should also be careful to consider the potential negative consequences put upon smallholder farmer women. In Rwanda, upgrading the high iron bean value chain excluded women's control over the commodity and its income generated (Johnson et al., 2015). But in the same country, ensuring women's participation in a new OFSP processed product value chain was achieved (75% of those farmers in the chain were female) through explicit gender-aware targeting.

[e] Food sovereignty is the right of peoples to healthy and culturally appropriate food produced through ecologically sound and sustainable methods, and their right to define their own food and agriculture systems.

3.4.3 Complementary Strategies

Some have argued that supplements, fortification of foods, and biofortification are interventions that have characterized and dominated global food and nutrition intervention programs (Frison et al., 2006), while some claim that more holistic, food-based approaches should be considered (IPES, 2015). These difficult debates arguably undermine the development of integrated efforts due to the reinforced divergence in thinking and action by focusing on single approaches, rather than providing a more comprehensive view to addressing the manifestations of malnutrition (Menon and Stoltzfus, 2012). Some have argued that there needs to be more thought and scrutiny in how biofortification is fitting into larger social justice and equity issues of local food systems (Jones et al., 2015). While food system research and the role of agriculture in meeting nutritional needs are ongoing, biofortification is increasingly being seen as one tool among many, not a rival (Kennedy and Moursi, 2015). Biofortification is seen to contribute to dietary diversity through a "food basket approach" that includes biofortified foods and other locally available foods (Kennedy and Moursi, 2015).

3.4.4 Summary of Step 4

Careful scrutiny of potential burdens and examining alternative approaches are necessary to ensure the efficacy of biofortification strategies. Another key component is observing what programs may already be in place and how biofortification can best fit into the local food system. Involving consumers, producers, and particularly women coupled with strategies that may complement biofortification are some ways to reduce burdens and move us to the next step of analyzing fair implementation.

3.5 Step 5: Is the Biofortification Program Implemented Fairly?

This segment of the framework requires the fair distribution of the benefits of a biofortification program, which relates to the ethical principle of distributive justice.[f] Two areas of concern are the distribution of the seeds/stems for growing the biofortified crop and access to biofortified foods in the community.

3.5.1 Distribution of Seeds/Stems

According to HarvestPlus, some of the crops, including sweet potato, cassava, pearl millet, and beans, can be replanted every year from plant cuttings or seed that the farmer has saved. In the case of hybrids, farmers would

[f] Distributive justice concerns the nature of a socially just allocation of goods in a society.

need to purchase fresh seed for each planting season in order to maintain high productivity. But HarvestPlus has a suggested a strategy to ensure its sustainability:

> *Biofortified nutritious crops are being made available as public goods to national governments. Wherever these seeds are typically sold in markets, they are competitively priced so that subsistence and smallholder farmers can afford them. In the long run, the cost difference for these seeds should be negligible from non-biofortified varieties.*
>
> ***(HarvestPlus, 2015)***

In many countries, particularly in sub-Saharan Africa, the distribution of any new variety faces the challenge of poorly developed seed systems. If certified seed does exist, it is costly and tends to be available for key cereals, such as hybrid maize. Vegetative propagated crops often fall outside of regulatory boundaries, as private seed companies are not interested in crops easily kept and shared among farmers. To assure better quality seed at affordable prices, efforts are underway in several countries to develop and promote guidelines for quality declared seed (QDS), particularly for open pollinated cereal varieties and vegetative propagated crops. QDS typically can be produced by trained farmer multipliers with cheaper, locally based inspection systems. This may contribute to a wider policy objective to diversify the seed supply system so that more choice is given to farmers (Food and Agriculture Organization, 2006).

Others concur. There will need to be public support at least initially for the new varieties to penetrate formal and informal seed markets (Qaim et al., 2007). Johnson et al. (2015) recommend that local, formal, and informal seed systems should be establish to ensure a consistent supply of seeds. As it stands right now, HarvestPlus, nongovernmental organizations, and public sector partners handle the production of those seeds and distribute them to farmers through the established seed system operations or by establishing new seed multipliers. Farmers are then expected to adopt those varieties, consume them at the household, and sell surplus at the local markets. In the case of high iron beans in Rwanda, a payback system has been put into place in which payback is double to what is received (i.e., a farmer who received 1 kg of seed are required to return 2 kg of grain) (Johnson et al., 2015).

