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Making programs worth their salt: Assessing the potential of the Double Fortified Salt Program in addressing iron deficiency anemia in Uttar Pradesh, India

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Abstract

Double fortified salt (DFS) – salt fortified with iron and iodine – has proven efficacy in addressing iron deficiency anemia under controlled settings. However, there is limited evidence of DFS effectiveness in large-scale settings, and few studies examine the implementation process of DFS programs. In 2017, the Indian state of Uttar Pradesh (UP) implemented its flagship DFS program. This dissertation focuses on a process evaluation of the UP DFS program, with the objective of examining the implementation of the program and its potential for impact.

Guided by the UP DFS program impact pathway (PIP), we adopted a mixed-methods design for the process evaluation. We conducted a household survey (n=1202) to examine DFS coverage and utilization. In addition, we conducted in-depth interviews with DFS consumers (n=23) and key program staff (n=25) to assess the fidelity of implementation (FOI) in the DFS program. Finally, we conducted a predictive modeling exercise using baseline data on individual iron intakes and DFS coverage estimates to document potential program impact at different levels of utilization.

The household survey determined whether the program is moving in the expected direction, and identified the drivers of DFS utilization. The program documented low FOI and its implementation deviated from design, as per the PIP. This helped understand where and how to course-correct, and subsequently convey remedial measures to program staff. The predictive modeling exercise provided the ability to estimate, under certain assumptions, the change in outcomes consequent to the implementation of the UP DFS program. This model could help policy makers optimize and adopt context-specific interventions that can address iron deficiency anemia.

Our process and findings provided important learnings for conducting and using implementation research to design and evaluate nutrition interventions at scale. Examining the DFS program in a real-world context and identifying inefficiencies in program delivery helped assess the adequacy of the program. At this early stage of the UP program, the potential for measurable benefits was constrained by low rates of DFS utilization. Findings from this process evaluation informed the design of an adaptive impact evaluation and provided generalizable insights for ensuring that the potential for impact is realized.

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Abbreviations

AAY	Antyodaya Anna Yojana
AGP	Alpha1-acid glycoprotein
aOR	Adjusted Odds Ratio
ASHA	Accredited Social Health Activist
BMR	Basal Metabolic Rate
BQ	Believer Quote
CAPI	Computer Assisted Personal Interviewing
CEB	Census Enumeration Block
CFI	Comparative Fit Index
CRP	C-reactive protein
DC	District Consultant
DFS	Double Fortified Salt
DWLS	Diagonally Weighted Least Squares
EAR	Estimated Average Requirement
EI	Energy Intake
FPS	Fair Price Shop
FOI	Fidelity of Implementation
GAIN	Global Alliance for Improved Nutrition
Hb	Hemoglobin
HH	Household
ICMR	Indian Council of Medical Research
IDA	Iron Deficiency Anemia
INR	Indian Rupee
ISN	Implementation Science in Nutrition
LMIC	Low- and Middle- Income Country
LSFF	Large Scale Food Fortification
NIN	National Institute of Nutrition
NRC	National Research Council
NQ	Naysayer Quote

PAL	Physical Activity Level
PCA	Principal Component Analysis
PDS	Public Distribution System
PIP	Program Impact Pathway
PSC	Pre-School aged Children
RDA	Recommended Dietary Allowance
RMSEA	Root Mean Square Error of Approximation
SGPGI	Sanjay Gandhi Post Graduate Institute
SJRI	St John’s Research Institute
SRMR	Standardized Root Mean squared Residual
SSNP	Social Safety Net Programs
TINI	The India Nutrition Initiative
TUL	Tolerable Upper intake Level
TQ	Thrifter Quote
WHA	World Health Assembly
WHO	World Health Organization
WRA	Women of Reproductive Age
UP	Uttar Pradesh
USI	Universal Salt Iodization

CHAPTER 1: Introduction

Anemia affects nearly a quarter of the global population (1), and results in severe capability deprivation (2, 3), making it a widespread and significant public health problem. Characterized by a low concentration of hemoglobin, anemia is a multi-causal (4, 5) condition, with etiologic factors that commonly include iron deficiency (6), other micronutrient deficiencies (vitamins A, B9 (folic acid), and B12) (7), infections (8, 9), chronic disease and genetic hemoglobin disorders (4, 10-12). Iron deficiency is often assumed to cause nearly half of all anemia cases (iron deficiency anemia), but its exact proportion varies among geographies (4, 13). Iron deficiency anemia can lead to several functional consequences in all age groups and affects women and children disproportionately (8). In women of reproductive age (WRA), iron deficiency anemia can cause fatigue and reduce work capacity (14). Maternal anemia can adversely affect pregnancy outcomes (15), mother-infant interactions and infant development (16, 17). Anemia in infancy can lead to poor psychomotor performance (18) and anemic pre-school aged children (PSC) are more likely to have impaired cognitive development and poor motor skills (19).

Low- and middle- income countries (LMIC) have a particularly high burden of anemia (10, 12, 20), which remains persistent in some regions (21). India has a disproportionately high anemia prevalence, accounting for more than a quarter of the global disease burden (22), and the National Family Health Survey- 4 (NFHS-4) indicates that 53% non-pregnant WRA and 59% PSC were anemic in 2015-16 (23). The latest NFHS-5 reports that anemia prevalence in PSC, adolescents, non-pregnant WRA and men increased between 2015-16 and 2019-20 in most Indian states (24). Several studies have demonstrated that nearly half of the anemia cases in India is due to iron deficiency (25-27). An inadequate intake of iron-rich foods, coupled with poor iron absorption, are some of the major reasons for India's high iron deficiency prevalence. For many Indian households, it is difficult to routinely consume iron-rich foods, such as dark green leafy vegetables, which are also culturally acceptable for the predominantly vegetarian diet. Most diets are based heavily on cereals and millets, which primarily contain non-heme sources of iron that are relatively harder to absorb compared to the more bioavailable heme-iron found in animal source foods (28). Incorporating iron-rich vegetables and citrus fruits, that can boost iron absorption, to the household diet is especially difficult with rising seasonal prices that make them unaffordable in most settings, especially in rural areas (29).

Improving low dietary iron intakes require making diversified, nutrient-dense diets available, accessible and affordable to marginalized populations, but this is often a challenging undertaking (30). However, large-scale staple food fortification (LSFF) programs have had a positive impact (31), especially in LMIC contexts where sufficiently diverse foods are often unavailable, inaccessible and unaffordable for people to prioritize nutritious choices (32), in addressing micronutrient deficiencies. Food fortification can be a cost-effective strategy (33) that adds essential vitamins and minerals – specified amounts of nutrient-rich premixes – to foods commonly consumed by the general population. Iron-fortified foods have been consistently successful in reducing iron deficiency and have shown an improvement in hemoglobin levels in some settings (31, 34). Over the decades, LSFF has gained significant traction in addressing micronutrient deficiencies – today, most countries iodize their salt (N=140), fortify their cereal grains (N=83), edible oil (N=20), sugar (N=9), and other staple foods (35). The most successful among these examples is the fortification of salt with iodine – an intervention which was first introduced in Switzerland and Michigan, USA, in the 1920s. The universal salt iodization (USI) program has since been very effective in addressing iodine deficiency on a global scale, even though several countries have struggled with delayed implementation or limited roll-out.

1.1. Double Fortified Salt (DFS)

Salt is affordable to almost all income groups in the population, found ubiquitously in household kitchens, and is consumed at constant levels, making it an ideal vehicle for fortification. Fortifying salt with multiple micronutrients was first proposed in 1969 (36), and double fortified salt (DFS) – salt fortified with iodine and iron – has since received extensive attention. Leveraging USI's success and adopting a DFS program to prevent iron deficiency anemia in a LMIC setting holds substantial promise. With the capacity and infrastructure for salt iodization already in place in several LMICs, transitioning to produce DFS is relatively straightforward (31) with current salt refineries only requiring to adopt one additional step of producing or procuring the iron premix (36).

USI's key factors for success were the simple production process and minimal investment requirements. DFS production, however, is much more challenging with high costs for both the input salt and the iron compound. While iodizing salt increased costs by 2-3%, the production of DFS increased costs up to 70-90%, with operational costs varying based on the context of implementation (37). Several attempts have been made in the past two decades to produce a stable, bioavailable product that does not exhibit any undesirable organoleptic characteristics, such as changes in color or taste, or reaction with iodine resulting in the latter's loss (38). Both ferrous and ferric forms of iron, in combination with various compounds and encapsulation techniques, have been evaluated to produce different types of DFS (38). These types of DFS differ in their exact formulation, and several efficacy trials have included characterizations of

DFS, assessed each type's stability (of iodine and iron), acceptability by consumers, and investigated their impact on the iron deficiency and anemia status of trial participants (39).

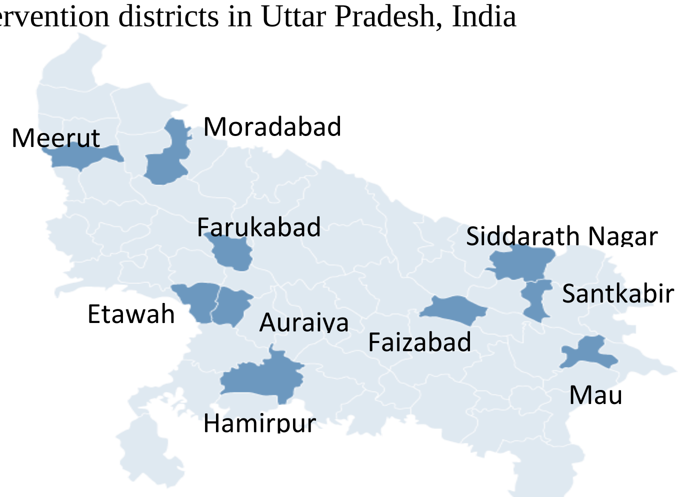
Efficacy studies have shown that DFS is successful in reducing the risk of iron deficiency and anemia under controlled settings. These studies examined impact among captive audiences, such as workers in tea plantations (40-42), school children (43, 44), and in other settings (45, 46) where it was easy to control trial conditions and intervention delivery. However, there are only two *DFS effectiveness studies* (47) that examine how these programs perform in real-world settings. One examined a DFS program where the fortified salt was distributed through school meal programs in Bihar, India (46). The schools in the intervention added DFS to midday meals, and positive impacts in hemoglobin and anemia levels were noted among students. The second DFS program (48) used social safety nets and markets – where households in the intervention districts could choose whether to purchase DFS, available both at subsidized rate or at full price. The effectiveness evaluation of this second DFS program, conducted by Banerjee et al, noted that DFS purchase by households was low and found no significant change in anemia or iron deficiency levels.

