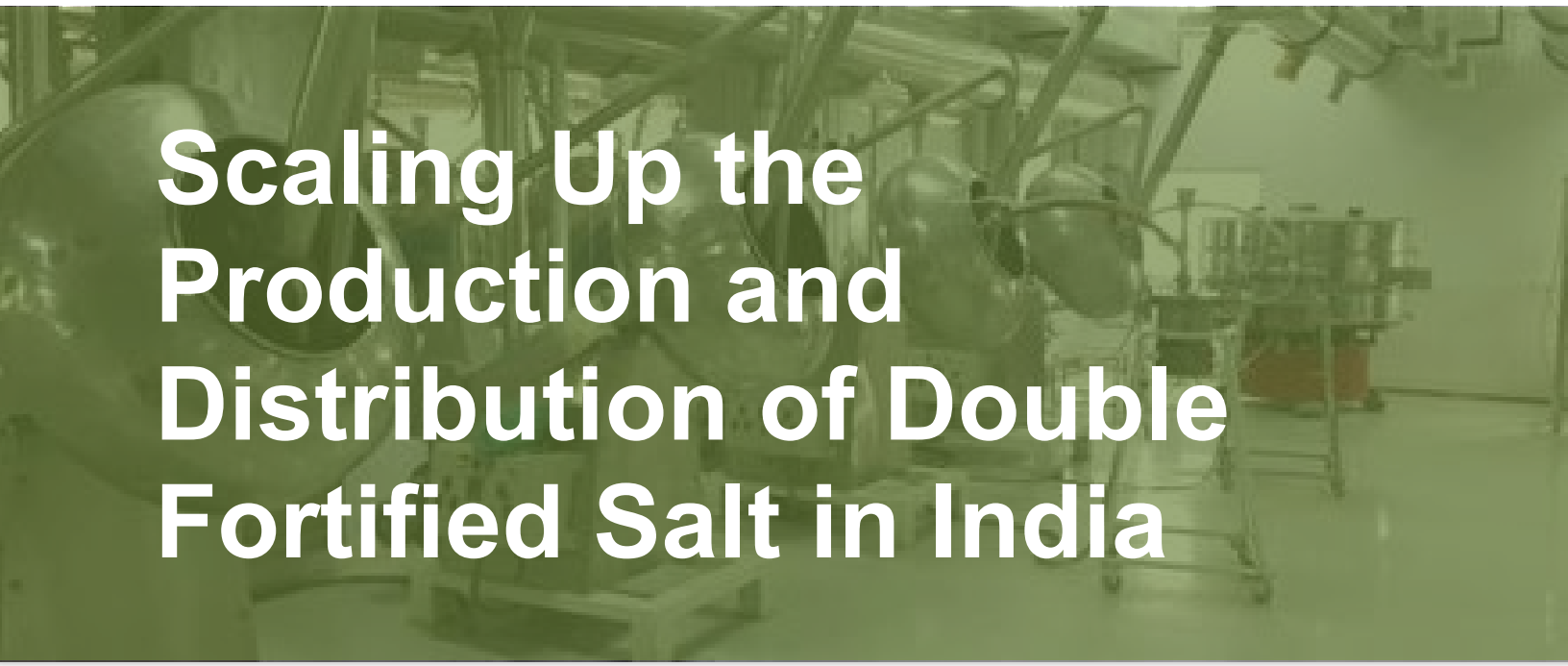
Final Technical Progress Report



Scaling Up the Production and Distribution of Double Fortified Salt in India

IDRC Project Number 108123

Research Organizations involved in the study: JVS Foods Pvt Ltd, Jaipur (JVS); St Johns Research Institute, Bangalore (SJRI); University of Toronto, Toronto (U of T); Nutrition Impact Solutions Inc., Ottawa (NIS) and Barometer Research Mumbai (BR)

Location of Study: India (Rajasthan, Uttar Pradesh and Jharkhand States) and Canada (Toronto)

By: Levente Diosady (UT), Venkatesh Mannar (NIS), Jaykumar Menon (NIS)

Report Type: Final Technical Progress Report

Period covered by the report: November 1, 2015 – June 30, 2018

Date: June 30, 2018

This work was carried out with the aid of a grant from Canada's International Development Research Centre (IDRC), www.idrc.ca, and with financial support from the Government of Canada, provided through Global Affairs Canada (GAC), www.international.gc.ca".

Global Affairs Canada Affaires mondiales Canada

IDRC | CRDI
International Development Research Centre
Centre de recherches pour le développement international

Canada

Table of Contents

1. Executive Summary..... 4
   - *Capsule Summary*
   - *Project Objective*
   - *Summary of Key Results*
   - *Key Research Findings and Lessons*
2. The Research Problem..... 8
3. Progress Towards Milestones.....10
4. Synthesis of Research Results and Development Outcomes..... 13
   - *4.1 Objective 1 – Scale up the production, distribution and consumption of Double Fortified Salt*
   - *4.2 Objective 2: Test models and approaches to optimize the technology and production processes for consumer acceptance and nutritional impact*
   - *4.3 Objective 3: Inform decision makers, actively promote and target Double Fortified Salt to processors and consumers*
   - *4.4 Objective 4: Ensure sustainable Double Fortified Salt production and distribution capabilities of local stakeholders*
   - *4.5 Cross-cutting comments, for all objectives*
5. Synthesis of Results Towards AFS Themes..... 31
   - *5.1 Availability*
   - *5.2 Accessibility*
   - *5.3 Utilization*
   - *5.4 Informing and/or influencing the development and implementation of food security policies*
6. Project Research Outputs..... 33
   - *6.1 Academic Presentations*
   - *6.2 Academic Publications*
   - *6.3 Stakeholder Presentations*
   - *6.4 Open Access*
7. Problems and Challenges..... 35
8. Overall Assessment and Recommendation..... 36
9. List of Annexes.....37

List of Abbreviations

BMGF – Bill and Melinda Gates Foundation
BR – Barometer Research, Mumbai
DFS – double-fortified salt
EFF – encapsulated ferrous fumarate
FAQ – frequently asked questions
FSSAI – Food Safety and Standards Authority of India
JH – Jharkhand state, India
JVS – JVS Foods Pvt Ltd, Jaipur
MP – Madhya Pradesh state, India
NIS - Nutrition Impact Solutions, Inc., Ottawa
PDS – Public Distribution System
SJRI- St. John's Research Institute, Bangalore
TINI – The India Nutrition Initiative, Delhi
TiO2 – Titanium Dioxide
U of T – University of Toronto
UP – Uttar Pradesh state, India

1. Executive Summary

Capsule Summary

DOUBLE FORTIFIED SALT GOES TO SCALE: 50 MILLION PEOPLE REACHED; 25X FINANCIAL LEVERAGE

Iron deficiency is the most widespread form of malnutrition in the world. It afflicts ~2 billion people, principally women and children, causing anemia, reduced energy, damped cognition, and increased maternal mortality. Addressing it would constitute a historic contribution to gender equity. This project brought salt double fortified with iron and iodine ("DFS") to scale, reaching ~**50 million people** at its apex in 2018, up from zero in 2016. It leverages iodised salt, which reaches *5 billion* people daily. It is highly cost effective: the incremental cost of adding iron to iodised salt is less than 25 cents per person *per year.* 10,000 village women health workers have been trained. Over 60 million 1 kg bags of DFS have been produced and distributed through 8000+ fair price shops. The project has ~**25X in financial leverage** from CIFSRF funding. It is a true Canada-India story, with technology from the University of Toronto reaching millions in partnership with Indian institutions. If the model proves out, the hope would be to reach one billion people in 10 years.

Project Objective

The project sought to address the most widespread form of malnutrition in the world. Iron deficiency afflicts nearly 2 billion people globally, principally women and children. Iron deficiency causes anemia, reduces energy levels and cognitive function, and increases maternal mortality. The project aimed to develop capacity for manufacture of salt double-fortified with iron and iodine (DFS) based on premix technology developed at the University of Toronto (U of T) and to enable the distribution of DFS in an efficient, transparent manner at scale. It builds upon the near universal reach of a vehicle like salt, pairing it with the vast coverage of a targeted distribution network like India's Public Distribution System ("PDS"), which supplies basic commodities at affordable prices to hundreds of millions of low-income people in India. The project seeks to have a major health impact, namely, the reduction of iron deficiency, iodine deficiency, anemia, and their functional consequences among malnourished populations, with particular impact on children under five and women of child bearing age.

Summary of Key Results

At its outset, the project sought distribution in 10 districts in the northern Indian state of Uttar Pradesh (UP), to approximately 10 million people. The UP Government launched the project in December 2015 with implementation and monitoring support from Tata Trusts, a key philanthropic organization in India, and technical support through the CIFSRF project. The Government committed Rs 405 million (CAD 8.1 million) per year for two years to purchase DFS and sell it at significantly subsidized prices through the vast network of over 8,000 fair price shops across the 10 target districts.

The project entailed technology development, technology transfer, establishment of production capacity, consumer research, supervision of manufacturing, monitoring of production and DFS stability, assistance with quality control, education, awareness building, monitoring of health outcomes and salt usage, and coordination of the different project elements and contributing organizations. Using a gender sensitive approach, DFS is designed to leverage existing salt iodization infrastructure in India, which already reaches 80% of the population.

In brief, the Food Engineering Group at the University of Toronto (U of T) with support from the Government of Canada through the Micronutrient Initiative (between 1995 – 2013), had developed microencapsulation-based technology to produce iron premix, which, when added to iodized salt, is stable and nearly indistinguishable. Through the current project focused on scaling up this innovation, the technology was transferred to JVS Foods India. Pilot trials were conducted to improve the quality and physical characteristics of the premix at optimum cost. A plant for producing the premix at scale with a capacity of 600 tons/year of premix, sufficient to produce 120,000 tons of DFS and supply over 40 million people, twice the annual requirement of the project, was built and commissioned. The plant has subsequently been expanded by JVS to 1500 tons/year of premix, sufficient for approximately 100 million people.

The premix produced was sold to designated salt processing companies selected by the UP government through competitive bidding. The salt processing companies, following a national technical standard for DFS, and standard operating procedures developed by the project, then added the premix to iodised salt at an approximately 1:200 ratio to form double fortified salt. The DFS was then shipped to warehouses and to over 8,000 Fair Price Shops serving consumers. To date over 60 million 1 kg bags of DFS have been produced and shipped. 10,000 women village health workers known as ASHAs (Accredited Social Health Activists) and ~8500 shop owners were trained on the rationale and benefits through use of DFS. The principal purchasers of the product are women. Stores have been fully stocked out each month. More recently two more Indian states, Jharkhand and Madhya Pradesh have followed the UP model and have started similar programs to distribute DFS at subsidized prices. More States are expected to follow. During this project more than 10 billion meals cooked using DFS have been served. Over the 32-month project period 1 Nov 2015 – 30 Jun 2018, the project reached at its apex an estimated 50+ million people in 2018, up from zero in 2016, making it arguably one of the world's largest and fastest growing new development innovations.

DFS is highly cost effective. The incremental cost of adding iron to salt is less than CAD 0.25 per person *per year*, currently subsidized by governments in India. The 2012 Copenhagen Consensus of eminent world economists, including several Nobel laureates, ranked investing in a bundle of micronutrients as the most cost effective in a list of 30 potential development investments. Per the World Bank, "probably no other technology available today offers as large an opportunity to improve lives and accelerate development at such low cost and in such a short time." And among micronutrient interventions, fortification of staple foods such as salt has the lowest cost per person.

St John's Research Institute, Bengaluru (SJRI) is leading an assessment of health impact of the project. In January 2016, the Bill and Melinda Gates Foundation (through the Global Alliance for Improved Nutrition, Geneva) announced their support for the evaluation of the impact of the intervention along

with SJRI to complement the evaluation currently planned under this project. The baseline evaluation in Uttar Pradesh revealed that 36% of women of reproductive age were anemic, of whom 62.7 % had low iron stores. In addition, 14.7% of non-anemic women also had low iron stores. Iron deficiency was therefore a primary cause of anemia in those populations. 91% of women with iron deficiency have access to the PDS (are cardholders or are on the registered list).

