CASE ANALYSES

1. Fortification of Salt & Flour in the USA
Historic examples of large-scale commercialization initiatives in the nutrition sector with clear outcomes

2. HIV/AIDS Medicine in South Africa
Health sector example of privately developed medicine that needed to reach low-income populations on a large scale

3. Vitamin-A Cassava in Nigeria
Priority value-chain, seed sector example of how a HarvestPlus developed technology has started to commercialize

4. Additional case examples are used throughout the final report to highlight example of success factors, bottle necks and partnership best practices

US FORTIFIED FOOD: Fortified Wheat Flour

The History of Food Fortification in the United States: Its Relevance for Current Fortification Efforts in Developing Countries (Bishai and Nalubola, 2002); Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification: Chapter 3, Overview of Food Fortification in the United States and Canada (Institute of Medicine Committee on Use of Dietary Reference Intakes in Nutrition Labeling. National Academies Press (US), 2003);

BACKGROUND

In the 1930's, vitamin-B enriched wheat flour and products were developed in the United States to prevent beriberi and pellagra; however, these diseases were not considered common public health problems at the time, and the public had little awareness of the diseases or their impact. Rather, nutritionists based the need for intervention on estimated consumption rather than existing disease burden and framed their efforts as an insurance against future nutritional deficiencies. As a result, demand for enriched products was low.

Government incentivized industry to enrich wheat flour and products through philanthropic appeals, but the cost of fortification meant that only large mills and bakeries (representing 40% of the total supply) could reach the economies of scale needed to enrich without increasing prices. Smaller mills and bakeries instead waited to see consumer demand and willingness to pay would increase, while still producing non-enriched products at a lower price than enriched products.

A public awareness campaign was launched to help increase demand, but it relied heavily on technical language that did not resonate with consumers, so it had no impact on demand. Large mills and bakeries, seeing their prices undercut by smaller competitors with non-enriched products reversed their decision to produce enriched products and the market for enriched foods diminished. Government attempted to support the market by issuing a wartime requirement for enriched foods for army procurement and a temporary mandate for all consumer foods to be enriched, but ultimately demand still failed to materialize.

It was not until government partnered with national health and science agencies, industry associations, and consumers to create a comprehensive marketing campaign that targeted consumers, industry, and legislators with focused, meaningful information about the benefits and impacts of enrichment that they were able to tip the scales on consumer demand, thereby increasing small processors' ability to compete profitably and ensuring a long-term market for enriched products. Ultimately, state-level legislation for enriched wheat products was facilitated by conducting public research on the vitamin deficiency burden, potential impact, and food fortification policy. In addition, federal labeling requirements were passed requiring that all unenriched products must be labeled as not containing essential vitamins. These initiatives contributed to the elimination of pellagra in the United States.

Enriched Flour USA Commercialization Process Map

Research and Development	Raw Material or Inputs	Production or Value Add	Processing or Manufacture	Distribution	Marketing	Product Sales or Home Consumption	Enabling Environment
• **Low priority health outcome:** vitamin-B enriched flour prevented beriberi and pellagra which were not considered common public health problems • **No existing target market:** case for enrichment was not existing disease burden, but as insurance against future deficiencies	• procurement processes were already in place and not impacted by the intervention	• production processes were already in place and not impacted by the intervention	• **No economy of scale:** smaller processors could not reach economies of scale without increasing consumer prices, **Lack of consumer demand:** incentivized small processors to make nonenriched products at lower prices than enriched products so that and larger processors reversed production of enriched products • **No profitable business model:** to justify the investment needed for processing enriched flour	• distribution networks were already in place and not impacted by the intervention	• **Failed campaign:** public marketing information used confusing language to describe benefits of enrichment to prevent unknown diseases, resulting in no increase in consumer demand • **Nutritional benefits of the product were not clear** or compelling to most consumers	• **No health outcome demand:** enriched flour prevented beriberi and pellagra which were not considered health problems by consumers and did not have existing disease burden • **Limited health impact:** flour enrichment did not offer an immediate and visible benefit to consumers • **Government procurement:** existed to buy only enriched flour for military consumption during wartime	• **Failed government appeals:** used philanthropic and patriotic language and threats of legislation to try to incentivize industry to enrich, but were not effective in pushing adoption • **Government-issued mandate:** that all flour must be enriched tried to leverage national defense to address nutrition • **No federal labeling requirements:** for enrichment, most efforts at state level and not uniform

Enriched Flour USA Commercialization Analysis

Research and Development	Raw Material or Inputs	Production or Value Add	Processing or Manufacture	Distribution	Marketing	Product Sales or Home Consumption	Enabling Environment
SUPPLY	SUPPLY	SUPPLY	**SUPPLY** • smaller processors could not reach economies of scale needed to enrich without increasing consumer prices	SUPPLY	**SUPPLY**	**SUPPLY**	**SUPPLY** • government-issued wartime mandate that all flour must be enriched to leverage national defense to address nutrition
DEMAND • prevented beriberi and pellagra which were not considered common public health problems	DEMAND	DEMAND	**DEMAND** • small processors incentivized to make cheaper nonenriched products, larger processors reversed enriched production	DEMAND	**DEMAND** • marketing info about benefits of enrichment was confusing and focused on preventing unknown diseases	**DEMAND** • health impact was abstract as flour enrichment did not offer an immediate and visible benefit to consumers	**DEMAND** • philanthropic appeal and legislative threat to incentivize enrichment were not effective in industry adoption
POLICY	POLICY	POLICY	**POLICY**	POLICY	**POLICY**	**POLICY**	**POLICY** • no federal labeling requirements for enrichment, most efforts at state level and not uniform
FINANCE	FINANCE	FINANCE	**FINANCE** • No business model (profitability) to justify the investment needed for processing enriched flour	FINANCE	**FINANCE**	**FINANCE**	**FINANCE**
OUTCOMES • case for enrichment was not disease burden, rather as insurance against future deficiencies	OUTCOMES	OUTCOMES	**OUTCOMES**	OUTCOMES	**OUTCOMES** • nutritional benefits of the product were not clearly marketed or compelling to most consumers	**OUTCOMES** • limited health impact as flour enrichment did not offer an immediate and visible benefit to consumers	**OUTCOMES**

KEY FINDINGS

SUMMARY:

- Efforts to increase demand through public awareness campaigns had little effect on demand for enriched products and willingness to pay
- For small mills and bakeries that could not produce enriched products at competitive prices, there was no incentive to sell enriched products at higher prices; rather, enrichment created a market opportunity to produce non-enriched products at lower prices and undercut compete-tors with products that consumers viewed as interchangeable
- With most processors producing non-enriched products, large processors that had adopted enrichment reversed their decision to meet consumer demand for low prices
- Government procurement helped during the war, but an additional, well targeted marketing campaign was needed afterwards to truly create the demand needed to push the industry forward with fortified production