The findings from the efficacy trials and the two effectiveness evaluations discussed above show inconsistencies in their conclusions, thus highlighting a critical evidence gap in the current DFS evidence base. While we know that the DFS intervention works in controlled settings, we are uncertain of its impact in real-world programs especially where the purchase and uptake of the fortified food remains voluntary. In such cases, several factors cannot be predicted or controlled – DFS compliance levels may vary, program delivery platforms may have challenges, and the product quality may not always adhere to the stringent standards that are met under efficacy trial settings. Understanding DFS impact under all these real-world challenges remains important before DFS interventions are scaled up in countries as an anemia prevention strategy. This evidence gap was addressed through the effectiveness evaluation of India's flagship large-scale DFS program, which was launched in the state of Uttar Pradesh (UP) in 2017. This dissertation focuses on a process evaluation that was embedded within the effectiveness evaluation, to examine the implementation of the program, prior to conducting impact assessments.

1.2. DFS program in Uttar Pradesh

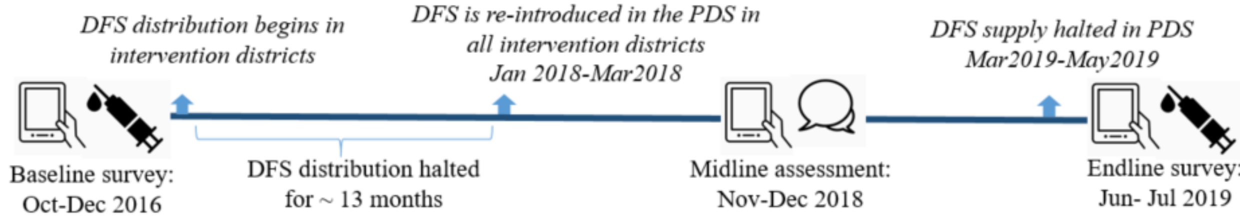
UP is one of the most densely populated and impoverished Indian states which, despite several efforts, has made little or no progress in nutritional status in the last decade. The level of anemia in the state is 52% in WRA and 63% in PSC (49), and over 70% of them have iron deficiency anemia (27). To address this issue, the UP government introduced the DFS intervention in 10 districts across the state, which were purposively chosen by the government based on a high burden of malnutrition **(Figure 1.1**). In these districts, DFS was distributed through the Public Distribution System (PDS), a social safety net program that uses a widespread network of government fair price shops (FPS) to distribute basic provisions, such as rice, wheat and kerosene, at subsidized prices to registered households, based on their income levels.

Figure 1.1: DFS intervention districts in Uttar Pradesh, India



Five of the 10 intervention districts were selected using simple random sampling and included in an impact evaluation, conducted by an external consortium of research partners. Five neighboring districts with no DFS distribution were selected as the control districts for the evaluation. The India Nutrition Initiative (TINI) was the implementation partner with the Government of UP, and responsible for routine program monitoring. A baseline survey was conducted between October - December 2016, after which DFS distribution commenced in the intervention districts (**Figure 1.2**). Thereafter, the program was halted abruptly due to change in the state government. However, TINI consistently advocated with the new state administration for the re-launch of the program, which took place in early 2018 after a brief hiatus. The evaluation team then conducted a midline assessment of program performance in the five intervention districts between November - December 2018, and an endline survey in selected intervention and control districts from June - July 2019. Computer Assisted Personal Interviewing (CAPI) techniques were used for all surveys to collect households level information. The midline assessment included additional in-depth interviews, and blood samples were collected during baseline and endline surveys from eligible participants after informed consent. The baseline and endline status of iron deficiency and anemia in both intervention and control districts were compared, after analyzing the blood samples, to assess DFS program impact (34).

Figure 1.2: Timeline of DFS program and evaluation



1.3. Beyond Impact: A Case for Implementation Research in Food Fortification

Food fortification, in theory, is a passive intervention that is simple to implement and requires no behavior change from consumers – USI programs are an embodiment of this, and have hence been very successful. In reality, however, there are a combination of factors that can influence most fortification programs to deviate from design, and affect its potential for impact. This can range from the extent of micronutrient deficiency in the intervention population, fortification regulation standards, fortification process (forms of nutrient chosen, production of the premix, choice of food vehicle), delivery of the fortified food, consumer acceptability, and its consumption in sufficient quantities at a desired frequency to have a population level impact (46). In the Banerjee et al study (46), for instance, only 14.5% of the households chose to purchase any DFS and this resulted in null findings – this meant a missed opportunity for that DFS program to course correct and improve its potential for impact.

While summative evaluations – which assess program impact – such as the Banerjee et al study (50) are required to evaluate the effectiveness of interventions and make good decisions on scaling-up (51), formative evaluations – those that first assess the potential for impact (46) – are imperative for programs that are in their early stages. Formative evaluations, such as process evaluations are often less resource-intensive, ensure that the program is moving in the expected direction, and help in making concurrent course-corrections before conducting more complex and costly summative evaluations (which can then assess the adequacy of the concurrent changes in the final outcomes). Conducting summative evaluations on programs which have not been adequately implemented (52) can result in a Type III error (53), resulting in a failure to identify if a lack of impact is due to the intervention design or due to poor program implementation (54).

Our effectiveness evaluation was a theory-based impact evaluation (55) that embedded insights from a formative (process) evaluation of program coverage and utilization. We adapted the Tanahashi framework (56), which is a conceptual framework of coverage evaluation that defines key stages of program coverage, to assess the implementation outcomes of the UP DFS program. The Tanahashi framework helps in the measurement and evaluation of health service coverage, and in identifying constraints or bottlenecks in the operation of the heath service. In our adapted use of this framework, we assessed UP DFS program coverage (households who 'ever heard', 'ever purchased' and 'typically purchased') and household-level DFS utilization ('any adherence', 'partial adherence' or 'complete adherence'). We used these insights to establish the adequacy of the intervention – i.e. how well program activities met the set objectives – at program midline. This adequacy assessment (32) was conducted by comparing DFS coverage assessments at midline to a set criterion, where we used an a priori threshold of 50% DFS utilization, i.e. at least 50% of the households surveyed in the midline had to use DFS in their food. Once this was determined, the endline evaluation was conducted only in the sub-sample of districts that met the adequacy criterion and demonstrated a potential for impact.

We adopted a mixed-methods approach for the process evaluation, designing survey tools and in-depth interviews, using insights from routine monitoring activities provided by key program implementation staff. Using a program impact pathway (57), the in-depth interviews examined how the implementation unfolded. We assessed this data using the Implementation Science in Nutrition (ISN) framework, to understand why program outcomes were or were not achieved (58, 59). The ISN framework (60) is adapted from the Consolidated Framework of Implementation Research (CFIR), which provides a practical framework to contextually assess implementation across five domains (61). These frameworks evaluate implementation quality across multiple settings, by examining 1) the nature of the intervention; 2) the implementing organization; 3) the enabling environment; 4) the target of the intervention (households or communities); and 5) the decision processes related to the implementation. We assessed the fidelity of the UP DFS program implementation, across multiple domains of the ISN framework, comparing actual implementation to that intended as per program design. This helped us understand where and how to course-correct, and subsequently allowed us to convey remedial measures to program staff, who worked closely with the evaluation team to incorporate the necessary changes.

1.4. Dissertation Aims

This dissertation addresses important gaps in the current DFS evidence base by examining the implementation of the UP DFS program and assessing the adequacy of program outcomes through its process evaluation. Findings from this implementation research provide important insights on the design and interpretation of the overarching effectiveness evaluation, and on decisions about scaling-up DFS as an anemia prevention strategy. The aims of this dissertation and the respective chapters are as follows:

1. To assess the levels of coverage and utilization of the UP DFS program at midline, understand the drivers of DFS adherence (use in household cooking), and consider whether an impact evaluation is warranted.

   Chapter 2: High coverage and low utilization of the Double Fortified Salt Program in Uttar Pradesh, India: Implications for program implementation and evaluation

2. To assess the fidelity of implementation of the UP DFS program, using a theory-based program impact pathway, and provide insights on improving the design and

implementation of all DFS programs that aim to reduce the iron deficiency anemia burden.

Chapter 3: Making programs worth their salt: Assessing the context, fidelity, and outcomes of implementation of the Double Fortified Salt Program in Uttar Pradesh, India

3. To predict the impact of the UP DFS program in addressing the risk of inadequate dietary iron intakes at the population level, and model the potential risks and benefits of excess or adequate iron intakes respectively, with improvements in program implementation.

Chapter 4: Modeling the potential impact of the Double Fortified Salt Program on the levels of inadequate iron intake among non-pregnant women of reproductive age in Uttar Pradesh, India

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CHAPTER 2: High coverage and low utilization of the Double Fortified Salt Program in Uttar Pradesh, India: Implications for program implementation and evaluation

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2.1. Abstract

Background: Double Fortified Salt (DFS) is efficacious in addressing iron deficiency, but evidence of its effectiveness is limited. The few published evaluations do not include details on program implementation, limiting their utility for programmatic decisions.

Objective: We sought to characterize the coverage of a DFS program implemented through the Public Distribution System (PDS) in Uttar Pradesh (UP), India, and understand the drivers of DFS adherence.

Methods: After eight months of implementation, we surveyed 1202 households in five districts and collected data on sociodemographic characteristics, asset ownership, food security and regular PDS utilization. We defined 'DFS program coverage' as the proportion of PDS beneficiaries who had heard of and purchased DFS, and 'DFS adherence' as DFS use reported by households. We used principal components analysis to create an asset-based index of relative wealth, and categorized households into higher/lower relative wealth quintiles. We conducted path analyses to examine the drivers of DFS adherence, particularly the mediated influence of household wealth on DFS adherence. The evaluation is registered at RIDIE-STUDY-ID-58f6eeb45c050.

Results: The DFS program had good coverage – 83% respondents had heard of DFS, 74% had purchased it at least once and yet, only 23% exclusively used DFS. Respondents had low awareness about DFS benefits and considered DFS quality as poor. Being in a lower household wealth quintile and being food insecure were significant drivers of DFS adherence and regular PDS utilization acted as a mediator. Adherence was lower in urban areas.

Conclusions: We observed significant heterogeneity in DFS implementation as reflected by high coverage and low adherence. Learnings from this process evaluation informed the design of an adaptive impact evaluation, and provided generalizable insights for ensuring the potential for impact is realized. Efforts are needed to increase awareness, improve product quality as well as mitigate against the sensory challenges identified.

Keywords: Double Fortified Salt, Implementation Research, Adaptive Evaluation, Coverage, Adherence

2.2. Introduction

Addressing micronutrient deficiencies through food fortification is cost-effective (1), and one such successful strategy has been salt fortification to reduce iodine deficiency. Salt is commonly consumed, relatively affordable and accessible, and as such is an ideal fortification vehicle that can reach vulnerable populations. Leveraging this potential, researchers have considered since the 1960s using fortified salt to target iron deficiency and iron deficiency anemia (2), which have deleterious health, functional and developmental implications. Indicated by lower iron stores in the body, iron deficiency often causes anemia (characterized by low hemoglobin concentrations). Although anemia has a complex multi-causal etiology (3-8), iron deficiency is one of its common drivers in at least a fourth of the anemic population (9). Iron deficiency anemia is defined as meeting the criteria for both low iron stores (iron deficiency) as well as low hemoglobin (anemia) (10).