The end line biomedical impact evaluation of the intervention is expected to be complete next year, after twelve months of continuous intervention have been taken place. If the experience in prior rigorous randomized controlled trials of DFS (performed by ETZ Zurich/SJRI outside Bangalore, and by Cornell in Darjeeling) holds, we would expect to see a significant reduction in the prevalence of iron deficiency in children under 5 years and/or women of reproductive age after 12 months of uninterrupted use of DFS. The impact on iodine status should also be salutary.

Key Research Findings and Lessons

- Salt can be used as a vehicle to deliver micronutrients in addition to iodine to tens of millions of people in small and regular daily quantities
- Double fortified salt ("DFS", with iron + iodine) is acceptable organoleptically (taste, smell, colour, etc.) to both men and women consumers
- DFS technology can be transferred to industry (both premix producers and salt processors) and produced at large commercial scale (current installed production capacity for premix and DFS can meet the needs of ~100 million people)
- Governments are keen to use DFS as an instrument to address the health and nutritional status of their populations and been willing to commit large scale funds (the equivalent of tens of millions of Canadian dollars) to procure and distribute DFS through the PDS at a subsidized price
- The digitization of the PDS system (now under way) will in the future a) provide the project with digital data to monitor household level purchases of DFS, and b) allow for the sending of audio or text messages on DFS to consumers on their mobile phones
- Players from end to end in the value chain – producers, distributors, retailers, consumers – have been willing to participate at scale in the DFS project
- Consumers have found double fortified salt acceptable and have been repurchasing it
- The intervention is highly economically efficient - the incremental cost of adding iron to iodized salt is less than CAD ~0.25 per person, *per year* and offers tangible health and wellbeing benefits to consumers on a sustained basis.
- Minimal external financing is needed. Canadian funding played an important but a catalytic role. Approximately 95% of this project has been funded domestically within India, via philanthropy, industry, state governments, and consumers. Limited external assistance will however continue to be beneficial for key technical support and monitoring and evaluation.

The DFS project is an example of multidisciplinary, cross-national, intra-national, end-to-end collaboration, catalyzed by actors across India and North America, and then taken forward and owned by multiple state governments in India. At the national level, the project has promoted by the Ministry of Women and Child Development and the Ministry of Health and is guided under the auspices of the Food Standards and Safety Authority of India ("FSSAI"). In parallel, U of T coordinated communications, training and monitoring of programs. In brief, few projects or products in any sector have gone from the

latter stages of lab work to 50 million people in less than three years, as happened here. This has transpired we feel by "designing backward from scale" – by leveraging the massive reach of iodised salt and the Public Distribution System, and by using an ultra-low cost and culturally acceptable approach.

The project builds on more than a decade of background work in terms of technology development and evidence of efficacy leading to policy and regulatory acceptance in India. From its inception, the implementation of the project has been underpinned by local ownership and financing. Anemia and iron deficiency are primarily women's health issues. The very reason for the project's existence is to address health and nutrition issues that principally and disproportionately affect hundreds of millions of women and girls worldwide. Increasing energy and cognitive power for women and girls is fundamental to empowerment and is indeed a very basis of it. The concept of introducing a staple condiment of daily use to provide a health and wellbeing benefit for them and their children has resonated well. The 10,000+ front line health workers who were trained to spread this message are all women who understood the problem and the potential of this product. The project is also a wonderful example of Canada's feminist international assistance policy to refocus its international assistance toward advancing gender equality and the empowerment of women and girls.

The significance of this project is manifold – that the intractable problems of iron deficiency and anemia[1], which have afflicted hundreds of millions of women for decades with little decrease, might be addressable at scale; that DFS could help empower tens of millions of women, removing the constraints of reduced energy levels and diminished cognitive capacity; that DFS can reach tens of millions of people within a period of a year; that perhaps even other micronutrient deficiencies can be possibly addressed among hundreds of millions to billions of people globally by using a vehicle such as salt; that iron, a key nutrient, can be encapsulated and protected from interaction with iodine and thus incorporated into salt; that the private sector can produce DFS at scale; that a strong team with an entrepreneurial bent and a long history of interaction and achieving results at scale is helpful; that the PDS system in India can deliver a health-oriented product; that an entire supply/value chain can be set up; that it is possible to work at scale in Uttar Pradesh; that governments at the central and state level in India can take strong action against malnutrition.

Reflecting on the rollout of the project over its 32-month duration, despite significant and ongoing challenges, we believe that it has succeeded in addressing the research problems leading up to the achievement of the overall goal to reach tens of millions of consumers daily. The EFF DFS technology was refined in a Canadian lab, the premix was made light gray in colour, and found stable and consumer acceptable. The technology was transferred to India and production facilities for premix and salt processing were created. State governments, after a novel collaboration between their health departments and their food and civil supplies departments, issued large scale procurement orders, and deployed DFS at scale through their PDS systems. In 2018, more than 15 million people in UP continue to consume DFS daily.

The activity that the project has not been able to complete within its duration is the evaluation of health impact, which needs 12 months of continuous intervention.[2] But even at the current stage, several conclusions can be drawn. From a development and policy perspective, adding additional nutrients to salt and having it taken up by governments and consumers has been shown to be possible, and has reached scale. From a scientific perspective, the technical challenges involved in creating DFS appear

[1] Anemia prevalence in several parts of the world – especially South Asia and sub Saharan Africa –has persisted at unacceptably high levels for nearly five decades.

[2] Since anemia is multifactorial, aggravated by infections as well as other nutritional deficiencies, it may remain unchanged even with increased iron intake and absorption. Nevertheless, improving iron status, even were anemia not to change, is an independent good.

to have been largely solved in terms of bioavailability/health impact and consumer acceptability, although lower cost is always welcome, as are improved organoleptic properties.

The innovation here is of regional and global relevance. Iodised salt is consumed by 5 billion people globally, and iron deficiency is the world's most widespread form of malnutrition, afflicting nearly 2 billion people globally. Other countries in South Asia look to food standards developed approved by the Indian government. In Africa, Nigeria has been exploring DFS at a national level. In sum, DFS is that rarest of interventions – a coalescence of a sharp focus on challenges facing women, user-oriented research, high technology, industrial production, policy support, leveraging an existing large-scale intervention, massive distribution platforms, cultural acceptability, gender focus, women's empowerment, efficacy, equity, and efficiency – that is enabling it to reach and benefit tens of millions, and potentially a billion people, and that may help women and children across the globe reach their full potential.

2. The Research Problem

The basic rationale of the project was to develop a cost-effective and sustainable means to reduce the incidences of iron deficiency and/or anemia at scale. Iron and iodine deficiencies remain the world's most widespread nutritional disorders disproportionately affecting women and young children with severe health and developmental consequences. In India, for example, the rates of anemia are staggering – 53% of women ages 15-49, and 58% of children ages 6-49 months are anemic (with iron deficiency the major cause). Women of reproductive age lose iron during menstruation and have high iron needs. Hundreds of millions of women worldwide are iron deficient, causing among other things decreased energy levels and cognitive functioning. The project has women's health at its very core. Addressing these issues would empower millions of women in a very fundamental and direct way - by enhancing energy and cognitive power, essences of life, in a sense - if not an overtly political one.

To improve intake of these vital nutrients, salt offers unique advantages. It is universally consumed in small and regular daily quantities across all continents and cultures, by even the very poor and food insecure adults and children, and is centrally processed. Iodized salt is well established around the world, consumed by 5 billion people daily, and is considered one of the great public health successes of the 21st century. DFS, in the form of encapsulated ferrous fumarate ("EFF") was specifically developed to leverage the success of iodised salt and its associated global infrastructure. This encapsulated formulation prevents iron and iodine from chemically reacting. That chemical reaction destroys nutrient availability and health impact, and creates unacceptable sensory/organoleptic issues, as described in section 4.2. The formulation proved efficacious in randomized controlled trials conducted by ETZ-Zurich/SJRI, and Cornell, in improving iron status, [3] [4] as well as in improving cognition.[5] These

[3] Andersson, M, Thankachan, P, Mutthaya, S., Goud, R., Kurpad, A, Hurrell, R, Zimmerman, M., , Dual fortification of salt with iodine and iron: a randomized, doubleblind, controlled trial of micronized ferric pyrophosphate and encapsulated ferrous fumarate in southern India, Am J Clin Nutr 2008;88:1378–87.
[4] Haas, et al, Double-Fortified Salt Is Efficacious in Improving Indicators of Iron Deficiency in Female Indian Tea Pickers, The Journal of Nutrition, 2014, 144: 6: 957–964.
[5] Wenger, et al, Consumption of a Double-Fortified Salt Affects Perceptual, Attentional, and Mnemonic Functioning in Women in a Randomized Controlled Trial in India, The Journal of Nutrition, 2017, 147:12, 2297–2308.

studies also demonstrated safety. No material adverse effects were found. The iron is supplied at a level of ~1/3 of the recommended daily allowance; far lower than iron supplement pills, and within levels set by the WHO for iron fortification of staple foods - such fortification is mandatory in scores of nations. The emerging science of the gut microbiome bears monitoring, however, and vigilance across all aspects is required.

With an evidence base of multiple published peer-reviewed studies spanning over 10 years, as well as a favourable policy attitude towards and regulatory acceptance of DFS by the Government of India, the present project sought scale-up of DFS to 10 million people across 10 districts in Uttar Pradesh, which became the first state in India to create a DFS project in its PDS, and indeed was the first large scale rollout of DFS to families in the world. Public and private channels were considered by the project team. We chose to focus initially on the former, specifically on the PDS. The PDS is a government run social safety net program that targets and reaches low-income citizens. It is the largest food safety net program in the world. All citizens are entitled to obtain essential goods from the PDS on a non-discriminatory basis, and low-income citizens are entitled to purchase the goods at subsidized prices. With the passage of the Food Security Act / Right to Food Act in India in 2013, the government plans to expand the PDS to provide subsidized foods (cereal grains) to approximately 800 million people in India, up from 500 million,[6] as it seeks to cover up to 75% of the rural population and up to 50% of the urban population. [7] Per a legislative expert committee, the Act "marked a paradigm shift in addressing the problem of food security – from the current welfare approach to a right based approach." The Act also contains an explicit women's empowerment provision, which designates women eighteen and above as the head of the household, for the purpose of issuing ration cards.[8] While the PDS suffers from inefficiencies and leakage, it has the unique ability to reach low-income families for all meals for all members at vast scale. These are the community members most likely to be malnourished, and who have limited purchasing power and high price sensitivity. Private/open market distribution channels are promising as well, particularly for the upper income quintiles, who also suffer from some malnutrition. These channels are in an earlier stage of development.

The research problems being addressed by the project encompassed comprehensive technical support and delivery systems required to make DFS available to large populations in the bottom economic quintile of the Uttar Pradesh population, who are largely rural and engaged in agriculture. They covered the full supply chain, including:

1. Optimization of the U of T Technology for making iron premix
2. Scale up of the iron premix manufacturing process, infrastructure and capabilities to blend the premix to salt on a large scale to meet the needs of the target population
3. Establishment of effective procurement and delivery systems and monitoring of coverage and compliance
4. Establishment of procurement and distribution systems for DFS through the Public Distribution System to make it broadly available at an affordable price
5. Health impact studies on the effectiveness of the intervention in improving the iron status of the treated population

---

[6] Kishore, Avinash; Joshi, Pramod Kumar and Hoddinott, John F. 2014. India's right to food act: A novel approach to food security, in Global Food Policy Report. Eds. Marble, Andrew and Fritschel, Heidi. Chapter 3 Pp. 29-42, at 31.Washington, D.C.: International Food Policy Research Institute (IFPRI)(2013).

[7] "National Food Security Act, 2013", description by Department of Food and Public Distribution, Ministry of Consumer Affairs, Food, and Public Distribution. Government of India, http://dfpd.nic.in/nfsa-act.htm (retrieved July 10, 2018).

[8] National Food Security Act, 2013, Chapter VI, Women Empowerment, 13. http://egazette.nic.in/writereaddata/2013/e_29_2013_429.pdf (retrieved July 10, 2018).