But there may be issues in distribution of biofortified varieties through these seeds systems and payback mechanisms. They may not exist, or some producers may not be able to access. “In Nigeria there are no well-developed seed systems for cassava planting material and new material is usually introduced through national or international public institutions or non-governmental organizations” (Birol et al., 2015). Very poor households may not have access to new seeds in the local seed systems. Often, the poorest smallholder farmers tend to rely on open pollinated varieties or recycled seed over buying hybrid seeds due to the cost constraints (Smale and Birol, 2013).

At the opposite end, in some Asian countries where private sector seed companies dominate in the development of varieties and their distribution, the challenge will be convincing such companies to incorporate biofortified traits into their lines. Moreover, if a private company were to distribute a variety developed in the public sector, negotiations over intellectual property rights would be needed.

Programs promoting biofortification are trying to build on the existing agriculture system and the strategy is seen as complementary not exclusionary to other interventions to improve health. To assure access to biofortified seed, heavy investments in improving public sector seed systems to serve poorer farmers has been required. Thus, programs are seen as improving overall delivery mechanisms for the sector itself.

3.5.2 Access to Biofortified Foods

Biofortified interventions need to reach the right decision makers and target households (Johnson et al., 2015), particularly the very, very poor. A priority in implementing a biofortification program fairly is that all in the community will have equal access to the biofortified food.

Those who are already systematically disadvantaged need to be taken into account as well. However the very poor again may be left behind. "…The willingness and ability to pay higher prices for biofortified foods are likely to be limited among the poor, who bear the brunt of micronutrient malnutrition. Also, at equal prices, consumers will only purchase micronutrient-dense crops if they meet their personal preferences in terms of taste, texture, and visual appearance" (Qaim et al., 2007). In Rwanda, they found that poorer consumers purchased mixed bean grains since they are cheaper thus they are "diluting" the effect of the biofortified single variety (Johnson et al., 2015).

3.5.3 Summary of Step 5

Overall, there is a strong emphasis to ensure access to seeds and foods are not a barrier for farmers and‘ consumers thus not violating distributive justice issues of biofortification.

Objective 2: What Ethical Considerations Are Needed to Guide the Planning and Introduction of Biofortified Foods Into the World's Nutritionally Vulnerable Populations?

In order to guide planning of biofortification interventions and programs, step 6 is incorporated (i.e., how can the benefits and burdens of biofortification be fairly balanced?) into the analysis of objective 2. What is the ethically desirable strategy for biofortified programming that is balanced and fair while achieving its larger public health goals? Stein (2015) provides some justification in a step-wise fashion for how biofortified crops should be introduced and sustained in populations.

1. Only those crops that are consumed by a large number of people with micronutrient deficiencies are likely to be cost effective. Thus, understanding the local epidemiology is key: understanding dietary patterns, micronutrient deficiency prevalence, and local preferences.
2. Once elite lines of micronutrient-rich traits are developed, these lines should be disseminated widely and fairly to facilitate further development and adaptive breeding into popular existing and promising new varieties using a food justice approach.
3. Once biofortified varieties are adapted and introduced, their large-scale dissemination at national levels should be a top priority. If there are acceptability issues (i.e., color, taste, GM scares), campaigns that address awareness and trust should be prioritized. The question remains, how to do that without corrupting self-liberties and determination.
4. Political backing and the support of opinion leaders are essential, particularly with GM crops/foods.

For point number 1, knowing the "local epidemiology" of where micronutrient deficiencies lie could also avoid situations where too much iron (in the form of supplements and biofortification) could be harmful in areas of high-malaria transmission without treatment and prevention programs in place (Stoltzfus et al., 1997). It is also important to know what other supplementation and industrial means of fortification are happening in the region and how biofortification will complement those strategies.

For point number 2, so far, the only biofortified crops that have been introduced on a larger scale are OFSP in sub-Saharan Africa (Low et al., 2007b). Thus, there is limited information on how other commodities are introduced into vulnerable populations, their acceptability and their longer-term sustainability as part of the local food basket.