It is posited that countries with successful experience implementing universal salt iodization, but struggling with high iron deficiency due to inadequate intakes, may gain from adding iron to the salt. Double fortified salt (DFS) is the dual fortification of salt with iodine and iron that simultaneously targets both micronutrient deficiencies (11). The efficacy of DFS in reducing iron deficiency has been demonstrated in small controlled trials (12) that were conducted in India (13-16), Morocco (17), Côte D'Ivoire (18) and Ghana (19). However, the feasibility and effectiveness of DFS in a large-scale programmatic setting remains under-explored (20).

Only two studies have evaluated the effectiveness of DFS to date, highlighting a gap in evidence. Both studies were in Bihar, India. DFS distribution in one program was via school feeding programs (21), while the other program used social safety nets and retail markets as delivery platforms (22). While these studies report mixed results on DFS intervention impact, coverage levels were either unreported or low, and data on program implementation quality is limited. We conducted an evaluation of a DFS program in Uttar Pradesh (UP), India to address the gaps in the current knowledge about program effectiveness.

2.2.1. Uttar Pradesh (UP) DFS program

India's National Family Health Survey 2015-16 reported that in UP 53% non-pregnant women of reproductive age of 15-49 years (WRA) and 63% pre-school aged children of 6-59 months (PSC) were anemic (23). Several studies have also demonstrated a high prevalence of iron deficiency in this context (24). In 2016-18, another survey specifically reported iron deficiency levels for children – in UP, 24% of young children (1-4 years), 9% of school-aged children and 17% of the adolescents had low iron stores (25).To address this widespread anemia and iron deficiency, the UP government chose ten districts with high anemia prevalence to distribute DFS using the Public Distribution System (PDS).

The PDS is a social safety net program in India, and PDS shops in UP distribute rations that include subsidized rice, wheat, and kerosene to eligible households every month. PDS eligibility is determined by the state government, and the lowest income households are categorized as Antyodaya Anna Yojana (AAY) cardholders while slightly better off households are categorized as Priority Household (PHH) cardholders. After a recent restructuring of the PDS, 25% rural households and 50% urban households are not covered by the safety net program (26). DFS is subsidized for both AAY and PHH cardholders, and is priced to be at least 3 times cheaper than iodized salt sold at an average price of INR 18/kg in the retail market. AAY cardholders receive DFS at INR 3/kg and PHH cardholders receive DFS at INR 6/Kg.

2.2.2. Evaluation of the UP DFS Program

The UP DFS program had an adaptive evaluation design that included baseline, midline (process evaluation) and endline assessments. Five out of the ten DFS program districts were chosen using simple random sampling for the evaluation. In conjunction with examining DFS effectiveness through baseline and endline assessments, the process evaluation specifically focused on assessing the implementation of this fortification strategy. We developed a program impact pathway and conducted a coverage survey. In this paper, we present data on the coverage of the UP DFS program, and assess the drivers of adherence. Additionally, this data was used to determine whether to conduct the endline assessment for the DFS program, using an a priori evaluability threshold, decided based on similar fortification evaluations (27), where at least 50% of the sampled population was utilizing DFS.

2.3. Methods

2.3.1. Sampling Strategy

Twenty clusters of villages or wards (urban neighborhoods in India) were selected using stratified random sampling and population proportion to size for the baseline survey and revisited for the coverage survey, between November-December 2018, after eight months of DFS rollout. Of the 20 clusters, five each were randomly selected from villages and wards from within the entire district and 10 consisted of villages or wards randomly selected from border areas (within 20 km of the district border). Within each ward, one Census Enumeration Block (CEB) was randomly selected using the 2011 Census of India data (28). After a mapping process, selected villages/CEBs were divided into four segments and three households were selected from each segment to get 12 households from every cluster. Household selection from segments in villages took place by spinning a pen from a randomly selected landmark, and assessing every fourth household in that direction for eligibility. Households in urban areas were selected using a similar segmentation approach, adapted from the multiple indicator cluster surveys (29).

The same eligibility criteria for the baseline survey were maintained for the coverage survey. PDS cardholder households with at least one non-pregnant WRA and a PSC were interviewed, where the primary respondent was the non-pregnant WRA. If more than one eligible WRA lived in the household, one was chosen randomly as the respondent. An additional household each was interviewed in two of the five districts due to oversampling and these interviews were retained for the analyses, resulting in a final sample of 1202 interviews.

2.3.2. Variable measurement

We assessed sociodemographic characteristics, housing conditions, asset ownership and food security. We identified different salt types in household kitchens, distinguished based on packaging information – DFS from the PDS, iodized packaged salt from retail shops or loose crystal salt from informal markets.We categorized caste – a symbol of social status – based on the classification provided by the Indian constitution, and further grouped them into groups of higher- and lower- caste (30). Additional household level assessments included PDS utilization, quality perceptions for PDS rations (defined using a 3-point Likert scale which rated ‘quality’ as perceived by the respondent, categorizing it as ‘poor’, ‘good’ or ‘excellent’) and DFS stock holding. Interviews queried respondents’ levels of DFS awareness **(Supplementary Table 2.1)** and we considered responses that mentioned ‘good health or nutrition’, ‘anemia prevention’ or ‘goiter prevention’ as having at least partial awareness of DFS benefits.

We measured wealth using household assets as a proxy, and used principal components analysis (PCA) for variables representing 36 assets that included household goods and vehicles, livestock as well as property ownership, and attributes of housing structure such as construction quality, light and fuel source to create household wealth quintiles. A dichotomous variable was created where households in the lowest two quintiles constituted the lower-wealth category, while the rest belonged to the higher wealth group.

Although PDS rations were available every month, some cardholder households did not regularly utilize the PDS for monthly purchase of subsidized rations. We therefore asked households whether they regularly utilized their PDS cards and categorized those households who responded affirmatively as regular PDS utilizers. We measured food insecurity using the Household Food Insecurity and Access Scale (31), and categorized households that were food-secure and mildly food-insecure as 'food secure' and moderate/severe food insecure as 'food-insecure'. All households, including food secure and mildly food-insecure households, worried about running out of food rarely, sometimes or often, but only moderate and severely food-insecure households had to cut back on the quantity of food consumed.

Adapting the Tanahashi framework on evaluating health service coverage, we examined a cascade of varying degrees of DFS program coverage (25, 32, 33). This coverage cascade indicated both DFS coverage and DFS adherence and, each indicator was conditional on having achieved the previous one **(Figure 2.1)**. DFS coverage estimated the prevalence of those who had ever heard of DFS, had ever purchased DFS and lastly, who purchased DFS with monthly PDS rations. To measure adherence, interviewed households listed all salt types in kitchens and their usage in food and beverages. 'Any DFS adherence' included two subsets of households – 1) households with 'partial DFS adherence' and 2) households with 'complete DFS adherence'.

‘Partial DFS adherence’ was used to categorize households reporting DFS as a secondary salt, used only in certain dishes or drinks, whereas ‘complete DFS adherence’ was for households who reported exclusive DFS use in foods and beverages.

2.3.3.. Hypothesized pathways

For all path analyses, the outcome variable of interest was ‘complete DFS adherence’, as it was most likely to capture the DFS program’s potential to benefit. We examined the relationship between household wealth and complete DFS adherence and theorized a path model **(Figure 2.2)**, which proposed that regular PDS utilization, household food insecurity and DFS awareness mediated this relationship.

Our fieldwork experience indicated that several households could not access the PDS in spite of being cardholders due to an ongoing restructuring of the safety net program, including installation of a biometric system and linking PDS cards to a national identity card (34). We also noted that PDS rations were sold as a bundle, and many had to purchase DFS in order to get grains and kerosene fuel. Some households who purchased DFS as part of these bundled sales used it for own consumption while others simply stored it, mixed it in cattle feed or donated it to those neighbors who used DFS. It was likely that some lower wealth cardholder households faced constraints to regular PDS utilization and accepted DFS donations, it being cheaper than purchasing alternate salt. Therefore, we hypothesized that lower wealth non-regular PDS utilizers are more likely to use DFS than higher wealth non-regular PDS utilizers, indicating a link between lower wealth in households to complete DFS adherence i.e. exclusive DFS use in foods (**Figure 2.2**, Path a).

In addition to this path, we hypothesized that household food insecurity and regular PDS utilization would mediate the relationship between household wealth and complete DFS adherence. First, we expect lower wealth households to experience food insecurity (**Figure 2.2**, Path b) and that greater food insecurity may lead to regular PDS utilization (**Figure 2.2**, Path c). Second, we expect lower wealth households to rely on the PDS for kerosene fuel, in addition to the food grains (**Figure 2.2**, Path d). Not all those who purchased DFS completely adhered to it due to quality concerns. However, we hypothesize regular PDS utilizer households to be more likely to use DFS as they accumulate it from monthly purchases (**Figure 2.2**, Path e). Finally, we expect that regular PDS utilizers will be exposed to DFS messaging by shop owners (**Figure 2.2**, Path f) and households aware of DFS benefits may be more adherent (**Figure 2.2**, Path g). DFS program staff had provided a one-time training to PDS shop owners, describing DFS contents and demonstrating their benefits for preventing anemia and goiter. PDS shop owners were asked to verbally communicate about DFS and its benefits to household members who come to purchase rations.

2.3.4. Analyses

We used descriptive analyses to assess individual characteristics such as respondent age and education levels, and household characteristics including family size, primary income source, and access to facilities, religion and caste. We examined and retained all outlier values after scrutinizing related variables and determining plausibility. Examination of bivariate associations and confounding assessment helped build the final path model, adjusted for household religion and household head's education. We examined all variables in the path model for missing data and found that values for household head's education were missing for 11 interviews. We adopted a listwise deletion approach to account for missing data (35) after determining the values to be missing at random. We expected pathways to vary based on location of residence, and created separate household wealth quintiles for rural and urban areas to examine location-specific path models **(Supplementary Table 2.2, Panel A)**. Except for one ordinal variable (household head education), all other variables in the path model were dichotomous.

We performed preliminary analyses in SAS software (version 9.4) and weighted path analyses in R (version 3.5.3). We utilized survey methods and structural equation modelling approaches (R lavaan and lavaan.survey packages, versions 0.6-5 and 1.1.3.1), adopting the diagonally weighted least squares (DWLS) method to account for both ordered and dichotomous variables to conduct a path analysis. All standardized coefficients were exponentiated to obtain the adjusted odds ratio (aOR), indirect and total effects were calculated. We assessed goodness of model fit using chi squared ($\chi 2$), Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI), and standardized root mean squared residual (SRMR). The RMSEA, CFI, and SRMR suggest reasonably good model fit when they are less than 0.08, greater than 0.90 and less than 0.08 respectively (35, 36).

2.3.5. Ethical Considerations

Institutional review boards at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Uttar Pradesh, and Emory University, Atlanta, GA reviewed and approved the data collection and analyses protocol. The evaluation is registered with 3ie's Registry for International Development Impact Evaluations (RIDIE-STUDY-ID-58f6eeb45c050).