3. Progress Towards Milestones (Milestones for Final Technical Report - 32 months)

Milestone	Achievement	Evidence/Indicator	Comments
1.1 At least 60% of consumers in 10 target districts in Uttar Pradesh (UP) purchasing and consuming the DFS product on a sustained basis	Completed and exceeded in UP. Also rolled out to MP and JH.	~70% coverage in UP from April 2017 onwards, per supply chain records and household surveys. MP (part of state; total population of covered area is 10 million people) and Jharkhand (entire state; total state population of ~33 million people) states commenced in 2017/18, with ~70% coverage in each.	Project paused upon change in UP gov't. New UP gov't recommenced project in Jan 2018, continues to date of writing (July 1, 2018) Program in Jharkhand currently paused. Program in MP continues.
1.2 Increased revenues via sales by salt producers to state government in response to tenders, new added value for a traditional product	Completed	Approximately $12M in DFS revenues for private producers to date. Zero DFS revenues for these producers before project.	Includes revenues for DFS premix producers and salt processors. Approximately 60,000 tons of DFS have been shipped to date.
2.1 Development of a cost-effective formulation of salt double fortified with iron and iodine, optimized for private sector food processors in India	Completed	Completed by Dec 2016 product rollout, with continued later refinements.	Raw materials in India differed slightly from those used in lab in Toronto, thus requiring reworking. Cost of premix brought down ~25% from project beginning. Months of trial runs to move product from lab scale to product scale. Premix plant created in Jaipur, multiple salt processors also equipped for DFS. Regulatory approvals for production obtained.

Milestone	Achievement	Evidence/Indicator	Comments
2.2 Model developed to speed up the distribution of DFS at scale by selected salt producers – targeting public distribution approaches	Completed	Completed by April 2017, when mass rollout in UP commenced.	Public distribution system has been providing DFS to tens of millions of people. One producer is selling in private markets, another is testing.
2.3 For consumers of DFS (particularly women and children, who are disproportionately impacted by iron and anemia deficiency), a 10% improvement in iron/anemia status of the target population confirmed through biochemical measurement. Comprehensive gender strategy, communication strategy, and action plans with clear responsibilities and timelines agreed upon by all partners during the inception workshop	TBD	Baseline complete. Endline data in Uttar Pradesh available roughly fall 2019. Prior randomized controlled trial /efficacy studies by ETZ Zurich/St Johns Research Institute and Cornell on DFS formed basis of the decision to scale up.	12 months of uninterrupted supply is required before end line; program was paused during change in government.
3.1 A comprehensive, cost effective solution developed and disseminated to inform public policy for large scale implementation of DFS delivery on a sustained basis	Completed	Disseminated, and fit for purpose, as program has already spread.	UP ongoing to 10 districts (to 15+M people), and wishes to scale up to full state, Jharkhand gov't commenced statewide (20+M people). MP gov't commenced to to~10 million people.

Milestone	Achievement	Evidence/Indicator	Comments
4.1 At least 2 salt manufacturers with sufficient capacity to produce and supply DFS at scale with total capacity of 100,000 tons of DFS per year created	Completed and exceeded	~10 salt processing plants equipped to produce DFS, with total capacity of ~500k tons/year.	Premix capacity also established. Total capacity sufficient to supply DFS to approximately 100 million people continuously.
5.1 At least 2-3 publishable articles and scientific manuscripts developed and/or submitted for peer-reviewed journals.	Completed and exceeded	5 articles published in peer-reviewed academic journals. 4 more in various stages of publication.	
5.2 End of Project conference/workshop to disseminate project results (including report on all outputs and outcomes), highlighting key recommendations and options to inform public policy for large scale implementation of DFS delivery on a sustained basis scaling up in India and other nations	Completed	Workshop held at Habitat Centre in Delhi, June 7, 2018.	June 8, 2018 made field visit to UP – to see warehouses, stores, and consumers/homes, and June 9, 2018 made field visit to premix production plant in Jaipur.

4. Synthesis of Research Results and Development Outcomes

4.1 Objective 1: Scale up the production, distribution and consumption of Double Fortified Salt

Main Research Activities and Results during the Reporting Period

In sum, this project moved from the lab to over 50 million people within three years. Upon the commencement of the grant period in November 2015, double fortified salt was in the later stages of lab development and was not in industrial production. In 2018, at its apex, over 50 million people have used DFS.[9] As for production, at the close of the grant period in mid 2018, production capacity sufficient to meet the daily needs of nearly 100 million people had been created. To date, over 60 million 1 kg bags have been produced and distributed to consumers via the PDS system.

Along the way, a myriad of challenges were solved and goals were achieved.

Production

To initiate production, the technology for producing the encapsulated ferrous fumarate iron premix was transferred from the University of Toronto to JVS Foods in Jaipur. No license or intellectual property fee was charged by U of T/ NIS for providing the DFS technology to JVS for use in government programs in Uttar Pradesh, a practice that has continued for government programs in Jharkhand and Madhya Pradesh as well. At some point in the future, to promote the economic sustainability of the work, a license fee may be charged, particularly to private sector entities providing DFS into commercial channels.

A full-scale commercial premix plant was built from scratch during the project and commissioned in Sep 2016, with a production capacity of 2 tons/day, and 600 tons/year. This is sufficient premix to create 120,000 tons of DFS/year, or twice the annual requirement of the project area covering the 10 districts.

To achieve this, several intermediate steps were required. Producing at lab scale (here, 1 kg) is very different from producing at pilot scale (100kg), or industrial scale (1000+ kg). At JVS, under U of T direction, pilot trials were conducted to improve the quality and physical characteristics of the premix at optimum cost. A new and better premix with improved shape, size, colour, surface morphology, and durability was developed, keeping the same composition but reducing production cost. Capacity was then scaled up from pilot to industrial scale. This all required intense interaction between industry and academics who have a production orientation – Professor Diosady at the U of T, in addition to being an academic has been a practicing professional engineer, a rare combination of skills. JVS invested significant amounts of its own time and funds (valued at INR 92.5 million - CAD 1.85 million), and even developed production equipment for this project. The JVS premix plant now has a production capacity of 1500 tons per year of premix, sufficient to create 300,000 tons (or 300

[9] Note that at the time of writing, Jharkhand State has suspended its program, which makes the total current DFS coverage approximately 25+m people, across UP and MP. Jharkhand is considering re-commencing its program. Other states are considering commencing as well. At the time of this writing, the chief minister of Karnataka announced that the state of Karnataka wishes to supply DFS as well through its PDS. "Less Rice, More Toor," *The Hindu*, July 6, 2018. https://www.thehindu.com/todays-paper/tp-national/tp-karnataka/less-rice-more-toor/article24345076.ece

million 1 kg bags) of DFS, which is sufficient to meet the annual DFS requirements of some 100 million people. Doubling that capacity is now in the works.

The premix produced by JVS was sold to designated salt processing companies selected through competitive bidding by the UP Government. The Project has been providing technical support at no charge to salt processors who wish to produce DFS. Nearly 10 processors across the country with a collective production capacity of nearly 500,000 tons now have DFS production capacity.

Distribution

The production and distribution of DFS has been promoted by the Government of India as a public health measure to address iron and iodine deficiencies. The Food Safety & Standards Authority of India (FSSAI) has drafted a national technical standard for DFS production to be issued shortly. At the State level, distribution of DFS through the PDS is predicated upon by the decision by the state government to include it in the list of commodities offered through fair price shops. Usually such commodities are procured and sold at subsidized prices – it therefore entails a financial commitment by the Government. In Uttar Pradesh, after a cabinet level process in which the ministries of health and food and civil supplies participated, in a novel collaboration, the state government authorized:

a) The inclusion of DFS, a novel product, into the state's Public Distribution System, which previously did not have salt at all, and which very rarely adds new products, thereby allowing it to reach low-income consumers through the PDS network of thousands of small "Fair Price Shops"

b) A financial sum of approximately CAD $10 million per year for two years to subsidize the price of DFS, making it 30-60% cheaper than the market price of iodised salt (a consumer price of Rs 3/kg[10] of DFS for the lowest income segment of consumers, and Rs 6/kg of DFS for others).

c) The DFS intervention to take place in the 10 districts recording the highest anemia prevalence in the state, (61.3% - 80.1% anemia in children under 5 years and 51.8% - 68% in women of reproductive age as per the latest district level National Family Health Survey). These districts, though geographically dispersed, were considered the highest in need of intervention

d) Purchase and procurement via public tender of the requisite quantities of DFS

The acquisition and distribution of DFS at scale in UP commenced in January 2017 has been ongoing, but for an interruption due to elections and a change in leadership in the state government. Fortunately, the DFS program, which was launched and closely associated with the prior government- indeed, the packets of salt featured the name of the governing political party - was continued, after an incredible manual process of blacking out the party's name by marker on millions of bags of salt. The successor government continued the program with a more neutral label on the packets of salt, featuring neither a party name nor symbol but rather simply the generic name of the product: Double Fortified Salt, as well as the name of the Government of Uttar Pradesh.

[10] 1 CAD = INR 50 (approximately)

Further, two additional states in northern India – Jharkhand and Madhya Pradesh, looking at the UP experience, have commenced programmes to procure EFF-DFS and distribute it via their public distribution systems. The Madhya Pradesh program covers approximately 10 million people across 89 blocks (dispersed across the State and covering severely malnourished tribal populations) commenced in January 2018 and is ongoing. The Jharkhand program is statewide, for approximately 30 million people. It commenced in September 2017 but was been suspended in March 2018, after a viral video circulated on social media claiming that the DFS was not soluble in water as it should have been (in fact standard salt is not soluble at that level either); the expectation is that the program will be recommenced shortly. Multiple other states, as well as the remainders of UP and MP, are considering following the model of this project. Pulling back, it is notable that Indian states, which are like countries in terms of their population size, are adopting DFS, sometimes accompanied by public statements by their chief ministers (e.g. UP, Jharkhand, Karnataka), who may be considered as the equivalents of heads of state, promoting the distribution and use of the product. This brings much recognition to the intervention.

Consumption

While DFS in this project has been consumed by the whole family, individual and family consumption of DFS is largely driven by women. Women are the holders of the ration cards, and the primary purchasers at the fair price shops. Cooking in the homes in the intervention districts is largely performed by women. Health advice and clarifications regarding the product are frequently addressed to the local ASHA health workers, who are all women.

Exceeding the project target of 10 million people, over 15 million people in the 10 districts in Uttar Pradesh have been consuming DFS regularly. This figure has been determined and cross verified in several ways:

1. First, the total population in the 10 districts is about 24 million people. Nearly 90% of the households in the target districts hold ration cards, making them eligible to purchase state-provided supplies via the PDS. In the 10 districts there are approximately 4.6 million card holders (1 card per household). Sufficient stocks to supply each of these households has been purchased by the government and distributed to warehouses and in turn to the fair price shops. Spot checks by the project team has shown that the DFS has been received by the warehouses and the fair price shops and the households. While there is generally a significant problem with "leakage" from the PDS system, it does not appear to have been an issue here. It is common knowledge that high value commodities such as rice and wheat are illicitly diverted from the PDS government program and sold at a higher price on the open market. Rice or wheat earmarked to be sold to consumers at Rs 1 kg in the PDS system can be sold for more than Rs 20 kg on the open market. Here, however, as the salt is a relatively low value commodity, and provided in much smaller volumes, it appears that the economic potential for diversion is more limited, and in any case, even if it were diverted, it would likely be consumed within the high anemia district rather than shipped far away, improving overall population health.

2. Second, the fair price shops have been reporting in interviews with project field monitors essentially 100% consumer offtake of the salt, with the store's supplies being completely exhausted at the end of each month. Consumers have found the product acceptable, and it is priced very reasonably, below market price. The digitization of the PDS system (now under way) will a) provide the project with digital data on household level purchases of DFS, and b) allow for the sending of audio or text messages about DFS to consumers on their mobile phones.

3. Third, spot checks of households by the district coordinators in the project team have shown that the DFS is indeed being used, and in fact repurchased.