OVERALL:

- **Demand (consumer and industry) bottlenecks** occurred throughout the commercialization process, indicating its role as a significant limiting factor
- **The processing or manufacture** step was the main bottleneck for industry demand due to high adoption costs and the lack of a profitable business model given that consumers were unwilling to pay the premium for it
- **Development outcomes** had some clustering of issues reflecting that the intended of impact of the product was not highly valued
- Because fortification occurs at the processing level, procurement of raw materials, initial production, and product distribution were not impacted by enrichment efforts

MAJOR BOTTLENECKS:

- Profitability is critical for commercialization, and the **key profitability bottleneck occurred around processing economies of scale**; enrichment was only profitable for large-scale processors that could reach higher economies of scale, but these processors only made up 40% of industry, so the market failed to coalesce around enrichment
- Additional significant **bottlenecks are clustered around demand because there was no proven disease burden**, prevention of beriberi and pellagra was not a compelling driver of consumer demand, and marketing information highlighted abstract health benefits that were largely imperceptible by consumers in highly technical language that did not resonate with consumers

KEY BOTTLENECK: LACK OF CONSUMER DEMAND

LACK OF CONSUMER DEMAND:

- Because there was no proven disease burden, prevention of beriberi and pellagra was not a compelling driver of consumer demand, and marketing information highlighted abstract health benefits that were largely imperceptible by consumers in highly technical language that did not resonate with consumers
- This also relates to there not being a compelling case for the 'Development Outcome' success factor -

INTERVENTIONS:

- Government and industry associations collaborated on **a comprehensive promotional campaign** to more effectively communicate the benefits of enrichment, and increase consumer awareness and demand; also partnered on industry-wide education program to educate millers and bakers about the enrichment process and its public benefits
- **National health, science, and engineering institutes facilitated state-level legislation** for enriched wheat products by conducting research on vitamin deficiency burden, potential impact, and food fortification policy
- **Federal labeling requirements** were passed requiring that all unenriched products must be labeled as not containing essential vitamins

LESSONS LEARNED:

- **Public research, consumer awareness, and government procurement were all important levers** for incentivizing industry supply of enriched foods
- **Without a clear, compelling business case for consumers, these levers were not sufficient to drive demand**
- Rather, **a comprehensive, targeted marketing campaign with clear messaging for consumers, industry, and legislators with meaningful information** about the benefits and impacts of enrichment was needed to tip the scales on consumer demand, thereby increasing small processors' ability to compete profitably and ensuring a long-term market for enriched products

KEY BOTTLENECK: PROCESSING COSTS

INDUSTRY DEMAND AND PROCESSING COSTS:

- Consumers were unwilling to pay higher prices for enriched wheat products to address diseases that were not considered large public health concerns
- Marketing information developed to increase consumer demand was confusing, technical, and focused on imperceptible health benefits addressing uncommon diseases.

INTERVENTIONS:

- **Public health campaign** launched to increase public awareness of beriberi and pellagra and stimulate consumer demand; however, the campaign used highly technical scientific language to describe largely unknown diseases and imperceptible benefits and consumer demand did not change
- **Government issued wartime procurement policy** that only enriched wheat products would be purchased for army contracts; also issued a temporary wartime mandate that all wheat products for public consumption must be fortified

LESSONS LEARNED:

- Consumer demand failed to materialize because the **public awareness campaign failed to communicate the disease risk effectively,** the public had no awareness of a visible disease burden, and the benefits of enrichment were imperceptible
- Processor willingness to enrich failed to materialize **because incentives were not based on profitability or demonstrated consumer demand** and instead relied patriotic or philanthropic appeals
- **Government procurement can drive initial demand, but it cannot be successful without simultaneous investment** in building strong consumer demand for ongoing commercialization

US FORTIFIED FOOD : IODIZED SALT

The History of Food Fortification in the United States: Its Relevance for Current Fortification Efforts in Developing Countries (Bishai and Nalubola, 2002); Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification: Chapter 3, Overview of Food Fortification in the United States and Canada (Institute of Medicine Committee on Use of Dietary Reference Intakes in Nutrition Labeling. National Academies Press (US), 2003); History of U.S. Iodine Fortification and Supplementation (Leung et al, Nutrients 2012)

BACKGROUND

In the 1830s the link was made between iodized salt consumption and goiter prevalence with early recommendations for increased consumption of naturally iodized salt. Although there were some early attempts to develop and promote iodine treatments for goiters in the U.S. and Europe, these efforts were small and not commercially viable. By the early 1920s, goiters were a significant public health concern in certain areas of the US and scientists had developed a complete understanding of how iodine could prevent them. At the time there were no precedents for the widespread addition of nutrients to food and scientists suggested that iodized salt be used to prevent goiter in livestock and with iodine droplets for children. In 1922, a pediatrician at the University of Michigan, persuaded the Michigan State Medical Society to set up an Iodized Salt Committee to promote the iodization of salt for human consumption.

The Michigan State Medical Society launched one of the world's first food fortification campaigns. After reviewing technical data on annual salt consumption, iodine toxicity, and the taste of iodized salt, the Society held several conferences with the Michigan Salt Producers Association. The society hired experts to work out the technology for large-scale manufacture and to investigate the salt industry's concerns. The salt industry was not fully on-board- some large manufacturers were excited by the potential to provide a public service and with others thinking that the expense of iodizing salt for consumer markets was not worth it.

In 1923, the Society began to work with Michigan state legislators to plan regulations that would mandate the production of foods that would protect state citizens from goiter. Salt makers feared that unless they iodized their product, they would be forced to produce only unrefined salt which contained iodine, but was not aesthetically pleasing. To help create a market for iodized salt, the Society then organized an educational campaign with the help of the University of Michigan, the advertising departments of the salt companies, the salt retailers, and the press- both physicians and school-teachers were recruited to give lectures and lessons about iodized salt.

In addition to the public campaign and proposed legislation - the State Department of Health in Michigan also wanted to show the clear health benefits and conducted a baseline survey of the incidence of goiter. A later survey funded by the salt industry showed that, relative to the baseline, there was a 74%–90% decrease in goiter incidence between 1924 and 1935 in the counties surveyed. It also showed a decrease in goiter incidence even among children who reported that they did not use iodized salt. This evidence, in addition to other studies led by the salt industry, were incorporated into marketing campaigns and consumer demand followed accordingly, particularly in goiter affected regions.