2.4. Results

Sociodemographic characteristics of the sample are presented in **Table 2.1**, stratified by location of residence. A majority of the respondents was Hindu, resided in rural areas and belonged to a lower caste. Most respondents lived with their extended family and household size averaged seven members. Overall education level was low, but the proportion of respondents with a college degree was almost 1.5 times higher in urban compared to rural areas ($p<0.001$). Urban households were also more likely to have access to electricity, piped water and gas stoves. Nearly half the rural households experienced moderate to severe food insecurity **(Supplementary Table 2.3)**. We also noted that more households in rural areas regularly utilized the PDS than those in urban settings. Two-thirds of sampled households found DFS quality to be poor, but a higher proportion of urban households noted the quality of PDS rice and DFS to be poor.

Figure 2.1 shows the DFS program coverage cascade. Rural areas had higher DFS coverage and adherence than urban settings. Among overall survey participants, 83% either had ever seen DFS packets or had ever heard of the product; 74% of all participants had purchased DFS at least once, and 68% reported purchasing it every month from the PDS along with the other PDS commodities. For DFS adherence, 35% of the survey sample reported any adherence, i.e. using DFS either partially or completely, and 23% reported complete adherence. There were district level variations in DFS adherence **(Supplementary Table 2.4)**, with two districts indicating higher adherence especially in the rural areas.

After removing the 11 households with missing information on household head education, the final sample for path models was 1191 households. Findings from the path model are illustrated in **Figure 2.3**. The model fit for rural sample were all within acceptable range – P-value ($\chi2$):0.003, RMSEA: 0.07, CFI: 0.99, SRMR: 0.01 (21, 36) – and no model re-specification was required. However, the urban model did not show a good fit – P-value ($\chi2$) : <0.001, RMSEA: 0.35, CFI: 0.99, SRMR: 0.02. Subsequent model re-specifications of the urban model based on theoretically vetted modification indices resulted in non-convergence, and we therefore do not present the urban model in this paper.

Table 2.2 describes direct, indirect and total effects separately for total (columns 1-3) and rural (5-7) models. With the overall sample size of path models containing a majority of rural households (n=861), the effects in the total sample were qualitatively similar to the effects rural models. We discuss only the rural effects here, and present direct effects for the total model in **Supplementary Figure 2.1**. Standardized direct effects in the path model for the rural sample (**Figure 2.3**) indicated that households in lower wealth quintiles had greater odds of complete DFS adherence (aOR: 1.08; 95% CI: 1.03, 1.12); they also had greater odds of experiencing household food insecurity (1.36; 1.30, 1.43). Odds of regular PDS utilization increased with greater household food insecurity (1.06; 1.02, 1.10) and with lower household wealth (1.05; 1.00, 1.10). Regular PDS utilization increased the odds of improved DFS awareness (1.09; 1.06, 1.11) Improved awareness and regular PDS utilization had a positive direct effect on DFS use. Significant indirect paths from household wealth to DFS adherence in the rural model (**Table 2.2**, col (6)) indicated mediation by regular PDS utilization, through household food insecurity, showing increased overall odds (**Table 2.2**, col (8)) of DFS adherence (1.28; 1.13, 1.44). The mediated path from PDS utilization and DFS awareness was not significant, and the total effect remained the same as the direct effect seen in **Figure 2.3** (1.17; 1.12, 1.23).

2.5. Discussion

After eight months of implementation, the UP DFS program had attained high coverage but low adherence. While bundling DFS sales with subsidized grains ensured continued DFS purchase, product quality concerns resulted in low DFS adherence. In another DFS program in Bihar, DFS use decreased over time, with many users trying and giving up DFS after finding black specks in food. Subsequently, null findings were reported when the evaluators conducted an impact assessment in Bihar (10). In UP, we conveyed the remedial measures to program staff in real-time, focusing on actions to improve DFS adherence, through better product quality and increased awareness about DFS benefits.

Rural households were likely to be more impoverished than urban households. A combined wealth index created for the overall population (**Supplementary Table 2.2**, **Panel B**) showed urban households to be largely concentrated in the higher two relative wealth quintiles. Compared to rural households, urban households relied less on subsidized rations and were more likely to self-select themselves out of the PDS. Our rural path model indicates that lower household wealth, regular PDS utilization and DFS awareness were strong drivers of DFS use. Building awareness around DFS benefits worked in this context where DFS adherence levels were higher among those who positively perceived DFS.

These findings reveal three lessons for the UP DFS program.

First and foremost, there is a need to overcome DFS product limitations and address quality concerns raised by users. DFS production is complex, with formulations for iron compounds constantly evolving. Four iron formulations for DFS currently exist(37) and the UP program tested one of these, which showed promise of addressing the discoloration problems faced in other DFS trials. However, as the program rolled out, DFS quality was compromised due to the significant investments required to produce and blend the iron formulation with high-grade refined salt, high production costs and a lack of standards for producing extruded iron compounds (38). In our qualitative assessments (results forthcoming), DFS users raised concerns about sensory changes in food, and non-adherent households likely valued product quality over price subsidies or perceived benefits. Similar sensory changes in food were noticed by participants in a consumer acceptability study conducted by the UP DFS program in New Delhi, India (38), testing the same formulation. The study reported that DFS caused varying levels of discoloration in food, which depended on heating methods used during preparation (boiling, pressure cooking, sautéing) with almost no change noticed in food that was prepared with no heat (for example, salads and cold beverages). However, cooking methods, dishes prepared and meal timings can vary regionally and ultimately influence DFS adherence, highlighting the need to invest in context-specific sensory trials.

Second, the DFS program should reinforce efforts to boost awareness around the safety and benefits of DFS. Awareness creation efforts in the New Delhi DFS sensory trial showed that over 85% of the participants were willing to use DFS after getting to know about its benefits (39). While improving product quality is paramount, an interim strategy could be to proactively inform users to anticipate sensory changes in food due to DFS, and create awareness about the reasons for this change such that they consider discoloration in food as signal of nutritional value. Similar programs that distributed micronutrient powders in multiple contexts have successfully adopted such a communication strategy, where users readily accepted the intervention once they were aware of what to expect and convinced about product safety and benefit (40-42).

Finally, it is important to consider strategies to expand DFS access and availability in urban areas, where 50% of the population are not covered by the PDS. Simultaneously, the need for complementary strategies – including non-DFS interventions (42, 43) – should be recognized to address state-level issues of iron deficiency and iron deficiency anemia. While reassuring to note that food-insecure, lower wealth households are getting access to DFS, iron deficiency and iron deficiency anemia are not restricted only to the poorer rural households in India (44-46). Concurrent efforts such as expanding the DFS distribution through retail markets or liaising with other iron- fortification initiatives with a larger reach (26, 47), such as wheat fortification, might ensure that we reach all population suffering from iron deficiency or dietary inadequacy.

These findings must be interpreted within the limitations of this study. There could be a social desirability bias – in either direction – for questions around PDS purchases and product quality rating, as we informed respondents prior to interviews that we were evaluating the DFS program to improve it. Second, it is difficult to establish temporal relationships with household wealth and food security due to the cross-sectional study design. Third, the urban model fit was poor indicating the possibility of an unmeasured mechanism and pointing to the need for more research, including qualitative interviews, to understand other potential drivers of DFS adherence in urban contexts, for example increased access to retail markets. Fourth, while bundling DFS with PDS rations were reported by the sampled population, the coverage survey questionnaire did not adequately capture this information to quantify the exact prevalence of this. However, we were able to use this insight to further examine PDS bundling in our qualitative assessments. Despite these limitations, the path models and coverage analyses provide important lessons for program implementers to improve coverage and adherence of DFS. Although not generalizable to all DFS programs and contexts, this evaluation of the UP DFS program has broader implications for the design and implementation of any nutrient intervention, especially those that use social safety nets as delivery platforms.

Insights on implementation fidelity are critical to interpret findings and inform the design of future evaluations. We used the results to inform programmatic course correction, and assess the evaluability of the program (48). Examining the DFS program in a real-world context and identifying inefficiencies in program delivery helped assess the adequacy of the program. It elucidated the extent to which the program is moving in the expected direction, and provided the opportunity for course correction, before moving on to conduct the endline evaluation. The coverage survey indicated districts which met the endline evaluability threshold **(Supplementary Table 2.4)**. It informed the selection of districts for the endline evaluation (49, 50), modifying it to focus on rural areas in the two districts that had more adherents.

Our process and findings provide important learnings for conducting and using implementation research for designing and evaluating nutrient interventions at scale. At this stage of the UP program, the potential for measurable benefits is constrained by the low rates of DFS adherence. The study reveals implementation issues that the UP program and DFS programs globally must address. Targeted efforts to improve adherence are needed – addressing product quality issues, investing in well-designed awareness campaigns that ensure behavior change (30) and strengthening DFS program delivery can help DFS programs to achieve the desired impacts on reducing iron deficiency and iron deficiency anemia.

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Table 2.1: Descriptive analysis of household and individual characteristics, stratified by location of residence

	Total		Rural		Urban		
Characteristic	**Percentage/Mean ± SD**	**N (1202)**	**Percentage/ Mean ± SD**	**N (861)**	**Percentage/ Mean ± SD**	**N (341)**	**p-value**
Average age of respondent	27.9 ± 4.6	1202	27.5 ± 4.6	861	28.8 ± 4.5	341	<.0001
Religion - Hindu (%)	84.53	1016	90.48	779	69.5	237	<0.001
Caste - Higher (%)	76.27	916	73.49	632	83.28	284	<0.001
Respondent's education (%)							<0.001
No education	28.55	342	29.05	249	27.27	93	
Primary or middle school	28.13	337	29.4	252	24.93	85	
Secondary or high school	32.2	386	33.96	291	27.86	95	
Graduate level or higher	11.1	133	7.58	65	19.94	68	
Household head's education (%)							<0.001
No education	26.6	317	30.18	258	17.56	59	
Primary or middle school	24.4	291	24.91	213	23.21	78	
Secondary or high school	28.6	340	27.37	234	31.55	106	
Graduate level or higher	20.4	243	17.54	150	27.68	93	
Average household size	7.1 ± 3.0	1202	7.1 ± 3.0	861	6.9 ± 2.9	341	0.221
Households living with extended family (%)	60.7	730	61.44	529	58.94	201	0.424
Main income source (%) *Non-agriculture*	67.2	808	57.26	493	92.38	315	<0.001
Primary light source (%) *Electricity*	82.6	962	78.37	652	93.09	310	<0.001
Primary fuel source (%) *LPG/Natural gas*	39.4	473	22.65	195	81.52	278	<0.001
Primary water source (%)							<0.001
Tube well/Bore well	78.4	942	87.22	751	56.01	191	
Piped into dwelling or yard	9.2	149	5.9	51	28.7	98	
Regularly utilizes PDS (%)	80.2	964	84.2	725	70.09	239	<0.001
Perception of PDS ration quality (%)							
Poor rice quality	17.36	155	14.52	99	26.54	56	<0.001
Poor wheat quality	6.71	61	6.46	44	7.46	17	0.732
Poor kerosene quality	1.84	12	1.69	9	2.52	3	0.587
Poor DFS quality	64.66	525	61.66	378	73.87	147	0.005
Households with any DFS stock currently present (%)	55.66	669	60.74	523	42.82	146	<0.001
Average number of salt types present in household	1.4 ± 0.5	1202	1.4 ± 0.5	861	1.3 ± 0.5	341	0.001