4. Fourth, in the end line studies, households will be surveyed and inspected to assess if they have been using the DFS.

Results on a) Scaling up of the most successful innovations and b) Research on testing scaling up models and/or approaches

DFS as noted has reached tens of millions of people across three states. Embodied within this scale-up are several innovations at once:

1. Product – Technology for encapsulating ferrous fumarate developed in Canada; transferred to an Indian Company and commercial scale capacity for premix production created with several production innovations. Leading salt processors have retrofitted their plants to manufacture DFS at scale, creating almost 500,000 Tons of DFS production capacity within two years.

2. Distribution - Adding a brand-new product with health benefits to the PDS is a first in several decades, reaching targeted consumers through all meals. Procurement by UP Department of Food & Civil Supplies through open tender; Winning bidders supply DFS directly to retail stores – reaching 50+ million in 3 states.

3. Demand – Strong Government backing at the Central and State levels helping create awareness of and demand for a new product; Incentivized sales push to ensure high coverage in a targeted manner Inclusion of key stakeholders at grass-roots level for education and communication.

4. Training of Accredited Social Health Activists (ASHA) and Fair Price Shop (FPS) owners

In brief, the product has moved rapidly through the innovation cycle - from invention to pilot to large scale adoption. The scaling up is still in its relatively early stages, with fragile state programs that are prone to interruption for a variety of causes, but the progress has been promising.

Several papers related to the research on testing scaling up on the project been published or are being prepared. These include papers on laboratory work and consumer studies. One common theme is for the scale-up research has been to "design backwards from scale." By this we mean that the desired mass distribution method - via the vehicle of iodised salt – was kept in mind from the start. This is arguably crucial in development, where market signals are weak, and one cannot assume that the erstwhile invisible hand of the market will take things to scale. Here, using iodised salt, which reaches 5 billion people daily worldwide, as a vehicle was crucial. Additionally, the team attempted to make the DFS as organoleptically (i.e. across all senses) equivalent to standard iodized salt as possible, to

encourage uptake. Further, when the team considered the various possible distribution channels, which included multiple government channels and multiple private channels, PDS was chosen as the most appropriate and effective mechanism. Other Government programs do not reach the whole family and provide only a few meals per week. The Mid Day Meals programs reach only schoolchildren, for only one meal a day during the school year, and ICDS provides but a single snack to preschool children on weekdays only. For fortification programs to be successful and deliver a meaningful quantity of nutrients versus the recommended daily nutritional intake, the nutrients need to be consumed regularly and consistently. Further, by focusing on staple food fortification in the first place, in which nutrients ideally fit seamlessly and automatically with foods eaten every day, rather than focusing on tablet or powders and tablets and other means (which are complementary strategies with value in their own right), scale and adoption at a population level were easier to achieve.

Figure 1

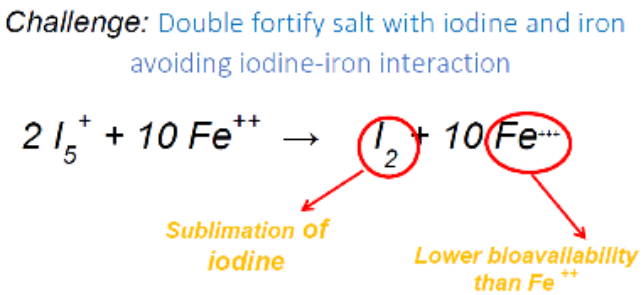


Figure 2

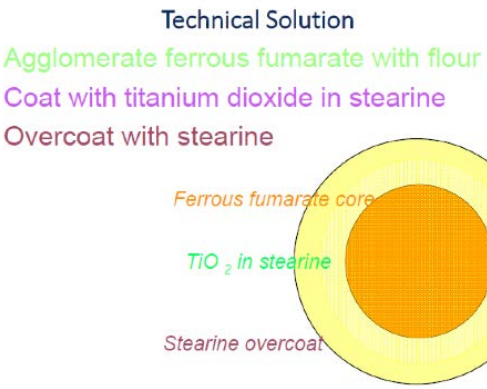
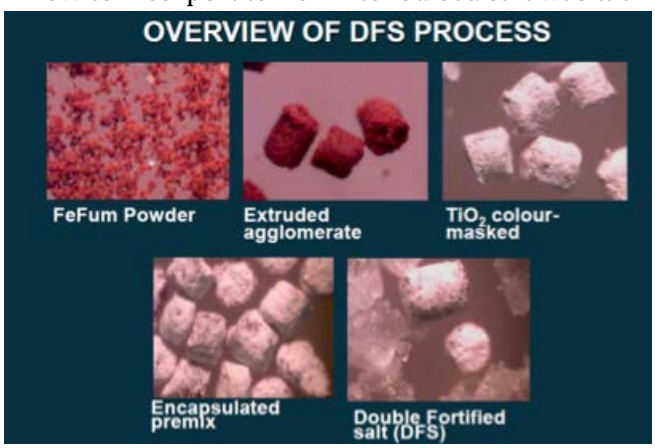


Figure 3

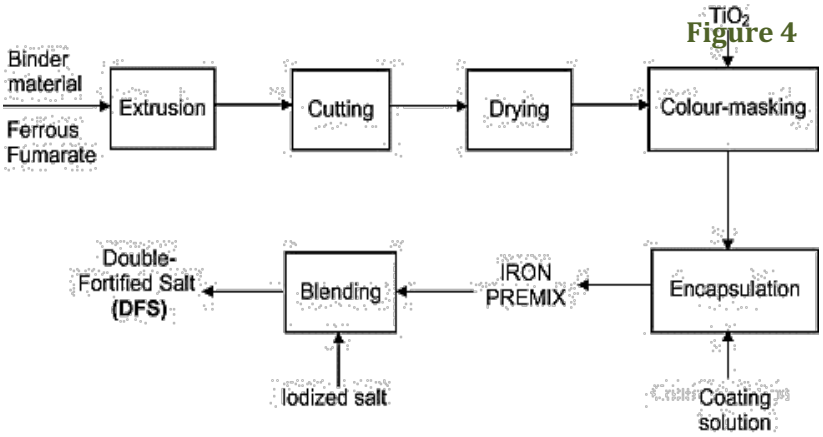


4.2 Objective 2: Test models and approaches to optimize the technology and production processes for consumer acceptance and nutritional impact

Achieving impact requires careful design and iteration. Often projects are driven by a scientist's or technologist's brainwave, and do not mesh with social systems and conditions and needs on the ground. Here, the team was inspired at the outset by the distribution vehicle (namely that of iodised salt), and attempted to design an intervention with the consumer, the iodised salt infrastructure, and health impact in mind. At the University of Toronto, the basic technological challenge of how to incorporate iron into iodised salt was tackled. The problem was that, left to themselves, iron and iodine interact. The iodine sublimates and evaporates, the iron becomes less bioavailable, and the salt turns black and has a metallic taste (Figure 1). The problem was solved, as shown in Figure 2, Figure 3, and Figure 4, by microencapsulating the iron, colouring it white so that the granule more closely resembled a grain of salt, and making the granule strong enough to survive shipping and storage, and yet not so strong that it passed through the body without breaking down to release the iron. This work largely took place prior to the

CIFSRF grant, but was further developed in this project.

Figure 4



4.2.1 Production

The team at the U of Toronto then sought to optimize EFF for use in large scale production. Various refinements were made to the premix to further reduce its production cost. Stability tests were conducted for the nutrients under varying conditions to assure that the nutrient levels and consumer acceptability would persist over time. Changes were made to account for the versions of the specified raw materials available in India. (Standard Operating procedures for Premix production and DFS Plant Operation Manuals along with Quality Control Manuals were prepared and shared with the Premix manufacturer as well as DFS producing companies (Annex 2.1 – 2.3).

The U of T team then collaborated with JVS. JVS and the U of T group refined the product from a cost, production, and consumer perspective, and took it to pilot and industrial scale. JVS built production facilities (Figure 5) sufficient to generate 5 tons of premix per day. JVS met standards and obtained the necessary production licenses from the Food Safety and Standards Authority of India.

Figure 5

4.2.2 Efficacy

Efficacy studies were conducted prior to this project but are worth mentioning briefly as they were the basis of this scale-up effort. These randomized controlled trials, rare in the nutrition space, showed that the encapsulated ferrous fumarate ("EFF") formulation of DFS was efficacious in reducing anemia in children (Bangalore/ETH Zurich- SJRI), and in decreasing iron deficiency among women tea pickers (Darjeeling/Cornell). The efficacy studies had aspects of effectiveness studies, in that the people involved used DFS in their homes as part of their daily life. In the Bangalore study, the prevalence of anemia declined among children ages 5-15 by 67% (from 15.1% to 5.0%) in 9 months. In the Darjeeling study among women ages 18-55, there were substantial improvements in hemoglobin, ferritin, sTfR, and body iron concentrations, with a reduction in the prevalence of iron deficiency from 23% to 9%.

4.2.3 Consumer Acceptability and Sensory Studies

Figure 6

The University of Delhi Institute for Home Sciences conducted numerous consumer tests to evaluate the acceptability of the DFS vis a vis Iodized Salt (IS) in daily food preparations by consumers in Delhi. The results of the studies are presented in Annex 3.1

Feedback on the dishes prepared using DFS and IS in the community revealed that 52.8% of the DFS group and 77.3% of the IS group found no difference in the cooked dishes as compared to their usually consumed salt brand. 13.2% of the DFS group reported a slight discolouration, 1.9% a poorer taste, and 17% some grittiness in a few food products. In view of the health benefits of consuming DFS, over 85% of the women were ready to use the salt in their daily cooking. Hence, one can infer that the overall acceptability of DFS in commonly cooked foods in the household was high.

In a second test, a panel of 24 experts and consumers were presented with 11 dishes prepared with DFS and with iodised salt ("IS")(see, e.g. Figure 6). The dishes were evaluated using a five-point Hedonic Scale based on appearance, colour, taste, texture and mouthfeel. All the panelists evaluated the dishes prepared as satisfactory to excellent. All panelists found all 24 dishes acceptable in a formal blinded test, with ratings ranging from satisfactory to excellent. Some preparations of DFS scored lower due to the presence of some specks, grittiness or a slightly darker colour being imparted to the preparation. However, none of the dishes were deemed unacceptable.

Overall, it was observed that dishes prepared using high heat methods (boiling, pressure cooking) and DFS were darker in colour than the ones using IS. There was a slight change in colour in dishes using DFS prepared using moderate heat methods (sautéing), which was often overlooked. However, there was no visible difference in colour of dishes prepared using no heat like cold beverages, curd preparations (raita), salads and cut fruits. Per the study design, any differences were noticed when DFS preparations were compared side by side with IS preparations; they may not have otherwise been noticeable.

Notwithstanding the observations of a minority of consumers, overall the Double Fortified Salt with microencapsulated ferrous fumarate (at levels close to iodized salt that is currently used) was found to be acceptable during laboratory sensory trials as well as community-based field trials and hence could be an effective vehicle to provide iron to the community.

4.2.4 Consumer Awareness and Attitudes

An additional set of consumer research - into consumer awareness and attitudes towards both anemia and DFS - was conducted by Barometer Research and its founder Hema Viswanathan. Viswanathan is a pioneer in the field of rural consumer market research in India. The study took place in Jharkhand state, where government approvals were more forthcoming. The results of the studies are presented in Annex 3.2.

The Barometer study consisted in part of 9 focus groups, with DFS samples being left for household use, and 30 follow up interviews about the DFS use. Regarding the acceptability of DFS, 25 of 30 households found it totally acceptable and continued using it. Five households did not continue using it, saying that they had used this salt before and that it would turn the food black. (The context here

was a major factor. There had been a prior DFS used in Jharkhand PDS with a different (unencapsulated ferrous sulphate) formulation. That program was discontinued due to widespread consumer complaints – the salt was widely reported to turn yellow or blue in the pack and to turn the food black; this coloured the current users' experience).