Iodized Salt Commercialization Process Map

Research and Development	Raw Material or Inputs	Production or Value Add	Processing or Manufacture	Distribution	Marketing	Product Sales or Home Consumption	Enabling Environment
• **Product Creation**: Initially created for animal consumption and supplements recommended for children • **Product Testing/ Development:** Medical Society compiled technical data on annual salt consumption, iodine toxicity, and the taste of iodized salt • **Health Outcomes:** Public/ private partnership to complete surveys showing reduced goiter prevalence	• **N/A**: No major bottlenecks related to raw material inputs were present in the US fortified food example which dealt with mostly large-scale processors who just needed to adjust some manufacture process	• **N/A:** Production/ manufacture step is not relevant to salt production • ***Non-US Example:*** *Literature for present day salt fortification efforts highlight the difficulty of small/ medium-scale raw salt producers to adopt iodization practices consistently and in a high-quality way*	• **Manufacture Process Development:** Industry did not bear the full costs of process development - the Michigan Medical Society hired experts to work out the technology for large-scale manufacture • **Adoption of new Process:** Not all industry actors were willing to adjust their processing	• **N/A:** Product was distributed through existing salt markets	**Demand Creation:** • **Public Campaign:** Dedicated campaign by Medical Society that brought in teachers, physicians and industry • **Industry Marketing:** Industry picking up medical claims and using them heavily in advertising	• **N/A:** Iodized salt was marketed as a perfect or enhanced substitute for non-iodized salt, so there were no major bottlenecks around sales and consumption at the consumer level.	• **State level legislation:** Michigan passed a 1924 law requiring all salt sold in the state to have minimum levels of sodium iodide • **National level legislation:** 1972 labeling requirements highlighting iodine as a "necessary nutrient" on both iodized and non-iodized products

Research and Development	Raw Material or Inputs	Production or Manufacture	Value Add or Processing	Distribution	Marketing	Product Sales or Home Consumption	Enabling Environment
SUPPLY: • not a given that iodization should be through food system – supplements were initially proposed until further R&D	**SUPPLY:**	**SUPPLY:** •	**SUPPLY:** • medical society did research and provided technical assistance for large-scale manufacture process	**SUPPLY:**	**SUPPLY:**	**SUPPLY:**	**SUPPLY:**
DEMAND: • consumer preference testing done by Medical Society	**DEMAND:**	**DEMAND:**	**DEMAND:** •	**DEMAND:**	**DEMAND:** • public campaign with a diverse array of partners from teachers to doctors to industry	**DEMAND:** •	**DEMAND:** •
POLICY:	**POLICY:**	**POLICY:**	**POLICY:** • threat of legislation helped prompt some industry cooperation for adopting iodization process	**POLICY:**	**POLICY:**	**POLICY:**	**POLICY:** • state level legislation to mandate all salt sales have minimum iodine levels
FINANCE: • medical Society bore most of the cost for R&D and product creation/ development	**FINANCE:**	**FINANCE:**	**FINANCE:** • industry ultimately paid for new processing systems, but with much technical assistance	**FINANCE:**	**FINANCE:**	**FINANCE:**	**FINANCE:**
OUTCOMES: • testing to prove health benefits jointly done by Medical Association (baseline) and industry	**OUTCOMES:**	**OUTCOMES:**	**OUTCOMES:**	**OUTCOMES:**	**OUTCOMES** • industry campaign that highlights the medical claims and benefits	**OUTCOMES:** • natural demand in the 'goiter belt' (Great Lakes States) areas	**OUTCOMES:** • national legislation for labeling requirements that highlight health benefits

KEY FINDINGS

OVERALL:

- **R&D bottlenecks** occurred throughout the commercialization process, given that fortified foods had never been developed before, significant investment was needed to prove the benefits and create demand
- **Development outcomes** were a significant driver of market creation and demand since there was a clear, demonstrable health need that allowed multiple stakeholders to come together
- **Enabling environment and policy** levers were not the main driver of success, but limited, strategic federal and state level support helped bring all required stakeholders to the table
- because fortification occurs at the processing level, procurement of raw materials, initial production, and product distribution were able

MAJOR BOTTLENECKS OR SUCCESS FACTORS:

- **Market and product development needed significant investment** upfront during the R&D process since fortified foods had never existing before and processors faced some upfront costs for adopting iodization
- Demand creation was achieved through **a broad, publicly supported campaign** that brought together multiple industries **to address a serious and prevalent medical condition** in many regions of the country
    - Additionally, **natural demand already existed in areas of the country where goiter prevalence was high**. Demand and market creation were initially concentrated in these areas and then leveraged for broader uptake

SUMMARY:

- Initial R&D was focused on developing supplement drops for human consumption, the health and research community did not initially think industry could be brought on-board
- State health society and officials were essential stakeholders for building out the R&D, industry buy-in, legislative awareness, and broad public campaign
- Health impacts were important and proven through studies that were sponsored by both industry and scientists
- Public campaign brought together health professionals who could give authoritative directives about product benefits, educators in schools who could reach wide audiences, government officials with legislative power, and industry partners with large advertising budgets who could support marketing campaigns

KEY BOTTLENECK: MARKET AND PRODUCT DEVELOPMENT

R&D FOR MARKET AND DEMAND CREATION:

- **Market and product development needed significant investment** upfront during the R&D process since fortified foods had never existing before
- Market development was assisted by the fact that iodized salt could be sold through existing salt sales channels, however industry buy-in and demand needed to be created to tap into this

INTERVENTIONS:

- **Product creation:** Researchers developed the product for livestock use, thinking that human needs would be addressed by iodine drops through the health system. Industry bore no costs for product creation
- **Product testing/ development:** Medical Society compiled technical data on annual salt consumption, iodine toxicity, and the taste of iodized salt so that industry did not have to incur product development costs
- **Health outcomes:** Public/ private partnership to complete surveys showing reduced goiter prevalence including a baseline survey supported by the Michigan Medical Society. All stakeholders used health results in marketing campaigns

LESSONS LEARNED:

- Industry-led product development may not be possible, but **early R&D that can make the business case** and build industry buy-in
- **Public-sector R&D for new or improved processing techniques** may also be a necessary intervention for industry buy-in
- **Science should support claims of product value and impact.** Independent studies can be important drivers of marketing and demand and may continue in the medium- long term to provide a sustained case for the impact

KEY SUCCESS FACTOR: DEMAND CREATION & OUTCOMES

DEMAND CREATION AND :

- Demand creation was achieved through **a broad, publicly supported campaign** that brought together multiple industries **to address a serious and prevalent medical condition** in many regions of the country

INTERVENTIONS:

- **Multi-stakeholder marketing campaign** which highlighted the medical claims and benefits
- **Leveraging high, natural demand** in the 'goiter belt' (Great Lakes and Appalachian States) areas allowed for the program to naturally build off existing demand and use a smaller market to make the business case for companies that could easily extend it into national coverage
- **National legislation** for labeling requirements that highlight health benefits was eventually passed in the 1970's with little industry push back, marking the wide scape acceptance and understanding of the both industry and consumer markets

LESSONS LEARNED:

- **Multi-stakeholder campaigns can use multiple levers** to bring industry to the table and drive demand
- **When development outcomes are strong enough, that can be enough to drive demand itself.** This happened in the 'goiter belt' areas of the United States where the Michigan State Health Association and legislators drove market creation
- **Development outcomes may not be enough to drive broad demand beyond the main, target beneficiaries**, however they provide a compelling case to bring major stakeholder investment into parallel marketing campaigns and government advocacy

CASE STUDY: HIV/AIDS MEDICATION (Global)

HIV Market Report (Clinton Health Access Initiative, 2018); AIDS Drugs for All: Social Movements and Market Transformations (Kapstein, Ethan and Joshua Busby. Cambridge University Press, 2013) Drug Companies Are Focusing on the Poor After Decades of Ignoring Them (McNeil, Donald. New York Times, 2019); Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa (McNeil, Donald. New York Times, 2001); Interview with Prabhu, Vineet, Associate Director of HIV Market Intelligence at CHAI (August 2019); This is Not Charity (Rauch, Jonathan. The Atlantic, 2007); Market Shaping Strategy (The Global Fund, 2015); A Dollar A Day: Creating the World Market for Lifesaving AIDS Drugs (Tweel, Tamara Mann. The Open Philanthropy Project, 2018)

BACKGROUND

High Prices, 1990's: $15,000 per person per year

In 1996, antiretroviral (ARV) treatments became available, and transformed HIV/AIDS from a death sentence to a chronic disease in countries where patients, their insurance companies, or their governments could afford to pay for treatment. While HIV/AIDS became an expensive, but treatable chronic disease in the US and Europe, it became too expensive to treat in low-income markets throughout Africa; in 1999, WHO stated that HIV/AIDS had become the fourth biggest killer worldwide and the number one killer in Africa.

In the 1990's, Brazil invested in large-scale procurement of generic ARVs as part of the government's constitutional obligation to provide guaranteed healthcare nationwide. Brazil turned to India, a crucial world source for generic drugs and active ingredients due to the government's ban on pharmaceutical product patents; only manufacturing methods were eligible for patents, which drove manufacturing innovation and disincentivized intellectual property ownership of specific drugs.

Indian generics manufacturer Cipla Ltd. began reverse-engineering ARVs, and they along with other generic firms created enough volume to supply Brazil

First Price Drop, 1996-2001: from $15,000 to $1,000 per person per year

In 1995, the WTO implemented the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In 1997 pharmaceutical companies used TRIPS to challenge generic ARV production when 39 pharmaceutical companies sued South Africa. The lawsuit galvanized activists and increased public awareness of the low-cost ARV access issue. The access campaign was comprehensive and critical, and used a "name and shame" approach to pressure pharmaceutical companies and politicians to drop the lawsuit; it was a public relations nightmare for pharmaceutical companies. Due to the pressure, pharmaceutical companies offered philanthropic drug prices for pilot projects to test the feasibility of managing complicated ARV regimens in low-income countries with limited health services.

Philanthropic prices were also financially motivated as pharmaceutical companies had no expectation of sales in low-income countries, they had to protect against low-quality products entering their high-income markets, and they needed to insure that they could still capture middle-income markets. Ultimately, philanthropic prices were not a long-term solution to access for while they did lower prices, drugs were still unaffordable and by 2001, only 2 percent of people in low-income countries were receiving life-saving drugs.

BACKGROUND (cont.)

Second Price Drop, 2001-2003: from $1,000 to $350 per person per year

During this time, Indian manufacturers like Cipla Ltd. were continuing to innovate in ARV manufacture, and they were able to combine multiple drugs into one fixed-dose pill, as well as develop heat resistant drug formats which no longer required cold chain. Despite these innovations, Cipla still did not have a large market for their drugs as there were few existing third-party buyers and ongoing issues with pharmaceutical lawsuits.

In partnership with activists, Cipla was able to lower prices of generic ARVs in 2001 through bulk discounts on raw materials, manufacturing innovations, packaging elimination, and leaving distribution to national health services. However, by the end of 2002 the number of people on ARVs was still well below 500,000; treatment viability and lower prices did not automatically ensure access or increase demand.

Third Price Drop, 2003-2005: from $350 to $140 per person per year

Given that patients lacked purchasing power, credible commitments of money to purchase ARVs were essential for the generics market to function, so the Global Fund, PEPFAR, and UNITAID started purchasing bulk orders of ARVs and distributing them to countries capable of reaching patients. These large-scale pooled procurements guaranteed the market, demonstrated demand, and incentivized increased efficiency.

As a result, generic manufacturers were able to shift from high-price low-volume to low-price high-volume manufacture and stabilize the generic market to ensure low-cost access. And WHO provided an independent regulatory quality assurance pathway for newly created generic pharmaceuticals that was as stringent as any in the world to ensure safe drugs.

In addition, CHAI negotiated forward prices with generic manufacturers that reflected the weighted average of their cost structure over time in order to bring ARV prices down even further. On the supply side, CHAI convinced manufacturers to accept smaller margins but produce more drugs, it helped source cheaper ingredients, and it funded the development of less expensive manufacturing and synthesizing techniques. On the demand side, CHAI persuaded manufacturers to sign multi-year deals that it had secured with large-scale third-party purchasers to aggregate national orders, smooth demand, and ensure that payments would not be defaulted.

This collaborative procurement was the first time any group had come forward with predictable multi-year volumes for manufacturers, and the CHAI approach lowered the overall costs of generic ARVs while increasing international demand.

BACKGROUND (cont.)

Ongoing Challenges

Distribution of HIV/AIDS medications increased from less than 1 million treatments in 2003 to 190 million from 2004 – 2007; competition in the market increased and the price fell more than 50 percent over five years. However, there is continuing pressure to keep lowering drug prices, but there is a price beyond which production is no longer sustainable, risking supply shortages and market destabilization.

In addition, global funding for HIV/AIDS has stagnated as it moves from a devastating pandemic to a chronic, treatable disease; as funding for pooled procurement diminishes, individual nations will have to coordinate to maximize buying power and maintain stable markets