Abbreviations: DFS: Double Fortified Salt; LPG: Liquefied Petroleum Gas, PDS: Public Distribution System; SD: Standard Deviation;

Note: p-value indicates difference between rural and urban estimates

Table 2.2: Drivers of complete DFS adherence: Adjusted path model showing standardized cooefficients of direct and indirect pathways thorough which lower wealth households adhere to DFS use in all foods

		Total Model[1] (N = 1191)				Rural Model[2] (N = 861)			
Paths and Dependent Outcomes	**Measured Predictor**	**(1) Direct effect**	**(2) Indirect effect**	**(3) Total effect**	**(4) aOR (95% CI)**	**(5) Direct effect**	**(6) Indirect effect**	**(7) Total effect**	**(8) aOR (95% CI)**
Complete DFS adherence *(Path a)*	Low HH wealth	0.068		0.07	1.07 (1.02,1.12)	0.074		0.07	1.08 (1.03,1.12)
HH FIS *(Path b)*	Low HH wealth	0.299		0.3	1.35 (1.28,1.42)	0.308		0.31	1.36 (1.30,1.43)
Regular PDS utilization *(Path c)*	HH FIS	0.071		0.07	1.07 (1.03,1.12)	0.057		0.06	1.06 (1.02,1.10)
Regular PDS utilization *(Path d)*	Low HH wealth	0.048		0.05	1.05 (1.00,1.10)	0.048		0.05	1.05 (1.00,1.10)
DFS benefits awareness *(Path f)*	Regular PDS utilization	0.062		0.06	1.06 (1.03,1.10)	0.083		0.08	1.09 (1.06,1.11)
Complete DFS adherence *(Path e)*	Regular PDS utilization	0.244				0.239			
through regular PDS utilization (Paths d & e)	Low HH wealth		0.012				0.011		
through HH FIS & regular PDS utilization (Paths b, c & e)	Low HH wealth		0.005	0.25	1.28 (1.10,1.49)		0.004	0.24	1.28 (1.13,1.44)
Complete DFS adherence *(Path g)*	DFS benefits awareness	0.148				0.157		0.16	
through DFS benefits awareness & regular PDS utilization (Paths d, f, & g)	Low HH wealth		0.000				0.001		
through DFS benefits awareness, regular PDS utilization & HH FIS (Paths b, c, f & g)	Low HH wealth		0.000	0.15	1.16 (1.11,1.21)		0.000	0.16	1.17 (1.12,1.23)

Abbreviations: aOR: Adjusted Odds Ratio, CI: Confidence Interval, DFS, Double Fortified Salt; FIS: Food Insecurity, HH, Household; PDS, Public Distribution System. Notes & Definitions: "Complete DFS adherence" refers to DFS use in all foods; "Direct effect" shows the direct associations between measured predictors and dependent outcomes; "Indirect effect" shows mediated effects from the measured predictor through the indicated pathways on complete DFS adherence; "Total effect" – the sum of direct and indirect effects – is exponentiated to get the adjusted Odds Ratios (aOR), with 95% CI indicated in parenthesis. Effects from the urban sample are not shown here because of poor model fit; Model fit statistics for total and rural models had reasonably good fit and are shown below:

[1]Total Model Fit: P-value (Chi-square):0.004, RMSEA: 0.05, CFI: 0.99, SRMR: 0.01

[2]Rural Model Fit: P-value (Chi-square):0.003, RMSEA: 0.07, CFI: 0.99, SRMR: 0.01

Supplementary Table 2.1: Awareness levels about DFS contents

	Rural		Urban	
	Frequency (%)	N (861)	Frequency (%)	N (341)
Good for health and nutrition	9.5	82	13.8	47
Mentions both Anemia/related issues and Goiter/related issues	2.3	20	5.9	20
Only mentions Goiter/iodine related issues	1.5	13	2.9	10
Only mentions Anemia/iron related issues	0.9	8	0.6	2
Not Aware	85.7	738	76.8	262

Supplementary Table 2.2: Wealth quintile creation for separate (panel A) and combined (panel B) sample populations

Panel A: Separate wealth quintiles created for urban (N=341) and rural (N-861) sample population					
	Urban		Rural		
Wealth Quintiles	%	N	%	N	Total N
Lowest	19.9	68	20.0	172	240
Low	19.9	68	20.0	172	240
Middle	20.2	69	20.1	173	242
High	19.9	68	20.0	172	240
Highest	19.9	68	20.0	172	240
Total	100	341	100	861	1202
Panel B: Composite wealth quintile created for total sample population (N=1202)					
	Urban		Rural		
Wealth Quintiles	%	N	%	N	Total N
Lowest	2.6	9	26.8	231	240
Low	5.0	17	26.0	224	241
Middle	14.1	48	22.3	192	240
High	29.3	100	16.4	141	241
Highest	49.0	167	8.5	73	240
Total	100	341	100	861	1202

Supplementary Table 2.3: Food Security by rural and urban areas

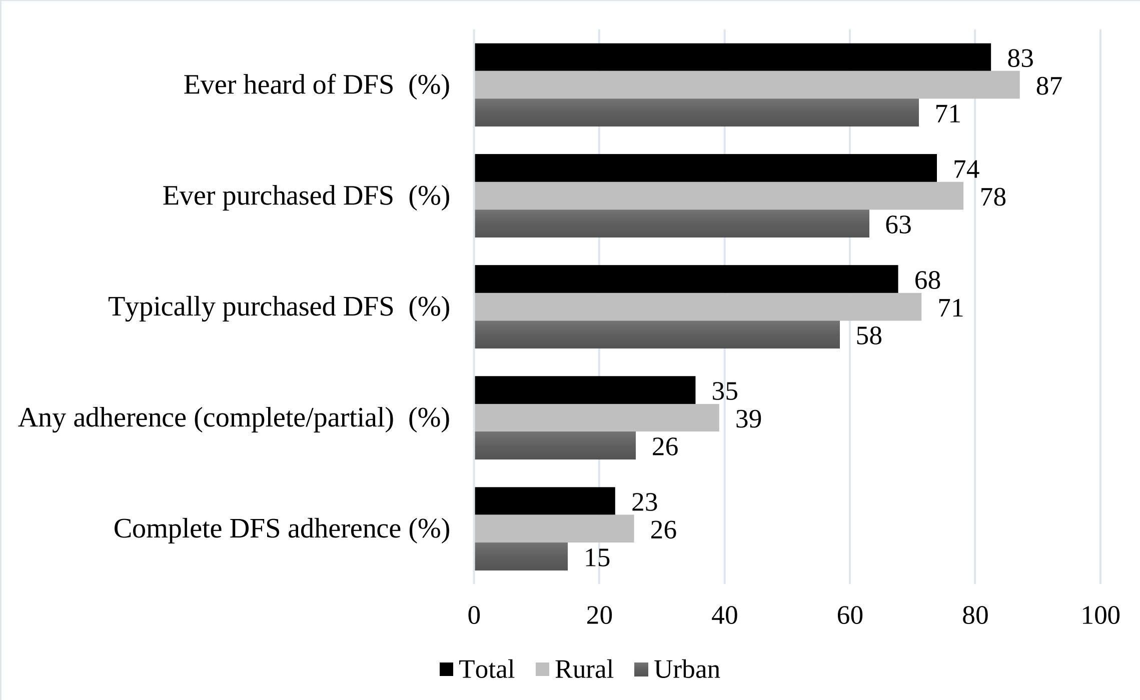
	Rural		Urban	
	Frequency (%)	N (861)	Frequency (%)	N (341)
Food secure	37.63	324	51.03	174
Mild food insecurity	13.01	112	12.32	42
Moderate food insecurity	37.4	322	28.74	98
Severe food insecurity	11.96	103	7.92	27
Total	100	861	100	341

Supplementary Table 2.4: District-level DFS adherence rates (complete or any adherence) in rural areas (N=861)

	DFS complete adherence		DFS any adherence		N = 861
District Name	Yes (%)	No (%)	Yes (%)	No (%)	
Moradabad	19.1	81.0	25.6	74.4	168
Etawah	37.4	62.6	54.6	45.4	163
Auraiya	41.1	58.9	56.1	43.9	180
Faizabad	17.7	82.3	29.3	70.7	181
Mau	12.4	87.6	30.2	69.8	169

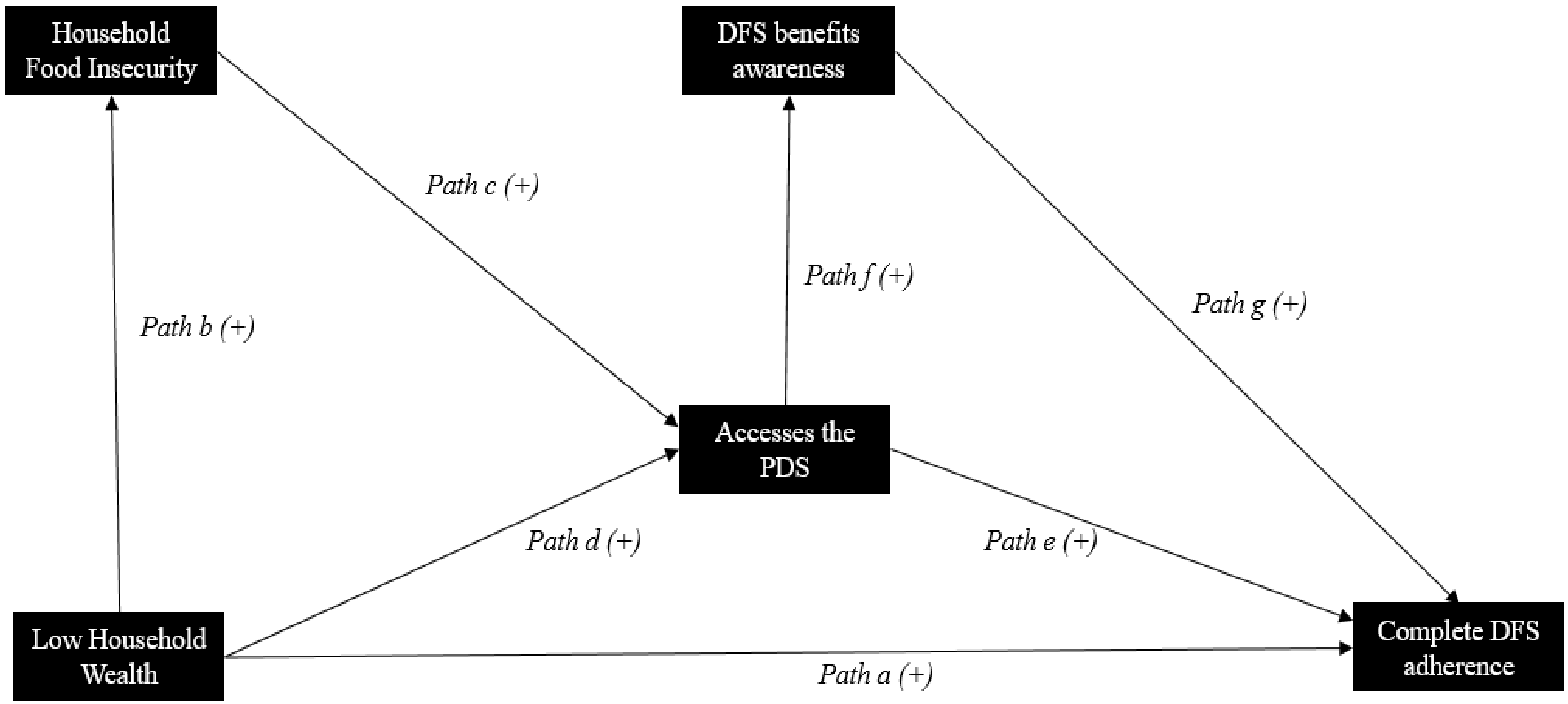
Note: Complete adherence is DFS use in all foods, any adherence is partial DFS use in some foods or complete DFS use in all foods. An a priori threshold of 50% adherence was selected for selection of a district for endline evaluation. No district met the cut-off for 'complete DFS adherence', two districts - Etawah and Auraiya - met 50% cut-off for 'any DFS adherence'

Figure 2.1: Double Fortified Salt (DFS) Program - Coverage Cascade, N=1202



Note: Each indicator in this coverage cascade was conditional on having achieved the previous one. Households reporting that they *'Typically purchased DFS'* bought DFS with their monthly purchase of rations in the Public Distribution System. *'Any DFS adherence'* included both households with "partial" and "complete" DFS adherence. Households with partial DFS adherence used DFS as a secondary salt, only in certain food or beverages. Households with *'Complete DFS adherence'* used DFS in all foods and beverages that required salt.