The Barometer study also included 1137 structured interviews measuring the extent to which anemia was understood and the concept of DFS would be accepted. Regarding anemia, over 54% of respondents recognized or understood the concept of anemia or *khoon ki kami* ("weakness of blood"). Most said anemia was characterized by weakness (80%), and treatment was strongly linked with iron tablets (79%). The English word "iron" was known widely. As for messaging and communications, which are still at a nascent stage in this process, it seemed that direct and interpersonal communication would be the most appropriate strategy, as opposed to mass media/mobile, (which still have limited impact).

Additional, albeit anecdotal, evidence regarding consumer acceptability has been gathered by the project team's 10 district coordinators in UP, who travel regularly across the district and perform regular home visits. Customers have been repurchasing the salt and found it acceptable; the PDS consumer hotline, which registers many complaints, has had essentially none about DFS quality. The rollout to ~15+ million people in Uttar Pradesh, 10+ million in Madhya Pradesh, and 25+ million in Jharkhand, has thus far seemed acceptable to consumers, with minimal complaints. Some have initially objected to darkened colour in cooked foods, but then dropped their objections after DFS and its iron content and health effects were explained to them. Iron is naturally prone to darken cooked foods slightly, such as when cooking in an iron vessel. This underscored the importance of having the education/awareness efforts in place right from the beginning.

4.2.5 Health Impact Studies

Major effectiveness studies are being conducted to evaluate the biomedical impact of DFS at a population level of millions of people. The studies will examine how the intervention performs in real life conditions. Such studies are rare; even pharmaceutical trials often stop at efficacy. Baselines have been completed in UP (funded by CIFSRF and BMGF) and in Jharkhand (funded by CIFSRF). The end lines, which can only be completed after 12 months of continuous intervention, await. These studies will examine health impact at a population scale, using statistical sampling, blood draws, and sophisticated testing for hemoglobin and other parameters, with the districts with no DFS interventions being used as controls. The protocol for nutritional impact evaluation in brief is as follows:

1. Impact evaluation on non-pregnant women aged 18 to 45 years through a quasi-randomized controlled trial
2. Non-pregnant women chosen as they are currently not provided with iron supplements
3. Comparison of prevalence of anemia at baseline at commencement of the roll out of the salt programme through the PDS and at end line at 18 months between 5 intervention (DFS) and 5 control districts through a longitudinal study

The results of the baseline surveys in the two States are summarized below.

Uttar Pradesh

In January 2016, the Bill and Melinda Gates Foundation (through the Global Alliance for Improved Nutrition, Geneva) announced support for the evaluation of the impact of the DFS intervention to

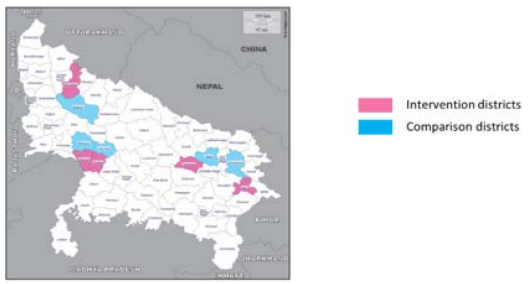
complement the evaluation currently planned under the CIFSRF project. Thus, the following was planned:

1. A state-wide survey in UP of mothers and children 6 months to 5 years of age to evaluate the prevalence of micronutrient deficiencies and their determinants funded solely by BMGF; and

2. A baseline survey with 2 objectives:
   a) The first objective, funded by CIFSRF, was to evaluate the impact of DFS delivered through PDS in UP on anemia prevalence in non-pregnant women
   b) The second objective, funded by BMGF, was to assess the need for and feasibility of a more comprehensive impact evaluation for the DFS project, based on the prevalence of iron deficiency and the reach and utilization of the PDS system by those at risk of iron deficiency.

Figure 7

DFS Survey districts: baseline evaluation



Source: SJRI analysis

The BMGF funded study was conducted across 25 districts which included 5 of the randomly selected districts where DFS was being rolled out through the PDS and 5 where it was not be rolled out to serve as the control districts for the impact evaluation study. Across the 25 districts, 1284 women in reproductive age group (WRA) with children under-five years of age and their pre-school child (PSC) in the state of UP with representation at state and rural/urban levels were surveyed to determine the prevalence of nutritional problems and their determinants.

As the UP government proposed to roll out DFS through the PDS in 10 districts, 5 districts were randomly selected along with 5 control districts where DFS was not rolled out. These districts are highlighted in Figure 7. The intervention districts selected were Moradabad, Etawah, Auraiya, Mau and Faizabad. The 5 adjacent control districts chosen were Budaun, Mainpuri, Kannauj, Gorakhpur and Basti. In the 10 selected intervention and control districts the baseline survey on iron status and iron deficiency was completed and provided the basis for the more comprehensive impact evaluation to move forward, based on need and potential for impact. It also provided the critical information needed for the final design of that evaluation. Key findings:

1. 70-80% of households purchased their requirements of rice, wheat, sugar and kerosene from fair price shops on a regular basis
2. 91% of women with iron deficiency have access to the PDS (are cardholders or are on the registered list)
3. 53.1% of children under 5-years old were anemic of whom 68.1 % had low iron stores; In addition, 13.4% of non-anemic children had low iron stores
4. 36% of women of reproductive age were anemic of whom 62.7 % had low iron stores. In addition, 14.7% of non-anemic women had low iron stores.
5. Iron deficiency was therefore a primary cause of anemia in those populations.

Jharkhand/Bihar

1. 3 districts each in Jharkhand (intervention state) & Bihar (control) were randomly chosen.
2. The control state chosen is an adjacent state with similar population characteristics.
3. The Baseline survey among women of reproductive age in Jharkhand revealed that 72.3% of women were anemic of whom 41.6% had low iron stores. Additionally, among non-anemic women 5.4% had low iron stores. Baseline survey in the control districts in Bihar is pending State Government approval

Conclusions from Baseline Surveys (among women of reproductive age)

1. Anemia prevalence is very high in Jharkhand (72.3%)
2. Prevalence of iron deficiency anemia is high in UP (62.7%)
3. Risk of deficient intakes is high in both UP and Jharkhand (84.4% in UP and 95.5% in Jharkhand)
4. Moving ahead: UP – DFS end line to commence in 2019; Jharkhand: still need to complete of survey of control state (Bihar). End line evaluation will take place only after resumption of distribution and uninterrupted consumption for minimum 12-month period.

Results on a) Scaling up of the most successful innovations and b) Research on testing scaling up models and/or approaches

As noted above, the DFS coverage has reached tens of millions of people. The infrastructure to perform a large scale a health impact research study across such a large scale has been put in place, with baselines completed. There have been trade-offs in cost versus looks—a more expensive iron premix granule is whiter and more similar to a grain of salt, and the team has experimented with a few and made its best estimations. The version being produced now has not been pure white but has been acceptable to consumers and has been more viable economically for the producers.

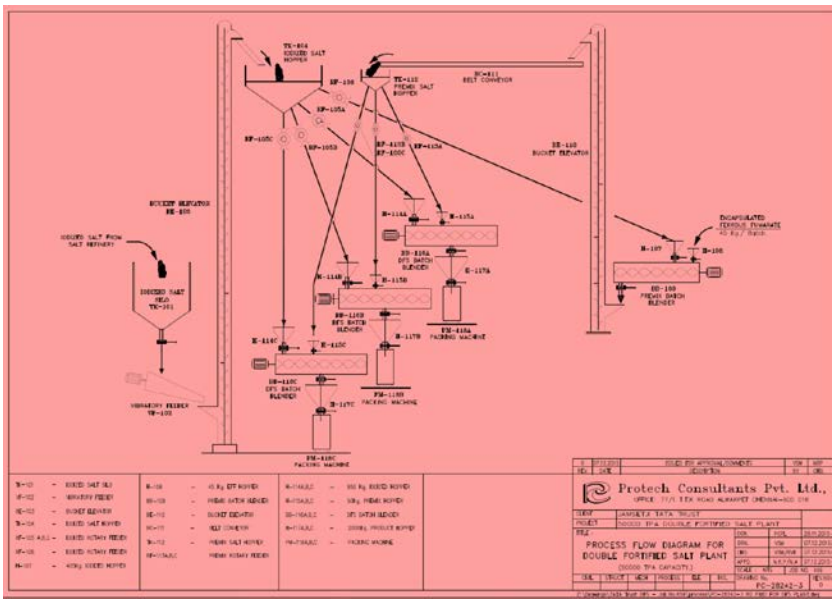
4.3 Objective 3: Inform decision makers, actively promote and target Double Fortified Salt to salt processors and consumers

Main Research Activities and Results during the project period

The information concerning DFS available to decision makers was evidently quite effective, as the senior policy makers in the state governments of UP, MP, and Jharkhand decided to implement large scale DFS programs, with the latter two states following UP's example of implementing EFF DFS through the PDS. The UP DFS program also survived a change of government in UP, even though it had been explicitly associated with the prior ruling political party.

Salt processors in the principal salt producing regions of the country viz., Gujarat, Rajasthan and Tamil Nadu, have been made aware of DFS, and in fact several of them have retrofitted their production facilities to add DFS capacity, with technical assistance from the project team, including technical specifications and drawings (Figure 8 below). Additionally, large national brands are carrying out internal testing of DFS samples.

Figure 8
DFS Blending System: Process Flow Sheet



The broadly applicable lessons here might be that governments might often wish to be of help to their citizenry on major problems, but need concrete ideas and avenues for doing so. Governments are particularly interested in inexpensive programs that can reach many people and add to their political capital. Additionally, making robust scientific evidence available is essential, particularly given the need for the programs to be designed correctly and to work.

Further, information about DFS has been presented at several public fora. These include:

1. A plenary session entitled "Role of Double Fortified Salt in reducing IDD and Anaemia - Sharing experiences from Uttar Pradesh" was convened during the 62nd National Conference of the Indian Public Health Association held in Lucknow from 9-11 February 2018. The theme of the Conference was on "Innovations in Health Care- Reaching the Unreached". The Conference was attended by more than 1000 public health specialists and physicians from across the country.[11] A DFS Policy Brief (Annex 1) was prepared and distributed at the meeting. The Brief has since been shared widely with Government policy makers at the Central and State Government levels.

2. A National Consultation on Anemia was organized by the All India Institute of Medical Sciences New Delhi jointly with the Ministry of Health & Family Welfare Government of India in 2018. The meeting attended by about 50 leading experts in the country from research institutions, central and state governments and non-governmental organizations reviewed the status of anemia in the country and current protocols for supplementation of different target groups. The meeting also highlighted the progress on Double Fortification of Salt. All the background papers prepared for the Consultation were published in a Special Supplement to the Indian Journal of Community Health Apr 2018, which included a paper entitled "Double Fortified Salt Coverage, Efficacy and Way Forward" by M. G. Venkatesh Mannar and J.K. Raman. The Consultation concurred that "…a daily intake of 10 grams of DFS provides an additional 10 mg of elemental iron to the dietary intake and DFS therefore has the potential to increase the daily intake of iron and contribute to reducing the existing gap of dietary iron intake in comparison to the recommended dietary allowance (RDA)…." The

[11] Following opening remarks by Dr Anindya Chatterjee, Regional Director Asia, International Development Research Centre, Canada, there were presentations on the "Development, Scale Up and Application of Technology for Double Fortification of Salt in India". By M.G. Venkatesh Mannar, U of Toronto, "Trends in Prevalence of Anemia and Iron Deficiency in India, efficacy study on EEF and Baseline survey in Uttar Pradesh" by Sumathi Swaminathan, St Johns Research Institute, Bengaluru and "Programming DFS in Uttar Pradesh through the Public Distribution System" by J.K. Raman, The India Nutrition Initiative.

recommendations of the Consultation are expected to be favourably reviewed and adopted by the Government of India for revisions to existing policy and program guidance related to the prevention and treatment of anemia.