HIV/AIDS Medication Commercialization Process Map

Research and Development	Raw Material or Inputs	Production or Value Add	Processing or Manufacture	Distribution	Marketing	Product Sales or Home Consumption	Enabling Environment
• **IP:** pharmaceuticals patented ARV IP for high-income markets • **Lack of transparent pricing:** from pharmaceuticals • **International patent and IP laws**: designed to protect corporate investments and not to open markets or public goods • **Generic drug development:** slowed down by political unwillingness in high-income countries	• **Limited ability to achieve bulk procurement of raw materials:** market demand was initially low and fragmented, so drug ingredients and raw materials could not be purchased in bulk for price discounts	• **Legal production limited:** to patent holding pharmaceuticals, which limited competition and innovation • **Inefficient generic production**: due to limited market information, threat of lawsuit, small market size, low growth, and high entry barriers • **Poor demand forecasting:** based on current orders rather than potential need and PO lag time led to production shortages	• **Limited quality control**: for generics produced without international regulations or centralized agency mandated to monitor quality	• **Undeveloped distribution networks:** for generic manufacturers who could not profitably reach last mile consumers • **High distribution costs:** limited pharmaceutical companies and philanthropies from reaching last mile, low income consumers • **Difficulties maintaining cold chains :** Early generation drugs needed to be kept cold • **Low-income consumers:** were hard to reach and required high-cost distribution channels to be built	• **No business case** for low and middle-income countries • **Limited uptake of new treatments:** driven by provider attitudes and client perceptions of side effects, as well as market ability to phase out previous generation medications • **Business model not profitable:** for pharma companies once IP laws were set aside, pharmaceuticals decided ARV market not worth pursuing	• **Unaffordable:** drugs developed by patent-holding pharmaceuticals • **Lack of transparent pricing:** from pharmaceuticals limited innovation for low-cost alternatives • **Generics and philanthropic pricing** decreased prices, but drugs still unaffordable and producers still need to cover costs • **Limited forecasting** possible for disorganized generic markets • **Large-scale procurement** has potential to distort markets**Limited political willingness**	• **Low priority** in most low-income countries due to complexity of ARVs, limited funds and infrastructure • **IP laws** designed to enforce the most restrictive laws • **Lack of market transparency** on volumes, prices, demand, and supply which decreased competition and split procurement • **Global commitment** needed to stabilize generic market prices which were irregular, opaque, and dependent on patent-holders • **Global intervention needed** to stabilize generic markets and create a viable business model for generic producers

Key Bottlenecks in HIV/AIDS Medication Commercialization

Research and Development	Raw Material or Inputs	Production or Value Add	Processing or Manufacture	Distribution	Marketing	Product Sales or Home Consumption	Enabling Environment
SUPPLY • **Lack of transparent pricing:** from pharmaceuticals	**SUPPLY**	**SUPPLY** • **Poor demand forecasting:** based on current orders rather than potential need and PO lag time led to production shortages	**SUPPLY**	**SUPPLY** • **Undeveloped distribution networks** • **Difficulties maintaining cold chains**	**SUPPLY** • **Generic market inefficiencies**: limited product availability, unaffordable prices & lack of tailoring to low-income markets	**SUPPLY** • **Limited forecasting** possible for disorganized generic markets leading to product not being available	**SUPPLY** • **IP laws** designed to enforce the most restrictive laws
DEMAND	**DEMAND** • **Limited ability to achieve bulk procurement of raw materials:** market demand was initially low and fragmented	**DEMAND** • **Limited market information:** led to inefficient generic production with small market sizes, low growth, and high entry barrier	**DEMAND**	**DEMAND** • **Low-income consumers:** were hard to reach and required high-cost distribution channels to be built	**DEMAND** • **Limited uptake of new treatments:** driven by provider attitudes and client perceptions of side effects	**DEMAND** • **Unaffordable:** drugs developed by patent-holding pharmaceuticals and initially by generic producers	**DEMAND** • **Lack of market transparency** on volumes, prices, and demand, which decreased competition and split procurement
POLICY • **International patent and IP laws**: designed to protect corporate investments and not to open markets or public goods	**POLICY**	**POLICY** • **Legal production limited:** to patent holding pharm companies, which limited competition and innovation	**POLICY** • **Limited quality control**: for generics produced without international regulations or centralized agency	**POLICY**	**POLICY**	**POLICY** • **Large-scale procurement** makes drugs affordable, but has potential to distort markets and must be tailored to specific product or country	**POLICY** • **Global commitment needed** to stabilize generic market prices which were irregular, opaque, & dependent on patent-holders
FINANCE • **IP:** pharmaceuticals patented ARV IP for high-income markets with profitable business models	**FINANCE**	**FINANCE**	**FINANCE**	**FINANCE** • **High distribution costs:** limited companies and philanthropies from reaching last mile, low income consumers	**FINANCE** • **Business model not profitable:** for pharma companies once IP laws were set aside	**FINANCE** • **Lack of transparent pricing:** from pharmaceuticals limited development of alternatives and viable business models	**FINANCE** • **Global intervention needed** to stabilize generic markets and create a viable business model for generic producers
OUTCOMES • **Generic drug development:** slowed down by political unwillingness in high-income countries	**OUTCOMES**	**OUTCOMES**	**OUTCOMES**	**OUTCOMES**	**OUTCOMES**	**OUTCOMES** • **Limited political willingness to** for low-cost innovations • lower prices could put high costs on new firms, generics, govts	**OUTCOMES** • **Low priority** in most low-income countries due to complexity of ARVs, limited funds and infrastructure

KEY FINDINGS

OVERALL:

- After initial drug development by multinational pharmaceutical companies for high-income markets, there were three key phases of market development to lower ARV treatment prices and these three phases broadly match the key bottlenecks identified in the commercialization framework

MAJOR BOTTLENECKS AND SUCCESS FACTORS:

- **Enabling Environment:** vertical cluster around enabling environment highlights the early perception that ARV drugs could not be used effectively in low-income countries and lack of corporate willingness to ease intellectual property patents and increase transparency around price considerations
- **Supply:** horizontal cluster around supply highlights how generic manufacturers were eventually able to bring drug prices down sufficiently through raw material discounts, product innovation, process improvements, packaging elimination, and country-level distribution through national health services
- **Demand:** horizontal cluster around demand highlights how global multi-lateral initiatives and national governments were able to consolidate demand in order to stimulate innovation in the market through development of affordable generics
- **Product Sales:** the inability of vertical cluster around sales highlights the inability of the generic market to stabilize and smooth demand in order to achieve the economies of scale and other production efficiencies needed to bring drug prices down further

KEY BOTTLENECK: ENABLING ENVIRONMENT (IP)

BOTTLENECKS:

- **International intellectual property and patent laws were designed to protect corporate investments, not to open markets**; therefore, aggressive enforcement of pharmaceuticals' patents internationally limited production to patent-holding pharmaceutical companies, which limited competition and innovation
- **Pricing considerations of pharmaceuticals were unknowable and therefore non-negotiable**; when pharmaceuticals later agreed to lower prices, they were negotiated individually in discreet deals that maintained price opacity and relied on company philanthropy rather than a viable business model

INTERVENTION:

- **Pharmaceutical companies initially discounted ARV prices** because they had no expectation of sales in low-income countries, they wanted to avoid poor quality products in the market that undermined confidence in their own products
- Key **public and private stakeholders created a generic drug market** by collaborating with existing drug manufacturers like Cipla Ltd. in India with proven expertise in making high quality, high volume, generic drugs
- Activists partnered with generics manufacturers to **lower prices of generic ARVs** through bulk discounts on raw materials, manufacturing innovations, packaging elimination, and distribution via health services

IMPACT:

- Under political pressure, pharmaceutical companies created a tiered pricing system for consumers at different income levels around the world; tiered pricing access showed activists ARV prices were negotiable
- Generic manufacturers agreed to lower costs and profit margins in return for high volume sales and reliance on NGOs and national health services for distribution
- Generic drug manufacturers looking for production and usage efficiencies developed fixed dose combination therapies and heat resistant medication formats that lowered drug production and distribution costs

LESSONS LEARNED:

- Pharmaceutical companies fought to enforce patent protections in low-income markets, they ultimately **advanced their business interests further by protecting intellectual property rights in their high-income markets while generating positive publicity for allowing generics into low-income markets** where they had no expectations of sales anyway
- **Intellectual property and market regulation policies can be amended to create a win-win** by protecting technology developers' interests in high-income markets while still ensuring that low-income consumers with a high demand for affordable drugs tailored to their product use needs have access to live-saving technology

KEY SUCCESS FACTOR: GENERIC SUPPLY EFFICIENCIES

BOTTLENECKS:

- **Generic ARV market was disorganized;** sales volumes were scattered, unpredictable, and difficult to forecast; and many purchasers paid late or defaulted altogether
- **Price reductions had to be implemented such that they did not impose inordinately high costs on the major players** in the market, including incumbent firms, generics manufacturers, and governments
- **Large-scale procurement through multilateral buyers is complex and nuanced, and has the potential to distort markets and market competitors**; it also requires interventions tailored to the dynamics of the specific product or country

INTERVENTION:

- **Generic market was stabilized by the creation of large-scale third-party purchasers** such as the Global Fund, PEPFAR, and UNITAID who sought to demonstrate that ARV delivery in low-income countries was effective, and who then helped pool global procurement in order to create sizeable market demand
- **Pooled procurement mechanism** consolidates recipient demand for products and negotiates procurement terms on behalf of recipients using strategic marketing shaping practices applied through pooled procurement such as promoting competition, incentivizing innovation, encouraging supplier entry to expand the local or global quality-assured manufacturing base, or enforcing quality assurance measures

IMPACT:

- Proof of concept programs and the decreasing price prompted the creation of substantial third-party purchasers and bilateral and multilateral funding mechanisms that, given that many patients lacked purchasing power to buy drugs on their own, provided credible commitments of money to purchase ARVs for the universal access market to function
- Distribution of ARVS increased from less than 1 million treatments in 2003 to 190 million from 2004 – 2007; competition in the market increased and the price fell more than 50 percent over five years

LESSONS LEARNED:

- **Public institutions can play a key role in creating and consolidating markets** to benefit low-income markets by leveraging public funds to pool procurement so that manufacturers can supply a smoother demand and quickly reach economies of scale
- **Promoting full market transparency- price data, volumes, demand, and supply- can contribute to increased competition and improved negotiations** even for buyers not participating in pooled procurement
- Smaller buyers were willing to participate in pooled procurement because the multi-lateral large-scale buyers did not require any individual buyer to cede its autonomy or individual negotiating power

KEY BOTTLENECK: AFFORDABLE PRODUCT SALES

BOTTLENECKS:

- Generic manufacturers brought drug prices down significantly through raw material discounts, product innovation, process improvements, packaging elimination, and country-level distribution through national health services; however, **initial lower prices did not automatically increase demand as it was still unaffordable in low-income countries**
- **Market factors that prevented access to affordable drugs through the generic market** included limited information, small size, low growth, high barriers to entry, and high transaction costs; this led to limited product availability, unaffordable prices, slow introduction of new products, and lack of products tailored for low-income countries

INTERVENTION:

- **International development organizations secured further price reductions** by helping improve demand forecasting, apply international quality standards, expedite national registration, secure distribution, promote multi-year tenders, and split high-volume orders across multiple suppliers
- **CHAI helped organize and pool demand** into larger volumes and aggregated national orders to ensure large and reliable purchasing orders that smoothed market demand and incentivized manufacturers to take slimmer margins in return for higher sales volumes

IMPACT:

- CHAI's procurement approach resulted in three price cuts: the first from higher volumes, the second from slimmer margins, and the third from negotiating forward prices with generic manufacturers that reflected the weighted average of their cost structure over time
- predictable volumes lowered the overall costs of generic ARVs while increasing international demand
- the cooperation between international development organizations and the pharmaceutical industry at that level was completely novel
- CHAI's efforts may have been so successful that prices have been driven so low as to discourage firms from staying in or entering the market

LESSONS LEARNED:

- Given the global nature of markets, **strong partnerships are especially important**; the cooperation between public institutions, nonprofits, and generic pharmaceuticals to lower drug prices was completely novel
- **Personal and institutional champions** to build those relationships and generate trust resulted in generics opening their pricing structures and shifting their profit models to lower prices for low-income markets
- **Addressing demand drivers was critical in lowering drug prices, but it was not enough to drive affordability;** market shapers must work on both sides of the equation, building advocacy for consumer demand and creating willingness by suppliers to engage on price

SUCCESS FACTOR: DEMAND CONSOLIDATION FOR GENERICS

BOTTLENECKS:

- **Early ARVs were expensive, complex treatments** that pharmaceutical companies, high-income country governments, and international donors assumed would not be used effectively in low-income countries which diminished political willingness to seek low-cost alternatives
- **Even in low-income countries, the ARV market was not a high priority given the complexity of treatments**, other pressing health challenges, extremely limited public funding, and lack of health infrastructure
- **Intellectual property and patent laws were designed to enforce the most restrictive regulations** and therefore promoted a lack of price transparency and process innovation

INTERVENTIONS:

- **A"name and shame" campaign aimed at pharmaceuticals and politicians enforcing patent laws** in low-income countries created a permissive legal environment for the production and purchasing of generic drugs that catalyzed a new market for generic drugs
- **Partnership between access activists, multilaterals, and generic pharmaceutical companies** was unprecedented and encouraged generic manufacturers to open up their pricing considerations and work collaboratively to find pathways to lower drug prices

IMPACT:

- Decreasing drug prices stimulated political willingness and public funding for ARVs as the proof of concept was demonstrated and high prices were no longer a reason not to fund public health initiatives
- Partnership with generic manufacturers led to transparent procurement and price systems that benefitted all buyers by increasing market transparency, enhancing competition, promoting a stable supplier base

LESSONS LEARNED:

- Without a serious **global commitment** to permit and promote generic production, ARV prices would have remained irregular, opaque, and completely subject to the companies holding patents
- However, while pharmaceutical companies relented on enforcing patent protections for ARVs, **they did not have to publicly defend their general pricing practices, and price opacity is still the norm for other drugs**
- In order to promote innovation for development of drugs for other diseases concentrated in low-income markets, the **enabling environment must be improved to facilitate generic development** and public-private collaboration to lower prices and increase access