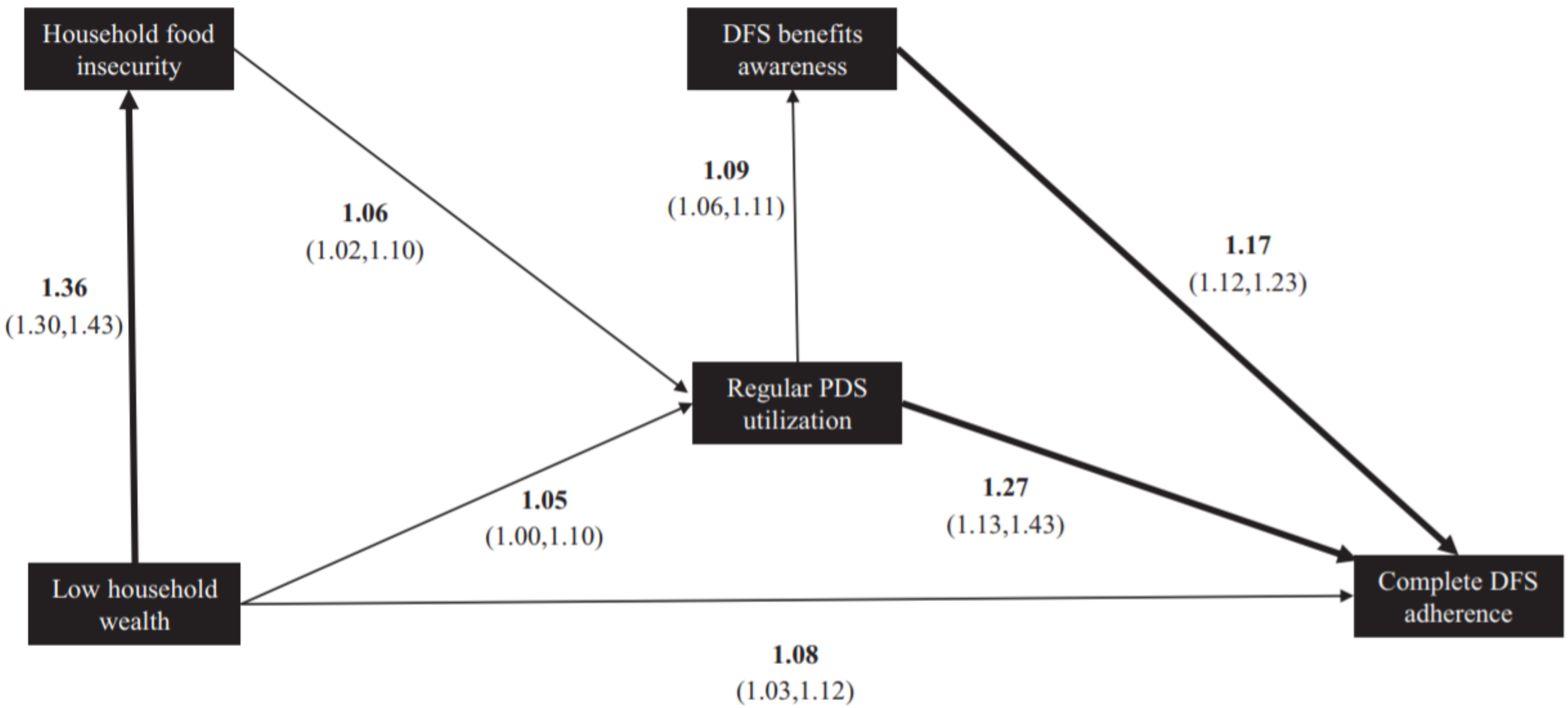
Figure 2.2: Hypothesized path model indicating measured variables, pathways and the direction of effect



Abbreviations: DFS, Double Fortified Salt; PDS, Public Distribution System

Note: Measured predictors are shown in boxes, hypothesized pathways are labelled and shown by the arrows. All hypothesized pathways have a positive direction of effect. Wealth quintiles were created and *'Low household wealth'* included the lower two wealth quintiles - wealth was measured using household assets as proxy. The Household Food Insecurity and Access Scale was used to identify moderately/severely food insecure households, who were categorized as experiencing *'Household food insecurity'*. Households purchasing monthly PDS rations were noted to have *'Regular PDS utilization'*. Households who had at least a partial understanding about DFS being beneficial for "good health or nutrition"/ "anemia prevention"/ "goiter prevention" were categorized as having *'DFS benefits awareness'*. Households with *'Complete DFS adherence'* used DFS in all foods and beverages that required salt.

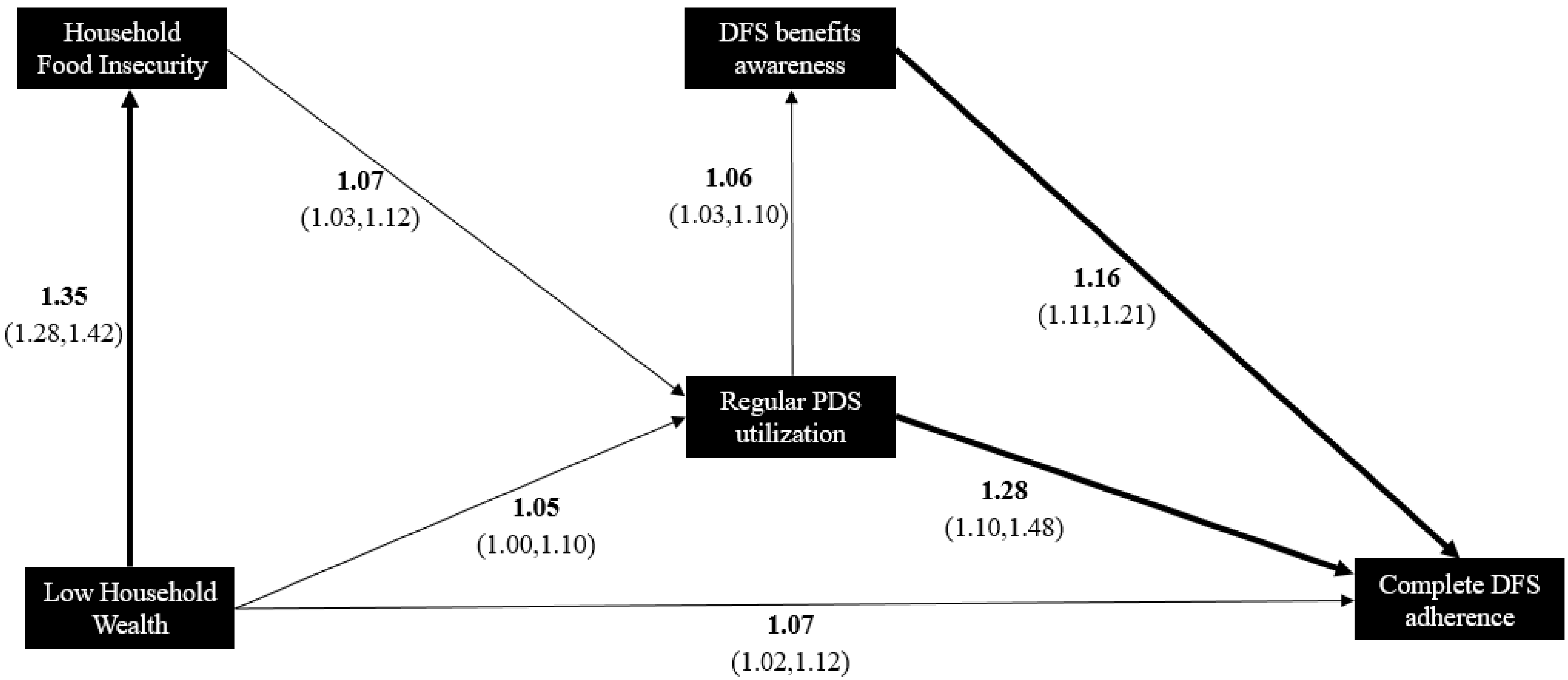
Figure 2.3: Rural path model showing standardized direct effects (N=861)



Abbreviations: DFS, Double Fortified Salt; PDS, Public Distribution System

Note: Only standardized direct effects between the measured predictors and dependent outcomes are shown in the figure. All direct effects have been exponentiated to get the adjusted Odds Ratios (aOR) and confidence intervals (95% CI) are indicated in parenthesis. Standardized indirect effects indicating mediated paths are not shown in this Figure, but can be found in Table 2. Thicker lines in the figure denote an odds greater than 10%; Model fit indices showed a good fit for this path model: P-value ($\chi2$):0.003, RMSEA: 0.07, CFI: 0.99, SRMR: 0.01

Supplementary Figure 2.1: Path Model for the overall sample (N=1191)



Standardized direct effects are shown in the figure; standardized indirect effects are listed in Table 2.2. Thicker lines denote an odds greater than 10%; Model Fit: P-value (Chi-square):0.004, RMSEA: 0.05, CFI: 0.99, SRMR: 0.01

CHAPTER 3: Making programs worth their salt: Assessing the context, fidelity, and outcomes of implementation of the Double Fortified Salt Program in Uttar Pradesh, India

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3.1. Abstract

Double fortified salt (DFS) has proven efficacy in addressing iron deficiency and anemia. However, its delivery in large-scale settings is less understood, with limited documentation of the fidelity of implementation (FOI) in DFS programs. We assessed the FOI of the DFS intervention in Uttar Pradesh, India, to improve the design and implementation of such programs that aim to reduce the anemia burden. We conducted in-depth interviews with DFS program staff (n=25) and consumers (n=23), guided by a program impact pathway. Transcribed interviews were thematically analyzed, and an adapted analytic framework documented FOI across four domains – objects of intervention, implementation staff, implementation context, and target of implementation. DFS utilization remained low due to a combination of factors including poor product quality, distribution challenges, ineffective promotion, and low awareness among consumers. While district-level staff motivation was high, frontline staff were not incentivized, and lacked supervisory support to effectively promote/distribute DFS. Adapting the DFS program to implementation realities was challenging, especially with top-down government decision-making and feedback loops. Three typologies of DFS users emerged – 'believers', 'thrifters', and 'naysayers' – who indicated differing reasons for DFS purchase and its use or non-use. The implementation of the DFS program varied significantly from its theorized program impact pathway. The adapted analytic framework helped document FOI, assess the program's readiness for impact assessments, and subsequent scale-up. The program needs product quality improvements, incentivized distribution, and stronger promotion to effectively deliver and improve the realization of its potential as an anemia prevention strategy.