Prior presentations and meetings on DFS include:

1. One day forum on DFS, convened by the national Department of Biotechnology, Venkatesh Mannar, Delhi, 2016
2. University of Toronto Convocation, June 2016 (Venkatesh Mannar)
3. Brown University Club of New York City, Jaykumar Menon, New York, March 2017
4. Spotlight on Nutrition, World Bank, Ratan Tata (chair of Tata Trusts), touching briefly on DFS, Washington, DC, April 2017
5. Sage Bionetworks open science conferences, Jaykumar Menon, Seattle, April 2017, April 2018
6. Entrepreneurship conferences in Silicon Valley: TiE (The Indus Entrepreneurs) annual conference; OPEN (Organization of Pakistani Entrepreneurs) annual conference; Brown University Club of Silicon Valley, Jaykumar Menon, May 2017
7. DFS stakeholder meeting convened by the Food Safety and Standards Authority of India (FSSAI) - with salt companies, government, research institutions and NGOs. Delhi, May 8, 2017
8. World Health Assembly in Geneva, Switzerland, Venkatesh Mannar (by video), May 2018
9. Regular presentations to the Tata Trusts in Mumbai and Delhi, by JK Raman, Venkatesh Mannar and Jaykumar Menon
10. Regular presentations to and discussions with the Gates Foundation and BGC3 in Seattle, Jaykumar Menon and Venkatesh Mannar

Figure 9

Information to consumers regarding DFS has been communicated in several ways, including via large signs dedicated to DFS on the walls of the PDS shops (aka Fair Price Shops) in Uttar Pradesh; the shops have no other large signs. While not all the shops have such signs, the government's plan is for 100% coverage. Additionally, over 10,000 ASHAs (village level health workers) have received a one-day training on DFS. Further, multiple presentations have been held in villages and local jurisdictions by the project's district coordinators.

The mass public communications efforts are still minimal, due largely to a lack of funding. The state government's budget is from its Food and Civil Supplies department, which does not do much promotion. And there are several hurdles to doing publicity in conjunction with a government program. As a result, knowledge on the ground amongst consumers of DFS still needs to be vastly improved. There have been some notable efforts however. These include a remarkable promotional flyer issued by the government in Jharkhand in 2018 featuring photos of the state chief minister and the national prime minister, as pictured in Figure 9, making a statement to the general public that the very highest figures in government were behind DFS.

As noted, a digital marketing campaign to send voice messages to consumers mobile phones regarding DFS is in the works with the UP government, which is starting to digitize its PDS. Further,

the national government's Food Safety and Standards Authority is in the process of issuing a circular on the basics of DFS.

In sum, information on DFS has been disseminated to and by government, and to and from commercial producers and consumers. Having the national and state governments on board with the project has been tremendously important.

Results on a) Scaling up of the most successful innovations and b) Research on testing scaling up models and/or approaches

The Barometer study provided valuable information on consumer awareness that could inform future communications campaigns. Additionally, national private sector brands, supported by this team, are conducting internal technical testing of DFS, with an eye on distribution through commercial channels.

4.4 Objective 4: Ensure sustainable Double Fortified Salt production and distribution capabilities of local stakeholders

The JVS iron premix plant in Jaipur as noted is fully operational, with capacity sufficient to supply the annual needs of nearly 100 million people, and expansions in the works. Additionally, the project team retrofitted salt processors in Rajasthan and Gujarat to take the premix and produce DFS, and other processors have been implementing on their own. If states continue to procure and subsidise DFS for their programs, the project should be economically sustainable, at least for the private sector producers.

Concerning distribution, as noted, three states have set up large scale DFS programs. Multiple other states are considering adding DFS to their PDS, as are UP and MP for the remainder of their states. Once commodities become integrated within public distribution programs, they historically persist for decades.

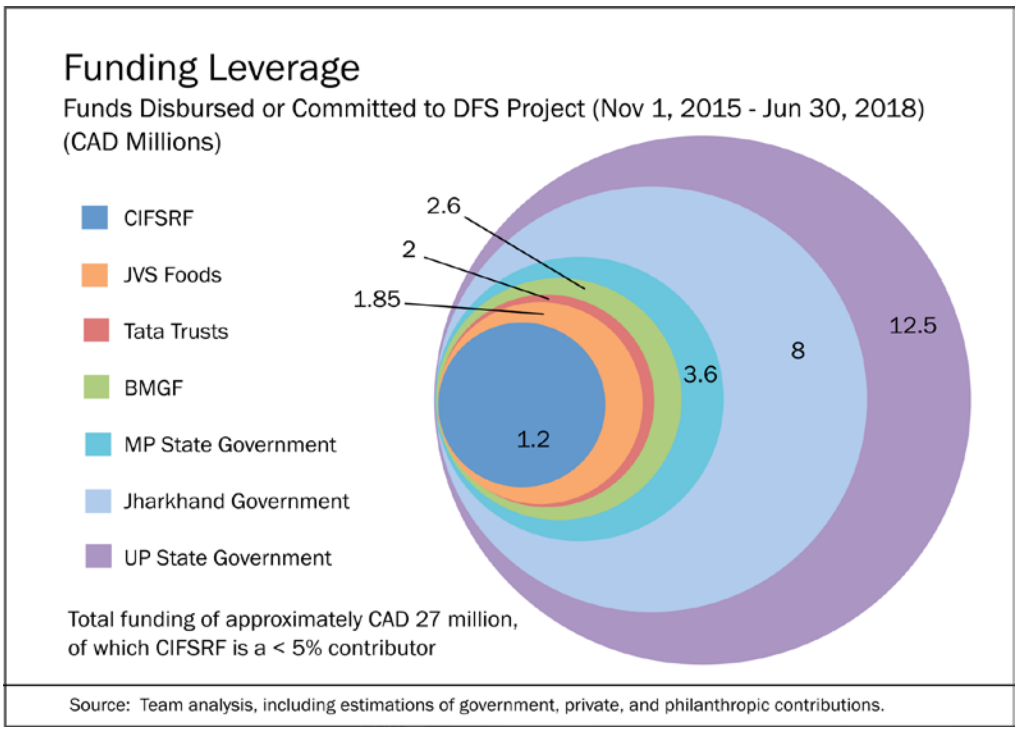
Governments/ruling parties appear to be using DFS as a selling point. Somewhat in tension with what might be needed from a purely economic standpoint, they are subsidizing not just the fortificant but the cost of the salt itself, so that DFS is available to the consumer at a price far below the private market price for iodised salt.

The above information concerns government programs, which were selected for their ability to reach huge numbers of low-income people very quickly. Private sector programs are still nascent. National brands are conducting internal testing of EFF DFS. Another commercial player- a large producer but not well known brandwise - has launched EFF DFS in a small way this year into private markets.

Economists at SJRI are estimating the economic impact of DFS use. Through the modelling of wages, iron intake, and anemia and simulation with salt intake (DFS), they expect to calculate the benefit-cost ratio for DFS as well as disability-adjusted life years (DALY's) for anemia (No. of DALY's saved through consumption of DFS). The report is expected shortly.

Additionally, if we consider sustainability in the sense of financial leverage, it has been considerable. Figure 10 below illustrates the financial leverage – here meaning funds disbursed by or committed by parties other than CIFSRF to the DFS project during the CIFSFR grant period itself.

Figure 10



Results on a) Scaling up of the most successful innovations and b) Research on testing scaling up models and/or approaches

Concerning results on scaling up, the premix developed at U of T and refined at JVS can now be produced in quantities sufficiently to supply DFS to nearly 100 million people annually. Regarding research on testing scale up models, the PDS DFS distribution approach that has been tested in this project appears to be spreading. The results of the end line surveys however will be key.

4.5 Cross-cutting comments, for all objectives

4.5.1 Unexpected, Surprising, or Innovative Results

Several results were unexpected in this project. These include:

1. The level of awareness among consumers of anemia, and of iron deficiency as a cause of it, was higher than we would have predicted.
2. The enthusiasm of states for roll-out of DFS via PDS was higher than expected. Two additional states (MP and Jharkhand) commenced large DFS programs before the end of the grant period.
3. UP and MP (post its commencement) expressed interest in expanding their DFS programs to their entire states (the total population of UP is ~205M, and of MP is ~83M), also before the end of the grant period.

The newer states have not waited for the end-line results of the UP effectiveness study. They are presumably working from the prior DFS efficacy (or more precisely, hybrid efficacy/effectiveness) trials by ETH-Zurich/St Johns and Cornell. All three states (MP, JH, UP) subsidized not just the fortificant but the cost of the salt itself, making DFS much cheaper than the market price of iodized salt. This likely has increased take-up; field reports show that essentially 100% of the DFS stocks in the stores are being bought each month by consumers. The team thought that perhaps just the fortificant would be subsidized, but the governments took their own decisions.

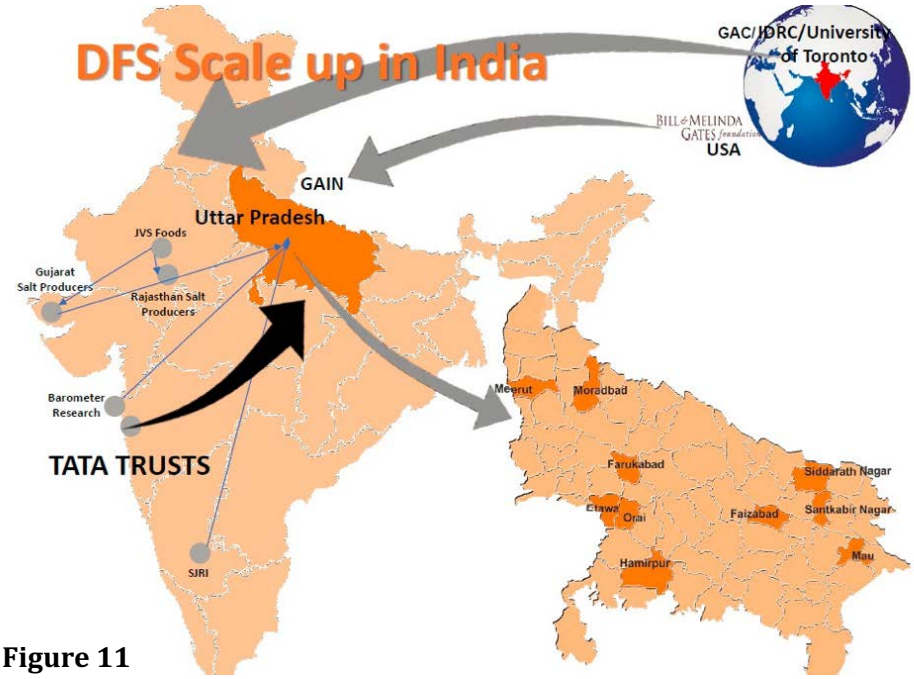


Figure 11

We infer the states may perceive political value in a broad spectrum anti-malnutrition program. Combatting malnutrition at large scale, and providing inexpensive products to the citizenry at large, may be beneficial to their party and government.

Malnutrition, and particularly iron deficiency and anemia, has been one of the most intractable and widespread problems in India and the region, especially for women, and has moved up on the political agenda. For example, there is now for the first time a formal national nutrition mission in the country, with among other things plans to add a new person dedicated to nutrition in every district. The coming months are an advantageous time to move forward on nutrition.

The DFS was not organoleptically identical to iodized salt but was nonetheless acceptable. The premix retained a slight dark gray colour visible on close inspection. A purer white premix was more expensive to produce, and would not be perfectly indistinguishable in any case, even in the lab. Further, some foods were slightly darkened in cooking. But nonetheless, the DFS proved acceptable to consumers, per formal tests and field reports.

As illustrated in Figure 11, this is a sprawling project, spanning multiple countries (India, Canada, US), funders (CIFSRF, the Governments of UP, MP, and Jharkhand, Tata Trusts, and BMGF), partners, regulators, jurisdictions, and disciplines. It could well have fallen apart under its own complexity, but did not.