CASE STUDY: VITAMIN A CASSAVA NIGERIA

Interviews with Pail Ilona and Donald Mavindidze, HarvestPlus Africa and Nigeria (August 2019); New, More Nutritious Vitamin A Cassava Released in Nigeria (HarvestPlus, 2014); A Technical Review of Modern Cassava Technology Adoption in Nigeria (1985–2013): Trends, Challenges, and Opportunities(Oparinde et al., HarvestPlus Working Paper, 2016); Bio-fortification in Nigeria: A Systematic Review of Published Studies (Onyeneke et. al., 2018); Vitamin A Cassava in Nigeria: Crop Development and Delivery (Ilona et. Al., AJFAND, 2017); Yellow is good for you': Consumer perception and acceptability of fortified and biofortified cassava products (Bechoff at al, 2018); Global Prevalence of Vitamin A Deficiency in Populations at Risk 1995–2005 (WHO Global Database on Vitamin A Deficiency, 2009); http://www.harvestplusng.org/ (Website accessed August 2019); HarvestPlus: State-of-Art and Program Strategic Priorities in Biofortified Crop Development and Commercialization - Page 28 (Pfeiffer, 2015); Improving nutrition through biofortification: A review of evidence from HarvestPlus, 2003 through 2016 (Bouis and Saltzman, Global Food Security, 2017)

BACKGROUND

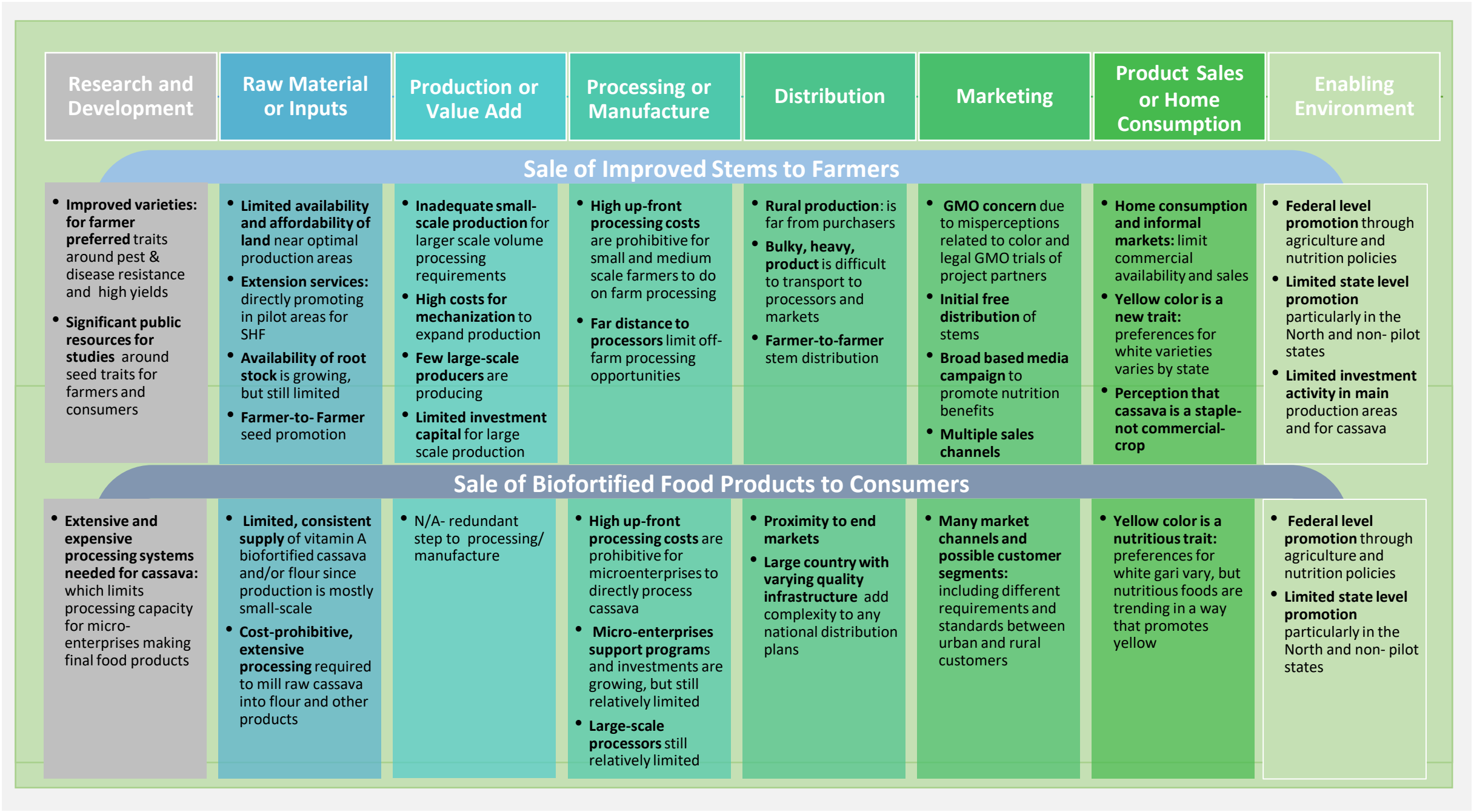
It is estimated that one-third of preschool aged children and one-fifth of pregnant women in Nigeria are Vitamin A deficient with higher rates seen in poor households and relatively consistent prevalence between urban and rural areas. Supplementation program exist to try to address the deficiency, however it is estimated that only about half of school aged children receive the treatment, while fortification requirements have increased consumption through fortified wheat and maize flours, vegetable oils, margarine and sugar. Consumption has increased but remains relatively low. In this context, biofortified vitamin A cassava was developed in Nigeria by IITA & CIAT from 2003 to 2011, when the first variety was approved for release. Another improved variety was released 2014, providing up to 40 percent of the vitamin A recommended daily allowance for children under five. In addition to it's higher beta-carotene content, Vitamin A cassava varieties also has improved pest- and disease-resistance, and is high yielding.

Programming to promote Vitamin A cassava has included public and private sector partnerships for multiplication and distribution of stems to farmers through extension agents and rural facilitators. Additionally, public awareness campaigns to promote consumer demand have been implemented leveraging mass media, Nollywood, education institutions and government advocacy. HarvestPlus is also working to increase and connect market outlets by promoting commercial processing for gari and fufu and through one-stop shops where consumers can buy vitamin A cassava stems, tubers, and ready-to-eat products. Concentrated advocacy efforts focused on strengthening national ownership of biofortification through effective integration into national nutrition and agricultural policies including the Agricultural Transformation Agenda and the Micronutrient Nutrient Deficiency Control programs.

A significant amount of literature has been published to date to both document these efforts and monitor uptake of the crop. Studies generally show the cost effectiveness of biofortification as compared to supplementation, consumer acceptance of the product especially when paired with health information, and general efficacy of biofortification in Nigeria in terms of estimated production, consumption and Vit A deficiency. HarvestPlus estimates that about 1.3 million improved cassava stems have been distributed to 672 communities and almost 460,000 farmers across Nigeria with 245 processing centers having been established. Vitamin A cassava remains one of the most successful HarvestPlus, biofortified crops in terms of estimated uptake.