Key words: Double Fortified Salt, Iron deficiency, Anemia, Fidelity of Implementation, Quality, Monitoring and Evaluation, Coverage

3.2. Introduction

Anemia is a widespread public health problem, affecting 1.93 billion people globally, and commonly caused by iron deficiency (1, 2). With debilitating effects that include adverse pregnancy outcomes (3) and impaired cognition in women and their offspring (4), anemia leads to significant losses in nations' economic productivity (4-6). The World Health Assembly (WHA) aims to address this by targeting a 50% reduction in the global anemia prevalence among women of reproductive age by the year 2025 (7). Several countries have adopted staple food fortification – the addition of nutrients during commercial processing of foods such as cereals, salt and edible oil – in an effort to attain WHA targets. It is estimated that an additional financing of $2.4 billion is needed for worldwide staple food fortification (8). Given the level of investment required, fortification programs need to be cost-effective and implemented to maximize benefit. While industrial fortification is cost-effective in addressing nutrient deficiencies (9), the process of implementing large-scale fortification programs is less studied.

In India, the *'Anemia mukt Bharat'* (Anemia-free India) campaign recommends fortification of staple foods with iron and folic acid, as an anemia prevention strategy (10). Consequently, Double Fortified Salt (DFS) – salt fortified with iron and iodine – which has been shown to reduce iron deficiency in controlled settings, was adopted by some states and distributed through their existing social safety net programs (SSNPs). Although distribution through SSNPs that reach vulnerable populations is a promising strategy to scale-up fortification initiatives, its utility as a delivery platform remains to be evaluated and, little is known about what influences DFS program delivery in real-world settings (11).

Addressing these evidence gaps requires documenting the fidelity of implementation (FOI) of DFS programs, i.e. whether programs are implemented as intended. Conducting impact evaluations on programs which have not been effectively implemented (12) can result in a Type III error (13), resulting in a failure to identify if a lack of impact is due to the intervention itself or due to poor program implementation (14). Ensuring FOI in DFS programs helps identify and resolve implementation challenges (14) prior to conducting impact assessments, which is critical for programs to realize their full potential. This increases their likelihood of translating initiatives to impacts (15), and not abandoning the program prematurely.

India's flagship large-scale DFS program was implemented in Uttar Pradesh (UP) (16) in 2017. Ten districts in UP, with a high anemia prevalence, received DFS through the SSNP called Public Distribution System (PDS). Fair price shops (FPS) operating under the PDS were used as a DFS delivery platform. All FPS in the 10 districts, serving nearly 3 million low-income households (approximately 15 million individuals), distributed DFS. An external team conducted an impact evaluation, which embedded a theory-driven process evaluation, of this DFS program. The team worked closely with the program staff to gain experiential learning (17) for the process evaluation, which included routine monitoring data collection and a midline evaluation. Using mixed-methods data, the latter highlighted how the implementation unfolded (18, 19) – the midline quantitative survey revealed heterogeneity in DFS program coverage, with villages reporting a higher level of DFS utilization than urban neighborhoods (20). This information, in combination with midline qualitative insights, helped program staff adapt across intervention districts to achieve sustainable impact.

In this paper, we present our analyses of the midline qualitative data, examining the UP DFS program's FOI, and formulate recommendations for the design and effective implementation of DFS programs in other contexts.

3.2.1. Key messages

- The DFS production, distribution, and awareness creation process documented low fidelity which influenced the perceptions of consumers and ultimately their utilization of the program.
- Several challenges identified in this program can be resolved through improvements in product quality, including effective color-masking and encapsulation of the iron-premix in DFS, and by improving motivation levels of the frontline program staff.
- The presence of 'believers' who used DFS, despite the organoleptic issues reported, suggests the potential for further expansion of coverage and utilization.

3.3. Methods

A theorized UP DFS program impact pathway (PIP) was developed through an iterative process informed by engagement with key program staff. It was used by the evaluation team to identify broad research areas for the midline evaluation. The routine monitoring process, led by the program staff, provided insights about program outputs, and the midline evaluation further explored these insights.

Briefly, the PIP **(Figure 3.1**) posited four components as key to successful program implementation: high quality product, an efficient distribution mechanism, effective training of frontline program staff, and awareness creation among consumers in households. We define 'high quality' of the DFS product broadly, as one which meets not only the exact chemical formulation of iron and iodine, but also the color-masking and encapsulation requirements (detailed in Diosady et al (16)), that make the 'premix particles' (iron premix added to iodized salt to produce DFS) similar to salt granules in appearance, even after cooking. Better awareness about DFS among consumers was expected to lead to sustained demand, subsequent purchase and continuous use of DFS, thereby ensuring impacts on nutritional and health outcomes.

3.3.1. Study sites and sampling

Five program districts were chosen using simple random sampling for the midline evaluation. From the list of villages not included in the midline survey, we selected two villages per district for qualitative research using convenience sampling (based on proximity to midline survey villages) for a total of 10 villages. Based on our midline quantitative assessments (20), we focused the qualitative research on rural areas, with higher DFS program coverage, and used this opportunity to examine experiences related to DFS use and program delivery in this context.

In each of the 10 selected villages, we interviewed a FPS owner and a community health worker (Accredited Social Health Activist (ASHA)). When multiple FPS owners or ASHAs were present in a village, one each was randomly selected. Two households were selected for interviews in the sampled villages. Following the same criteria as the midline household survey, households were included in qualitative research only if there was at least one woman of reproductive age (18-49 years) who had a child between 6-59 months; the same woman was then selected as the primary respondent (consumer) for the in-depth interview. In each district, we also interviewed a district-level program staff (District Consultant (DC)).

We considered code saturation (21) as the main principle for ascertaining sufficiency of the sample, and towards this end, three additional consumers were interviewed in one village in which we had not achieved saturation after two. We had a final sample of 48 interviews, across four types of respondents in five districts: FPS owners (n=10), ASHAs (n=10), consumers (n=23) and DCs (n=5).

3.3.2. Data collection and analysis

Four research assistants received training on the overall DFS process evaluation, interview guides, qualitative interviewing and reflexivity. They were divided into two teams, consisting of an interviewer and a note-taker. Semi-structured, in-depth interviews were then conducted in Hindi, and audio-recorded with participant permission. For interviews with FPS owners, ASHAs and DCs, the focus was on DFS program-related responsibilities and motivation levels. For the consumer interviews, we examined DFS utilization patterns and associated reasons for partial use or non-use, probing on themes around meal preparation, salt usage and experience with DFS. Daily team debriefs were conducted to help address quality of data collection, refine the interview questions or probes, identify emerging themes and assess code saturation.

The in-depth interview recordings were transcribed verbatim and translated from Hindi to English. The translated transcripts were reviewed, de-identified, and uploaded for analysis in MAXQDA. Using a thematic analysis approach, we first reviewed and memoed (22), i.e. annotated, all interviews. A set of deductive codes were identified using the PIP with additional inductive codes developed using a data abstraction matrix implemented during daily team debriefs. Codes were further refined through additional review and memoing of transcripts. From this process, a coding framework was developed and applied to all transcripts. A second coder independently applied the same codebook to a third of the DFS consumer interview transcripts, and the process was discussed to adjust the framework and identify emerging themes.

The institutional review boards at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Uttar Pradesh, and Emory University, Atlanta, GA reviewed and approved the data collection and analyses protocol.

3.3.3. Analytic Framework

As a guide for our analysis, we relied on the Implementation Science in Nutrition (ISN) framework (23), adapted from the Consolidated Framework of Implementation Research (24) to fit diverse nutrition program implementation contexts. We adapted the ISN framework as an analytic tool to examine the implementation process and document FOI in the UP DFS program across four domains (**Figure 3.2**). Specifically, under Domain 1 we examined three objects of implementation: 1) *Product*, assessed by the quality of the premix (including color-masking and its encapsulation); 2) *Price*, examined through the procurement and distribution of the intervention through the PDS; 3) *Promotion*, operationalized through awareness creation strategies. Under Domain 2, we used interview data with DCs, FPS owners and ASHAs to examine how their motivations, knowledge and skills, and levels of self-efficacy influenced intervention delivery, thereby affecting the fidelity of implementation. For Domain 3, we used emerging themes from interviews with DCs and FPS owners to gain an understanding of the implementation environment, and how it affected the DFS distribution mechanism. Finally, Domain 4 focused on the target of implementation, i.e. consumers – individuals nested in households and communities, and how they perceived the program. Specifically, we examined how community norms, household socio-demographic characteristics, and individual perceptions influenced consumer interactions with the DFS program. Here, Domain 1 (objects of implementation) affected consumer experience and regularity of DFS use, Domain 2 (program staff) influenced their DFS awareness levels and Domain 3 (program context) affected their motivations for DFS purchase.

3.4. Results

Findings from our thematic analyses, including representative quotes, are presented in **Table 3.1** organized by thematic domains, themes and sub-themes.

3.4.1. Domain 1: Objects of Implementation (Product, Price and Promotion)

Product: DFS product quality was compromised due to inadequacies in premix production. The DFS production technique, developed at University of Toronto, was transferred to India for scale-up in the UP program (16). In theory, the iron compound was to be sized to match salt granules, color-masked and encapsulated to ensure that it remains inconspicuous in salt. The premix was to be procured and mixed with iodized salt by a local salt manufacturer to produce DFS and distributed to households in the program districts through the PDS (**Figure 3.1**). In reality, processes related to premix procurement and DFS production by salt manufacturers were largely opaque, and enforceable controls on premix quality standards were absent (25). Even though the product met stipulated quality specifications as per the Indian standards, these pertain only to the chemical content of the premix, and do not provide regulations on color masking or encapsulation. Consequently, inadequacies in color masking and encapsulation of the premix particles were common, making it easily distinguishable from salt granules (**Table 3.1**, Sub-theme: premix quality).

Price: FPS owners implemented alternative distribution strategies to recover costs incurred in DFS procurement and transport. The PDS distributes subsidized rations - rice, wheat and kerosene fuel – every month to low-income households through the FPS network. In the 10 DFS program districts, the UP government added the DFS as an additional item to the PDS. Every household with four or few members received one DFS packet (1kg) and those with more than four members received two. The government procured and transported PDS rations and DFS to a decentralized network of warehouses. Each program district had warehouses present in different blocks (smaller administrative area), and FPS owners purchased their monthly ration and DFS quota from their respective block-level warehouses. DFS quantity allocation for every FPS was pre-determined by the UP government, and FPS owners were required to deposit the full payment in advance.