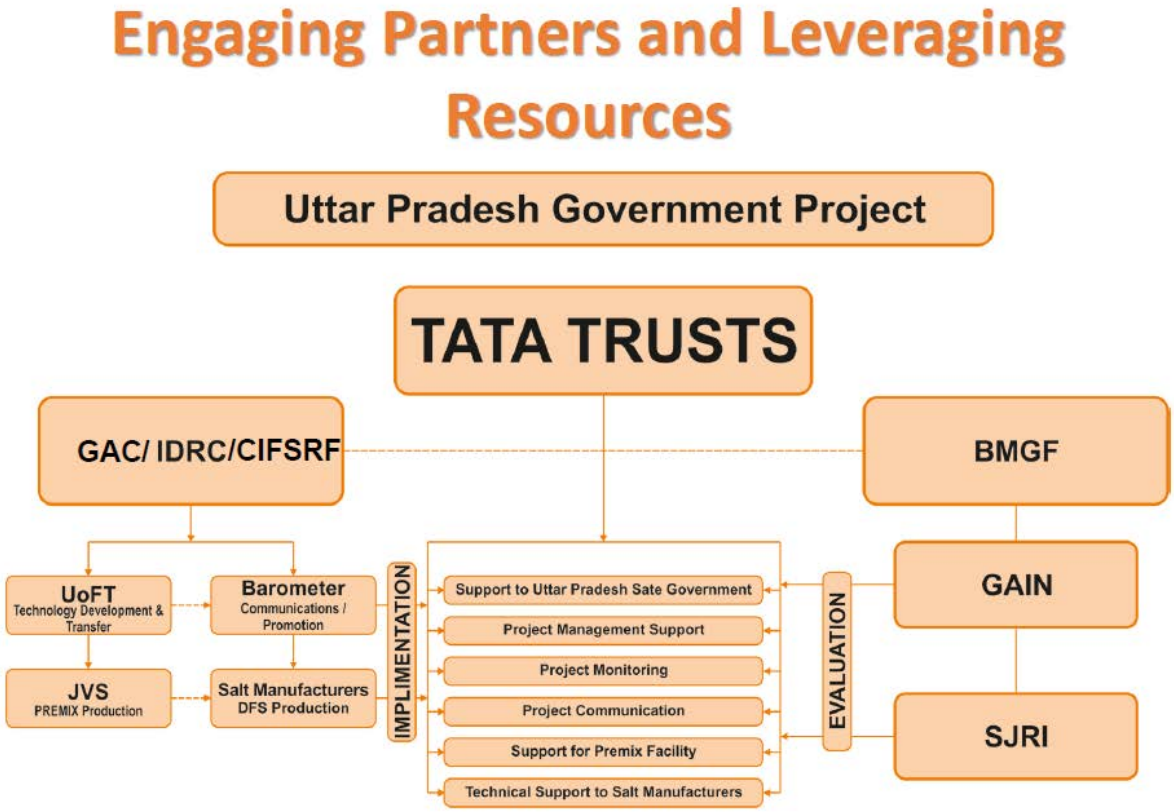
4.5.2 Partnerships

The partnership aspect of this project has been quite interesting, and pivotal to the relatively rapid progress to date.

Perhaps unusually, the partners in this project had long prior histories – 3 to 20 years – of collaboration. The team came to CIFSRF having worked together and will continue to work together

after the close of the CIFSRF grant. Without this prior history – trust, integrity, ability to work together, complementary skills, sincerity – this project would not have worked. These extant partnerships have deepened with the intense collaboration during this project. All project partners (Figure 12) are essentially at or near the top of their respective fields, and highly professional, with a dedication to issues of justice and representation.

Figure 12



Another vital element was entrepreneurial talent. The components of the intervention, encompassing many disciplines, were largely in place, but it was nobody's job to bring them together. What was needed talent and energy and time to knit elements together, and to bring things into being. A certain glue was necessary. The CIFSRF grant helped provide that. This may be a sore need in the development sector today. Another key element was that the project spanned partners from end to end—from lab to production to distribution to consumer to biomedical evaluation studies.

Although all the members were known in some respect to the project leads, some of the project partners within the web were new to each other. New South-South collaborations include: JVS Foods and TINI/Tata Trusts; multiple state governments and private sector DFS producers; JVS Foods (iron premix) and salt processors; TINI and SJRI. The working relationship between the University of Toronto and the Bill and Melinda Gates Foundation on DFS commenced in earnest since the inception of this project.

Some new partnerships apart from DFS have been spawned by this project. These include a project for quadruple fortified salt by Grand Challenges - Saving Lives at Birth and the U of T/NIS (and the partners in India, if or when QFS moves forward) for $250,000, a project for quintuple fortification

of salt (including zinc) funded by the Bill and Melinda Gates Foundation, and a possible fortified tea project by Grand Challenges Canada. This project has also informed a new Tata Trusts project concerning PDS digitization in UP.

The capacity of all partners has improved in one critical sense: awareness of the entire chain. Each party had known their own discipline, but the interactions and formal in person meetings have helped the understanding of the other areas. Everything needs to mesh for this project to work. The team is also more effective, as the project and area of work is more familiar. We have now gone through the cycle, and future iterations and efforts will be easier.

Regarding improved decision-making and policy concerning nutrition, we observe that discussions concerning micronutrient deficiencies and how to address them via DFS have been taking place at various loci in government, philanthropy, and the private sector. Some of those discussions, even on micronutrients more broadly, were catalyzed in small part by this project. Hopefully the level of discourse—including a sense of urgency in addressing malnutrition, the importance of partnerships, the importance of having a sound scientific basis, the centrality of those affected – has improved.

Lastly, as requested by CIFSRF, it goes without saying that the scale-up of DFS to tens of millions in India is an example of the increased use of Canadian knowledge and resources to address nutritional problems in developing countries. As noted, Canada plays a key role in this India-Canada-global story. The idea was originally conceived in India, the technology was developed at the University of Toronto, transferred to an Indian private company in Jaipur founded by a Canada returnee. The project was co-led by faculty members from the University of Toronto, with some help from a McGill affiliate. It was catalyzed and brought into being by a Mumbai philanthropy, and the Indian salt processor industry, and the governments of several Indian states. It should also be noted that the invention of the DFS technology in the first place, pre-scaleup, had financial support from the Government of Canada, via the Micronutrient Initiative (now Nutrition International). And going back even further, the Micronutrient Initiative itself was incubated within the government of Canada, at IDRC.

4.5.2 Awards/Formal Recognition

The reporting guidelines for this project request information on any formal recognition or awards for organizational or individual achievements. Here, these include:

a) Nokia Health Award (Venkatesh Mannar) (issued prior to project commencement)
b) Order of Canada (Venkatesh Mannar) (issued prior to project commencement)
c) Order of Ontario (Venkatesh Mannar)
d) Honorary Doctorate - University of Toronto (Venkatesh Mannar)
e) Gold Medal Award, Engineers Canada (highest honor for a Canadian engineer, given to one person annually) (Levente Diosady)
f) Fellowship conferred by the Canadian Association of Engineering (Venkatesh Mannar)
g) William Rogers Award (Brown University Alumni Association's highest honor, given to one person annually) (Jaykumar Menon)
h) Council on Foreign Relations, Life Member (Jaykumar Menon)

We also note that this project is being closely followed at the highest levels of various state and national governments and philanthropies.

4.5.3 Governance

The project was initiated in UP after extensive review by the state government, including approvals by its state health department, and after going through formal cabinet processes. It is a UP project, owned by the state government. The government procurement process is an opportunity to promote transparency and accountability, which will hopefully improve as time passes.

The project is somewhat top down, in that it works via government and centralized systems. On the other hand, this is project is very much locally owned, in that the state governments, as per good development practice, have taken the lead. Further, every fair price shop owner is a resident of the local community, and sells to areas of just a few thousand people, and is very much in touch with the clients' wishes. Lastly, the project has trained over 10,000 ASHAs (Accredited Social Health Activists), who are women health workers who reside in and are a part of the communities that they serve - with essentially one ASHA per village. The ASHAs served as advisors and as a conduit for clients' ideas and opinions. Also, by doing extensive interviews (over 1000) and focus groups re DFS, we have attempted to be closely aligned with people's real needs and views.

Equity is at the very heart of the project's distribution strategy. The project has elected to focus for now principally on the PDS, which targets and reaches low-income citizens. As noted, all citizens are entitled to obtain essential goods from the PDS on a non-discriminatory basis, and low-income citizens are entitled to purchase the goods at subsidized prices.

Within the project team, there is a balanced gender representation, although there always room for improvement. The research efforts at Barometer, the University of Delhi, and GAIN for this project are led by women, as are the field operations in Uttar Pradesh. Additionally, the second senior most researchers in food/chemical engineering, and the majority of the biomedical scientists (senior MDs and PhDs) on the project at St Johns are women. The University of Toronto group had one female professor, two female post doctoral fellow and two female graduate students – actually outweighing the male participation.

4.5.4 Research Ethics

The research studies in biomedical status (baseline and end line), and consumer acceptability studies/sensory analysis, consumer awareness studies, were all formally approved at the state government level by the relevant ethics bodies, as well as by the respective university committees. For each study, detailed protocols were prepared and submitted for review and approval by the relevant ethics committee.

4.5.5 Use of Research Results

The research results here (prior efficacy studies, current published studies, informational presentations at various fora, news articles covering the projects) have been widely shared. The impact can already be seen, with the decisions by various states to adopt DFS programs. Uptake has already been achieved.

5. Synthesis of Results Towards AFS themes

5.1 Availability

While availability has been defined terms of *agricultural* productivity, and this is not an agricultural project, nonetheless a brief comment may be in order. Production capacity of DFS has, as detailed above, been dramatically increased by this project. DFS production capacity for nearly 100 million people has been created, with over 60 million 1-kilogram bags of DFS shipped to date.

5.2 Accessibility

By working through the state's Public Distribution System, which targets low income citizens, DFS has been made very accessible, and has reached over 50 million people, largely rurally-based. The PDS has a shop in nearly every village. Salt is an inexpensive commodity to begin with, purchased and used daily even by very low-income families. DFS via the PDS has been priced nominally, at Rs 1 (CAD $0.02) / kg in MP and JH, and at Rs 3 (CAD $0.06) or Rs 6/kg (CAD $0.11) in UP, all well below the market price for iodized salt, and on a par with or below the price of un-iodised salt and is thus ultra-affordable. DFS stocks, per field visits, have essentially sold out of each shop every month.

Regarding gender issues and constraints, it bears emphasizing that the very purpose of DFS itself is to address problems – iron deficiency and anemia – that principally affect women, and secondarily, young children. Women of reproductive age lose iron during menstruation and have high iron needs. Hundreds of millions of women worldwide are iron deficient, causing among other things energy levels and cognitive functioning. Addressing these issues empowers women in a very literal way, albeit not an overtly political one.

DFS is designed to be widely accessible in that it is an essential constituent of all meals, via a staple food already in use. It thus sidesteps accessibility constraints that face many interventions and projects that have variable and uneven coverage and require their own distribution systems.

Regarding partnership models, this is perhaps the first time ever that a product has gone from the lab to public distribution system of India. In areas where market signals are weak, or where one wishes to do something distinctive (e.g. Apple and its vertical integration), we must perhaps try to assemble the value chain ourselves, from end to end, across disciplines, which is what has been arguably done here.

5.3 Utilization

Hundreds of millions of people globally, particularly women and children, suffer from micronutrient deficiencies. Malnutrition can be of course present even when caloric intake is adequate. Large quantities of rice and wheat, for example, are insufficient to address a human's varied and fundamental nutritional needs. DFS (as well as the QFS being developed) seeks to supply these basic nutrients, as a

complementary strategy to dietary diversification and other worthy approach. But distribution means nothing without utilization. Here, as per the hundreds of household visits carried out by the UP project's field coordinators every month (and as per the prior published Darjeeling/Cornell and Bangalore/St Johns-ETZ Zurich studies), it appears that citizens indeed consume DFS once it reaches the household. They find it acceptable and are repurchasing it when it becomes available.

Salt is not consumed on its own. It is typically mixed with food. While cooked and other food may or may not be distributed equitably, DFS for the most part will not have its own pattern of distribution. DFS is used equitably within the household, in that its intra-household use is automatic and distributed across all food preparations. There also is the question of varying nutritional needs within the household. The amount of iodine and iron delivered via DFS is proportional to the amount food eaten. Children eat less food than adults, but their micronutrient needs are lower. Generally, DFS is designed to deliver approximately 1/3 of the recommended daily allowance of iron. Removing iron deficiency has been shown to increase energy levels and cognitive abilities, which can be often associated with increased incomes, not to mention an improved flourishing of human potential and an enhanced quality of life.