While these numbers represent significant adoption, uptake has been mostly concentrated in south and west, half a million farmers is a small percent of the estimated 14 million small holder farmers in Nigeria, and processing has been most focused on micro-enterprises that have limited reach. The logistics and costs of expanding medium and large-scale commercial production and processing of cassava are not insignificant. Particularly access to land and proximity to large urban markets remains a challenge for large scale uptake. Promotion to small-scale farmers and microenterprises is a time and labor-intensive process particularly in light of HarvestPlus and GAIN targets to reach hundreds of millions of consumers with biofortified products in the next 5 years. Although stem sharing has organically occurred in non-targeted areas, it is still a relatively slow process.

Vitamin-A Biofortified Cassava Nigeria Commercialization Process Map



Commercialization Framework for Vitamin-A Biofortified Cassava Nigeria

Research and Development	Raw Material or Inputs	Production or Value Add	Processing or Manufacture	Distribution	Marketing	Product Sales or Home Consumption	Enabling Environment
SUPPLY • **Extensive and expensive processing systems needed for cassava**	**SUPPLY** • **Limited availability & affordability of land** • **Availability of root stock** is growing, but still limited	**SUPPLY** • **Inadequate small-scale production** for larger scale volume processing requirements	**SUPPLY** • **High up-front processing costs** are prohibitive for small scale farmers and limited number of large-scale processors	**SUPPLY** • **Proximity to end markets** • **Bulky, heavy, product** is difficult to transport	**SUPPLY** • **Multiple sales channels** and possible customer segment requires differentiated product delivery	**SUPPLY** • **Home consumption and informal markets:** limit commercial availability and sales	**SUPPLY** • **Federal level programs** to promote and improved, nutritious production
DEMAND • **Improved varieties: for farmer preferred** traits around pest & disease resistance and high yields	**DEMAND** • **Farmer-to- Farmer** seed promotion is growing but still limited	**DEMAND**	**DEMAND**	**DEMAND** • **Farmer-to-farmer** stem distribution	**DEMAND** • **GMO concern** due to misperceptions related to color and partner programs • **Initial free stems**	**DEMAND** • **Yellow color is a new trait:** preferences for white varieties varies by state	**DEMAND**
POLICY •	**POLICY**	**POLICY**	**POLICY** •	**POLICY** • **Large country with varying quality infrastructure** add complexity to any national distribution plans	**POLICY**	**POLICY** •	**POLICY** • **Limited state level promotion** particularly in the North and non- pilot states
FINANCE	**FINANCE** • **Cost-prohibitive, extensive** processing required to mill raw cassava into flour	**FINANCE** • **High costs for mechanization** • **Limited investment capital** for large scale production	**FINANCE** • **High up-front processing costs** are prohibitive for small and medium scale farmers and microenterprises	**FINANCE**	**FINANCE** •	**FINANCE** •	**FINANCE** • **Limited investment activity in main** production areas and for cassava
OUTCOMES • **Significant public resources for studies** around seed traits for farmers and consumers	**OUTCOMES** • **Extension services:** directly promoting in pilot areas for SHF	**OUTCOMES**	**OUTCOMES** • **Micro-enterprises support programs** and investments are growing, but still relatively limited	**OUTCOMES**	**OUTCOMES** • **Broad based media campaign** to promote nutritional benefits	**OUTCOMES** • **Yellow color is a nutritious trait:** growing in popularity, although preferences for white gari still vary	**OUTCOMES** •

KEY FINDINGS

SUMMARY:

- Biofortified, Vitamin A cassava was released in Nigeria in 2011 after being developed in partnership between global and local agricultural research institutions – including HarvestPlus which is developing several biofortified crops across the global
- Vitamin A cassava in Nigeria has been one of the more successful HarvestPlus crop in terms of uptake. This has been driven by farmer, industry and consumer demand creation initiatives including government advocacy, a multi-stakeholder media campaign, marketing through multiple media channels, and promotion of the crop through the agricultural extension system
- Although the commercialization has been relatively successful, wide-scale adoption remains relatively limited outside of pilot areas. Expansion through small-holder farmers and micro-enterprises is steady, but slow and limited in scope. Adoption by large-scale producers and processers remains limited by supply bottlenecks

OVERALL LESSONS:

- Strategies for commercialization of seed need to **consider bottlenecks for both how seed will reach farmers and how biofortified grains and products will reach consumer markets**
- Both **small scale (SHF and micro-enterprise) and large-scale production and manufacturing are viable options for broad commercialization but comes with trade-offs.** Outreach through small and medium sized channels may need more time and resources for widescale adoption, while large market channels may not reach the most vulnerable, target populations (including small-holder farmers)
- **Complex supply, market, and distribution channel eco-system requires a multi-pronged marketing** and outreach campaign that still may only reach limited customer segments

MAJOR BOTTLENECKS OR SUCCESS FACTORS:

- **Supply bottlenecks for cassava exist for both the seed to farmer and industry to consumer processes.** Large-scale production is limited due to high costs for land and mechanization. Processing at all levels is limited by complex processing requirements that limits the entry of micro-enterprises and by limited availability of raw input
- **Limited availability of raw material inputs** at a large scale reflects the limited production and marketing capacity of SHF as well as the fact that major production areas are not necessarily located near major processing zones and the product is difficult to move
- **Initial success factors around outcomes and demand** may indicate that market uptake can takeoff once supply challenges are solved

KEY BOTTLENECKS: Adequate and profitable input supply

ADEQUATE SUPPLY AND PROFITABLE SUPPLY CHAINS:

- Large-scale production is limited due to high costs for land and mechanization as well as limited investment opportunities to expand production
- Large-scale processing is limited relatively by challenging supply chain logistics for raw cassava and a limited number of large-scale producers who can provide industrial level quantities;
- Micro-enterprise and on-farm processing is limited by complex process for processing raw cassava

INTERVENTIONS:

- **Initial free distribution** of stems to small-holder farmers
- **Government supported promotion campaigns to farmers** through agricultural extension services including national programs and policies for agricultural transformation and fighting malnutrition
- **Mass media campaign** to customers through multiple platforms
- Some **market matching and technical assistance** from HarvestPlus and international research centers to support industry adoption and micro-enterprise development

LESSONS LEARNED:

- **Demand creation may not be enough** to drive supply chain partners when significant processing, distribution and marketing costs and barriers exist
- **Successful farmer promotions can have spillover effects outside of target areas**, but more investment may be needed to speed up market penetration timeline
- **Successful small and medium scale production is limited in scope.** Broader reach to national, state or urban markets likely need larger-scale partners and a different strategy for production and market supply