For point 3, it is critical to analyze best methods for dissemination to ensure target audiences are being reached. Working with extension agents and established international NGOs may be one way to build trust and provide information without jeopardizing liberties (Johnson et al., 2015). Collaborating with different sectors may be advantageous in the case of biofortification since messaging can target multiple decision makers at the household level. The context is extremely important, for example if VAD women and children are not regularly accessing health clinics then messaging at health centers would be missing a large population (Johnson et al., 2015). Using a participatory approach that also engages intended beneficiaries will help build capacity to sustain practices and ultimately improve livelihoods.

As for point number 4, involvement in understanding the political economy of nations and how they handle food security and policy, is critical. Emphasis has been placed in ensuring that in order to make agriculture and nutrition innovations work together, institutional innovation to facilitate and generate political pressure is essential (Haddad, 2013).

Lessons can be drawn from Golden Rice as an example. Golden Rice is a GM crop developed to produce beta-carotene, a precursor of vitamin A, in the grain of rice. It is a food-based approach with the goal of improving vitamin A status (International Rice Research Institute (IRRI), 2016). In India alone "widespread consumption of Golden Rice could reduce the burden of VAD by 59%, which includes the saving of almost 40,000 lives each year" (Qaim, 2010). Using the common measurement of DALYs, even under pessimistic assumptions the cost of saving one DALY is less than $20 (Stein et al., 2006). Compared to alternative strategies Golden Rice is considered to be more cost effective (Stein et al., 2008; Wesseler and Zilberman, 2014). Even though seeds would be distributed free of cost to farmers the fact that Golden Rice is produced by using GM technology makes this crop controversial and poses a burden to implementation. As a result, over a decade has gone by since Golden Rice has been developed but the regulatory framework for GM crops has caused a major bottleneck in bringing it to the public (Dubock, 2014; Enserink, 2008; Potrykus, 2010). Because there is such strong ethical opposition to the technology itself, much of the work to move the intervention forward has been delayed as seen in the Philippines with activist organizations destroying field trials (Kupferschmidt, 2013). Involving communities and producers at the initial stages and getting political support appear necessary to overcome overall acceptance of such an intervention.

4. DISCUSSION

Is there ethical justification for biofortification as an intervention to solving some of the malnutrition burden? The evidence suggests yes, so far although much more research needs to be done on ethical, sociocultural, and societal value of these crops. Our analysis suggests that biofortification strategies are mainly ethically defensible, and at last in the short term, should be implemented. Fig. 3 shows the steps in which biofortification has met the criteria of having clear evidence (green check marks), and where more research is needed although some evidence base is being built (green with orange checkmarks). However, in the long run, a few points of discussion that are frequently debated but do not have easy answers.

First, is it ethical to deny biofortified crops to poor populations while we wait for more robust evidence to accumulate on the technology's potential? Should we ensure autonomy, beneficence and nonmaleficence, and justice are secure before making policy and programmatic choices? Perhaps not. In the 1960s, Ester Boserup, economist, challenged Thomas Robert Malthus's essay concluding that as our population continued to grow, food production would not be able to keep up with demand, and there would be massive famines (Malthus, 1872). She instead argued that food production will increase to match the needs of the population through inventions of new technologies and farming methods (Boserup, 2005). While some very poor, rural populations are stuck in a Malthusian trap, Boserup has been largely correct in

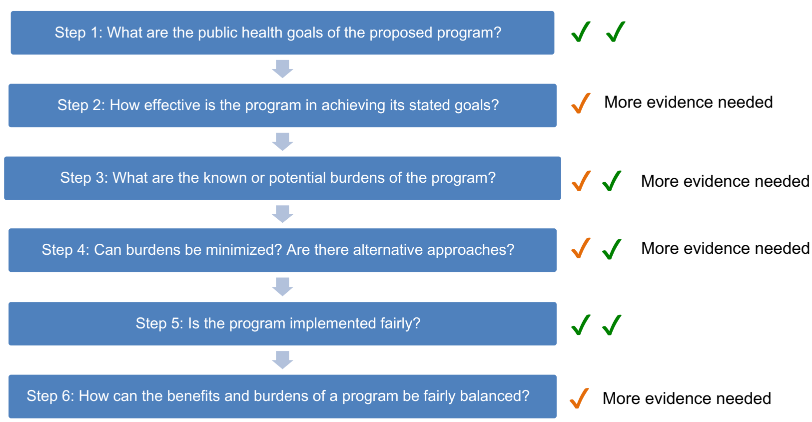

Fig. 3 Ethical defensibility of biofortification.

that technologies have created positive ratchets allowing for food supply to keep pace with population growth (DeFries, 2014). Present day challenges of the distribution of current food supplies largely rest on inequities and waste (Ehrlich and Harte, 2015). With the continued increase in population that we will see over the next 30 years, there is a significant need for more positive ratchets and we must ask ourselves, are we ignoring some of the technological advances that can save ourselves from what Malthusian predicted?