5.4 Informing and/or influencing the development and implementation of food security policies

Women's Empowerment

This project can be considered a concrete and effective exemplar of Canada's feminist international assistance policy ("FIAP"), which seeks to refocus Canadian international assistance toward advancing gender equality and the empowerment of women and girls.

The very reason for this project's existence is to address health and nutrition issues that principally and disproportionately affect women and girls worldwide. Iron deficiency and anemia have to date provided quite intractable, afflicting hundreds of millions of women. Imagine increasing basic energy levels and cognitive power for tens to hundreds of millions of women; that would be a worthy and even historic contribution to gender equity and women's empowerment.

As noted, iron deficiency is the most widespread form of malnutrition in the world, principally affecting women of childbearing age and young children. In India, for example, the rates of anemia are staggering – 53% of women ages 15-49, and 58% of children ages 6-49 months are anemic (with iron deficiency the major cause). Adolescent girls and women of reproductive age stand to benefit most from this project.

Introducing a staple condiment of daily use to provide a health and wellbeing benefit for women and their children has resonated well. The 10,000 front line health workers who were trained to spread this message are all women who understood the problem and the potential of this product. The PDS system ration cards for each household are placed in the name of women, as part of an explicit Government of India women's empowerment strategy. Women are the main purchasers of commodities from the PDS. In the project's geography, women are also principally in charge of the intra-household distribution and use of the product. As such, there is very much an element of by women, for women, to the project.

With regard to the AFS theme of engaging policy makers, as noted above, the scale reached here was predicated on DFS being adopted by policy makers in three different states. They made the very

significant decisions to open up their state's Public Distribution System to DFS, to allow sensitive scientific effectiveness studies, including the drawing of blood to measure the project's effectiveness, and to subsidize its price. National policy makers played a key role too, including issuing a circular requesting the use of fortified foods in state programs, and setting a technical standard for EFF DFS that allowed it to be used.

How was this take-up by policy makers achieved? Several elements contributed: severe need in the country; recognition of that need by policy makers, through the efforts of a myriad of parties; prior policy and regulatory directives on DFS by the national government, including a national regulatory standard on DFS, and government circulars encouraging its use; provision of a strong evidence base, including efficacy trials; and critically, strong reach and credibility in the country through the leadership of the Tata Trusts, one of India's oldest and largest philanthropies.

The demand for research on DFS by policymakers was considerable, as they considered adopting the program, and also which type of DFS to use- encapsulated ferrous fumarate or ferrous sulphate. Their health ministries held consultations and absorbed research, as did their food and civil supplies departments. Notably, the DFS program launch in UP, the first state in India to use DFS in its PDS, was made possible by, and presided over by, Mr. Ratan Tata, the chair of the Tata Trusts and the ex chair of the $100 billion in revenue Tata Group, and also by R. Venkataramanan, the managing trustee of the Tata Trusts, and by the then-chief minster of the state, Mr. Akhilesh Yadhav – in other words, by action from the very highest levels.

Bottlenecks have included lengthy state approval times, and also interruptions of procurement due to an array of issues- budgetary, logistical, political, and electoral. The Jharkhand project has been interrupted for unspecified reasons.

6. Project Research Outputs

6.1 Academic Publications

Several academic works have already been published:

1. Ramírez-Luzuriaga, M, Larson, L., Mannar, V., Martorell, R. Impact of Double-Fortified Salt with Iron and Iodine on Hemoglobin, Anemia, and Iron Deficiency Anemia: A Systematic Review and Meta-Analysis. *Advances in Nutrition*, 9(3) 207-218 (2018)
2. Mannar, V., Raman, J. Double Fortified Salt in India: Coverage, Efficacy and Way Forward. *Indian J Community Health*, 30 (Supp), 63-71 (2018)
3. Singh, Anubhav P., Juveria, S., Diosady, L.L. Characterizing the pH-Dependent Release Kinetics of Food-Grade Spray Drying Encapsulated Iron Microcapsules for Food Fortification. *Food Bioprocess Technology,* 11(2) 435-446 (2018)
4. McGee, E.J.T., Diosady, L.L., Investigation of Discoloration of Packaged Fortified Salt Under Conditions Relevant to Product Packaging and Storage. *Food and Nutrition Sciences,* (7) 1221-1231 (2016)
5. Dueik, V, Diosady, L.L. Microencapsulation of iron in a reversed enteric coating using spray drying technology for double fortification of salt with iodine and iron. *Journal of Food Process Engineering*, 42(2) (2016)

Additional academic works are in press, or have been submitted for review:

6. Diosady, L. L., Mannar, V., Krishnaswamy, K. Improving the Lives of Millions through new Double Fortified Salt Technology. *Maternal & Child Nutrition Journal*. (submitted for review)

Further academic works are in preparation:

7. Optimization and Storage Studies on Iodine Retention in Double Fortified Salt (DFS). Oluwasegun Modupe, Kiruba Krishnaswamy & Levente Diosady (in preparation)
8. Microencapsulation of Extruded Iron Premix Using Different Coating Materials in Double Fortified Salt (DFS). Oluwasegun Modupe, Kiruba Krishnaswamy & Levente Diosady (in preparation)

Additional academic papers are planned:

9. Lack of association of dietary iron intake with anemia in women- Insights from UP and Jharkhand (St Johns Research Institute)
10. Effectiveness of DFS on Anaemia and Iron Status (contingent upon performing endline study)(St Johns Research Institute)

Other items:

11. Xuaref, Eva, Stability of double fortified salt - University of Dijon, (AGROSUP), Visiting Student Report

6.2 Academic Presentations

1. Diosady, L.L. Mannar, V. Fortification of Salt, International Union of Food Science and Technology 19th World Congress on Food Science and Technology, Mumbai India, October 2018 (scheduled)
2. Diosady, L.L. Salt as a Fortification Platform - International Symposium on Global Engineering (XXIX Interamerican Congress of Chemical Engineering Incorporating the 68th Canadian Chemical Engineering Conference) Toronto, October 28. 2018 (scheduled)
3. Diosady, L.L., Mannar, V. Salt as Micronutrient Carrier for Saving Lives at Birth – IUNS International Congress on Nutrition, Buenos Aires, October 19. 2017 (Poster)
4. Diosady, L.L. and Mannar, V. Technology Development and Scaling Up for Double Fortification of Salt with Iodine and Iron, IUNS International Congress on Nutrition, Buenos Aires, October 16. 2017
5. Krishnaswamy, K., Diosady, L.L. Food Fortification for Improved Nutrition. Centre for Global Engineering (CGEN), CGEN Research Day. March 17, 2017
6. Krishnaswamy, K, Diosady, L.L. Double Fortification of Salt with Iron and Iodine, American Society of Agricultural & Biological Engineers, Northeast Agricultural & Biological Engineering Conference (ASABE- NABEC) Aug, 2017, Connecticut
7. Krishnaswamy, K., Diosady, L.L. Food Fortification: an effective approach to improve global health. Engineering World Health (EWH 2016) Symposium. Feb 22, 2016.

6.3 Stakeholder Presentations

As listed in section 4.3, the DFS project has made multiple presentations to stakeholders or public audiences.

6.4 Open Access

In accordance with IDRC Open Access Policy, the research papers are in or will be submitted preferentially to journals with open access. If accepted by a journal without open access, the papers will be archived in the open access spaces maintained by University of Toronto. Grey literature (such as reports) will be placed in the IDRC Digital Library.

7. Problems and Challenges

This project faced numerous challenges:

Working in India, and particularly in Uttar Pradesh, one of its lowest-income states, and the locus of many of its most intractable problems, is notoriously difficult. To attempt to create multiple production facilities from scratch and move a new product to tens of millions of people in less than three years was ambitious.

These included a lengthy government approval process, a change in government in Uttar Pradesh, an alternate formulation for DFS that had been developed and promoted by the government itself, funding difficulties and technical challenges. The process of the UP government approving DFS for use in its PDS was protracted, and involved numerous committees, and scientific, cabinet, and budget approvals. After a change in ruling party, the new government had the prior ruling party's name blacked out on 10+ million 1 kg packets of DFS by magic marker by hand, and the DFS distribution proceeded. The new government then paused again for several months before deciding to repurchase supplies.

Another set of challenges stemmed from an alternate and prior DFS formulation developed by the Indian government's National Institute of Nutrition (NIN), which offered a confusing choice. Additionally, those involved in salt iodisation policy and programs were concerned that the DFS project, though it works in conjunction with iodised salt, would set back iodised salt. Ultimately, they were reassured and became project allies. These new government programs are still quite fragile. Supplies do not reach on time, and the programs can be interrupted via external events, whether a change in ruling party, or an anonymous viral video. Much effort is required to keep the programs on track.

Continuous vigil on the roll out of the project is essential. Given the increasingly powerful influence of social media across a country like India, there is always the risk of false rumours spreading quickly and turning viral – leading to consumer resistance. Project managers in the States need to be continuously watchful to address any concerns swiftly.

The project involves important ethical considerations. Providing a food item to millions of people behooves all those involved to ensure its safety and acceptability. In this regard, the project team adhered to WHO and national and state guidelines for micronutrient levels; drew from the experience of other countries that have fortified staple foods with iron for decades, often mandatorily; spoke deeply with consumers, and have been using the product ourselves. Further, research involving

humans, here including the drawing of small samples of blood to determine their iron and nutritional status and providing some areas with the intervention but others not, must always done with ethics and care.

7. Overall Assessment and Recommendations

We note with appreciation that the team from CIFSRF were extremely attentive and engaged. The CIFSRF team was very responsive (for example issuing rapid responses to emails, even on weekends), courteous, and knowledgeable of conditions on the ground. Annie Wesley visited with the team multiple times in both Canada and India and was with this project for the duration. Kevin Tiessen engaged closely with the project from his post in Delhi. Frank Schneider and Santiago Alba-Corral (along with Annie Wesley) spent three full days with the project in India recently, attending an all-day workshop in Delhi; making a field visit to rural UP to see the stores, households and warehouses; and making a field visit to Jaipur to see the premix production plant.

Some minor suggestions on rubrics. Each project in CIFSRF was required to use a template of four standard project objectives. We found those objectives to be a bit overlapping. For example, in our project, scale up of production and distribution were key, and yet appeared in multiple objectives, and it was difficult to parcel them across multiple objectives.

Given the complexities of scale up, particularly in a country like India, this project would have benefited from a longer time frame. Note that our rapid scale-up here was predicated on a decade plus of prior work.

8. List of Annexes

1. **Policy Brief** on Double Fortified Salt

2. Technical Documents and Schematics
2.1 JVS EFF Premix Standard Operating Procedures
2.2 DFS Plant Operations Manual
2.3 DFS Plant Quality Control Manual

3. Study Reports
3.1 DFS Consumer Awareness Report, Barometer Research
3.2 DFS Consumer Acceptability and Sensory Analysis Report, U of Delhi

Epigraph

Su Nombre Es Hoy

Nosotros somos culpables
de muchos errores y muchas faltas,
pero nuestro peor crimen
es el abandono de los niños
negándoles la fuente de la vida.

Muchas de las cosas
que nosotros necesitamos
pueden esperar, los niños no pueden,
ahora es el momento,
sus huesos están en formación,
su sangre también lo está
y sus sentidos
se están desarrollando,
a él nosotros no podemos contestarle
mañana,
su nombre es hoy.

Her Name is Today

We are guilty
of many errors and many faults,
but our worst crime
is abandoning the children,
neglecting the foundation of life.

Many of the things we need
can wait. The child cannot.
Right now is the time
her bones are being formed,
her blood is being made
and her senses are being developed.
To her we cannot answer 'Tomorrow.'
Her name is 'Today."

"Su Nombre es Hoy/ Her Name is Today," Gabriela Mistral, Chile, winner, 1945 Nobel Prize in Literature.

(Translation note: The possessive pronoun in Spanish is *su*, which applies to both boys and girls. Here it has been translated as she/her.)