Second, is focusing on specific foods with key nutrient alterations the best approach to improving overall dietary diversity? McDonell (2015) argues that "miracle food" curative approaches should be swallowed with a dose of caution in the historical context of global hunger and international development discourse. She argues that these approaches offer an antidote to but at the same time, depoliticize malnutrition, which can be considered a political issue (Fanzo, 2015a, b). She wrote: "As 30% of people in the 'developing' world suffer some sort of diet-related ailment, it is imperative that we stop the futile search for a magical complex carbohydrate and begin facing the ultimate causes of malnutrition: power, inequality, and capital-intensive agriculture that dispossess." While perhaps this view is not completely fair to the incredible progress that has been made in addressing health and nutrition inequities, more can be done.

Third and related to point two, we know that food-based approaches are an important piece of the puzzle in addressing the burden of malnutrition and micronutrient deficiencies and finding the best possible solutions such as biofortification, will help mitigate the massive burden that society faces. Food itself has a number of characteristics that make it quite distinct from other goods and services, or exceptional. Besides the fact that everyone needs food to survive, which are not only alienable goods, but also consumed when they are eaten (with the exception of seeds which can be saved), there is unique moral significance to ensure that food needs are constantly supplied and available (Thompson, 2010). So perhaps focusing on food-based interventions should be prioritized in development because of its exceptionality.

But delivering nutrient-rich food will not solve the larger systemic issues in which these problems were born. Sen has emphasized that food is not the issue but a symptom; the more dominant concerns are poverty, exclusion, and disability (Sen, 1981). Thus, addressing malnutrition burden requires a more comprehensive approach to address food insecurity and health as a larger issue of extreme poverty, exploitation, and social injustice. Some research done by Headey (2013) and Headey et al. (2015), using country cases, found that the best way to reduce undernutrition (using stunting as the outcome) would be to address asset ownership, female secondary education, fertility rates, and health care service. The biofortification literature does not discuss deep-rooted matters of poverty, malnutrition, and inequity that are central to the underlying causes of micronutrient malnutrition.

One can argue that because of the limited view that biofortification has on addressing larger systemic issues, investments in the technology is a misallocation of already scarce, competitive resources for improving development of countries, communities, or individuals. If poverty is the stem of issues such as malnutrition in which most would agree is, there needs to be substantive improvements in food and health system inequities. Framing hunger and malnutrition as quantitative problems has shaped policies over the last 4 decades (De Schutter, 2015), that may not have yielded the best results—there are still 815 million who are undernourished and 150 million children stunted (FAO, 2017; UNICEF et al., 2018).

On the other hand, in order for biofortification to be adopted, enhanced micronutrient content has to be built into better adapted varieties. If biofortification enhances investment in breeding, which has been severely under-resources in developing countries, this provides a counter view to scarce resources being misallocated. Organizations, such as HarvestPlus, are working to develop drought tolerant and virus resistant varieties (OFSP, for example) targeting smallholder farmers. Thus one can argue that agricultural researchers have a moral obligation to produce biofortified versions when/if the genes can be cost effectively integrated into their breeding lines, which could provide larger food system benefits.

In considering future tactics to ensure the sustainability of biofortified foods within the larger food basket and environment within communities, issues such as minimizing harm and disruption to communities and individuals, providing a compelling benefit to produce the crop and consume the food, maximizing awareness of the benefits that these foods potentially provide to human health, and being sensitive to social norms and justice issues of fairness and equity, are all important aspects that need to be studied, considered, and respected.

While this chapter provides some food for thought on the ethical and sociocultural issues that biofortification could pose, more research is necessary to understand how to integrate and scale up these crops/foods into society in which self-determination, food justice, and fair distribution is valued and addressed within the larger context of sustainable development.

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