With several households finding "*black*" premix particles in DFS, FPS owners found it challenging to sell the product and recover costs. While procurement and transportation costs incurred for high-demand items like grains and kerosene were easily recovered, DFS sales were neither incentivized nor were expenses reimbursed (**Table 3.1**, Sub-theme: quantity and costs). Moreover, DFS purchase orders were never adjusted for lower demand, forcing FPS owners to procure all allotted quantities irrespective of stockpiles already held in the shop. Consequently, FPS owners adopted strategic cost-recovery measures such as bundling where DFS and other highly desired rations were sold as a package instead of individual items (**Table 3.1**, Sub-theme: DFS bundling).

Promotion: In spite of a programmatic push for DFS promotion, trainings for FPS owners and ASHAs had limited effectiveness. An over-reliance on awareness creation was necessitated with consumers finding conspicuous premix particles in DFS. However, the program was unprepared to incentivize promotion activities or invest in a dedicated workforce to support the more intensive DFS promotion efforts (**Table 3.1**, Sub-theme: intensity). Therefore, in the absence of effective communication, consumers finding "black" premix particles and related food discoloration saw it as a deterrent from continuing DFS use.

FPS owners were provided an information board, with details about DFS prices and available quantities for households, and a one-time block-level training was conducted. During these training sessions, FPS owners were asked to proactively inform DFS purchasers to anticipate a darkening of foods and to share strategies such as altering the timing of salt addition while cooking to alleviate the discoloration. Trainers used examples of food darkening while cooking in cast iron pans in an effort to normalize it, and reinforced messages around safety and benefits of DFS. However, some FPS owners found the training sessions to be less credible as officials from the PDS department did not routinely attend. Additionally, follow-up of actions promised at the training went unfulfilled, causing some FPS owners to believe that the session was held only as a "*formality*" (**Table 3.1**, Sub-theme: FPS owners training).

ASHAs also attended a training session at the inception of the program, where they were informed about the DFS program and its benefits. However, not all ASHAs recalled attending a DFS-specific training and confused it with their routine job trainings from the health department that often included topics related to iodized salt. DFS-specific message recall was poor among these ASHAs (**Table 3.1**, Sub-theme: ASHA training), and follow-up trainings with DCs did not take place after the program inception. We found that the DFS training sessions lacked specificity around message content and target households. ASHAs were simply asked to add DFS communication onto their other awareness creation efforts during home visits, but were not provided any job aids or incentives for taking on this additional work.

3.4.2. Domain 2: Implementing Organization and Staff

District-level staff: District consultants (DCs) had strong faith in the DFS program and believed that the program needed more time to become successful. They were highly motivated individuals who had complete confidence in the program, maybe naively so (**Table 3.1**, Sub-theme: DC motivations). They had a vision for programmatic success, believing that accepting a new product like DFS will take time in the community (**Table 3.1**, Sub-theme: DC vision). They were accountable for the overall implementation, with responsibilities across two levels. At the block-level, DCs visited warehouses to monitor DFS supply and collect DFS samples for laboratory assessments of levels of iron and iodine. They also liaised with FPS owners to resolve any supply disruptions or procurement lags and organized the one-time training session for FPS owners and ASHAs at the time of inception (**Figure 3.1**). At the community level, DCs visited FPS owners to collect routine monitoring data on DFS sales and discuss any implementation challenges faced at the local level. DCs also conducted short exit interviews at the FPS, with consumers, to collect program monitoring data on awareness and use of DFS.

Frontline staff – motivation: DFS trainings failed to motivate some FPS owners. In spite of attending DFS training sessions and being knowledgeable about the program benefits, most FPS owners wanted to reduce their responsibilities, with some believing that ASHAs should play a bigger role as DFS is intended as a health intervention (**Table 3.1**, Sub-theme: FPS owners' (lack of) motivation). They were demoralized and frustrated about being forced to both procure and sell DFS. They wanted a reduction in DFS quantities by 50% and introduction of other subsidized commodities, such as soap or detergent, in its place. FPS owners found that most consumers raised problems with food discoloration due to the "*black*" premix particles, even after telling them about DFS benefits. They felt that the product quality needed improvements, and addressing discoloration issues will make it easier for them to sell DFS.

Frontline staff – beliefs and self-efficacy: Awareness creation efforts by FPS owners and ASHAs were influenced by their knowledge and perceptions about the program, and levels of self-efficacy. The FPS owners we interviewed had varying degrees of success in DFS promotion. A few of them adopted DFS promotion strategies such as highlighting the use of DFS in their own homes, thereby building community's trust in the product. They leveraged their training knowledge to effectively communicate strategies to minimize discoloration and address safety concerns, thus encouraging many people to utilize DFS (**Table 3.1**, Sub-theme: successful awareness creation). Other FPS owners, who did believe in the DFS benefits but held a more paternalistic view, tried to convey the message that the government intervention is meant to improve the health and well-being of the people. However, this group of FPS owners failed to recognize the agency of consumers to accept or reject a new product and therefore, could not effectively connect with their communities (**Table 3.1**, Sub-theme: unsuccessful awareness creation). The same training messages on DFS benefits, safety and strategies to minimize discoloration had a much lesser impact in this context. A few FPS owners lacked the self-efficacy to push messages around DFS benefits to the public without support, and advocated for a stronger awareness campaign in villages led by others (**Table 3.1**, Sub-theme: low confidence).

Most ASHAs appeared to have greater self-efficacy (**Table 3.1**, Sub-theme: high confidence) and were aware of the premix in DFS. Several ASHAs communicated DFS benefits to community members during and after their house visits for routine immunization and pre-natal checkups. They were confident communicators, and were able to address most people's apprehensions about DFS, convince them about the need to consume DFS to prevent anemia and goiter. Three ASHAs we interviewed were unaware about the iron content in DFS, but nonetheless noted promotion of DFS use in their communities in an effort to address goiter.

3.4.3. Domain 3: Implementation context and enabling environment

The overall implementation context and policy environment had three implications for the UP DFS program. First, the policy context made it challenging to address some of the implementation issues. The current regulatory standards focus on the chemical composition of DFS, and need to be broadened to include color masking, encapsulation and other production aspects that affect consumer acceptance of the product. Enforcing product quality controls will remain difficult from a programmatic perspective, unless the regulatory standards and their enforcement are strengthened to include not just the safety, but also the physical appearance of DFS. Second, long feedback loops and bureaucratic channels to reach government officials delayed incentivizing promotion strategies (**Table 3.1**, Sub-theme: bureaucratic process). Third, some FPS owners suggested a simultaneous introduction of DFS through privatized retail markets, as a strategy to boost DFS sales in their own FPS. This strategy seemed more lucrative to FPS owners for their own DFS promotion (**Table 3.1**, Sub-theme: PDS vs. Retail). They believed that PDS cardholders perceived state-subsidized products to be of lower quality than their full priced private market alternatives, and thereby considered the latter as more aspirational.

3.4.4. Domain 4: Target of Implementation (Individuals, Households, Community)

Community perceptions about the government influenced individual engagement with the DFS program. Some households revered and trusted the government, leading them to purchase and use DFS. Others remained fearful or frustrated, causing them to seek out alternate sources of information and validation regarding DFS safety after noticing the "*black*" premix particles.

We identified three emerging typologies of the consumers for the DFS program, based on their perceptions about the program, awareness about DFS benefits, experience with DFS, and subsequent engagement with the intervention. We classified these typologies as 'believers' (n=4), 'thrifters' (n=10) or 'naysayers' (n=9). They had similar socio-demographic characteristics (**Table 3.2.1**) and we compare their responses including representative quotes about DFS perceptions (**Table 3.2.2**).

Believers: 'Believers' considered DFS as beneficial to health and adopted mitigation strategies to overcome any adverse organoleptic experiences. 'Believers' were mostly convinced that the DFS program was introduced by the government for their benefit *(***Table 3.2.2**, *Believer Quote (BQ): 1)* and considered DFS to be a "*good salt*" *(BQ 4).* They had a positive attitude towards DFS after hearing about its benefits from either the local doctor/ASHA or the FPS owner in their village. While DFS bundling was a reason some of them purchased DFS *(BQ 2)*, all 'believers' used DFS in most, if not all, their food preparation. During cooking, they found that DFS caused food to turn *"slight[ly] dark in color*" *(BQ 5)* but continued its use because of its benefits *(BQ 3)*. Some 'believer' households adopted strategies to mitigate discoloration, for example "*add[ing] more turmeric*" *(BQ 12)* or sprinkling DFS only on top of prepared food instead of adding it while cooking. One 'believer' found that that the taste altered *"after the dish has cooled down" (BQ 7),* but none of the believers perceived any side-effects from DFS use *(BQ 8)*.

Thrifters: 'Thrifters', purchased DFS only because it was bundled with other commodities, and used DFS when they could not afford to purchase other salt in the retail market *(***Table 3.2.2**, *Thrifter Quote (TQ) 2).* While some knew of DFS' iron content *(TQ 3),* most had no awareness about the "*tiny black crystals*" and considered these to be limestone particles or "*Nirma*" (local detergent brand), based on its texture *(TQ 4)*. 'Thrifters' predominantly preferred and used *kada namak* (crystal salt), a cheap locally available unrefined salt, for all their food and beverage requirements. Crystal salt had to be washed and crushed before use; some families mixed in DFS with the crushed salt, while others simply stored DFS as a back-up option to be used when they ran out of readily crushed crystal salt *(TQ 9)*. A few of them used *"the filter to get the pure salt*" from DFS packets by separating the premix particles *(TQ 12)* and some others kneaded dough with DFS, to make *rotis (*flatbread*)* or *pooris* (deep-fried flatbread), where discoloration was minimal. They avoided using DFS while cooking vegetables or lentils as the discoloration was more prominent, especially when the food wasn't consumed immediately after cooking. They hesitated serving discolored food to guests and relatives, saying "*it doesn't even feel good*" *(TQ 6),* and family members were ashamed to open their packed *tiffin* (lunch) in front of others due to the dark color. One user also noted that DFS watered down the food and *"everything became tasteless" (TQ 7)*. Some family members in 'thrifter' households experienced "*itching*" after DFS use *(TQ 8),* and therefore refrained from using it. However, many recognized that these rashes may not be caused by DFS use, but could be due to external factors (exposure to sun or seasonal allergy).

Naysayers: 'Naysayers' had apprehensions about DFS and mostly used "*Tata salt*" which was available in the retail market *(***Table 3.2.2**, *Naysayer Quote (NQ): 1)*. After initially trying DFS, 'naysayers' found the food discoloration unacceptable, saying "*the program should take such a step so that the food will look good*" *(NQ 12)*. Most of them had no awareness about DFS contents *(NQ 4, NQ 5)* and considered it to be mixed with impurities, such as "*pebbles*". A few 'naysayers' also found that cooking with DFS made their food bland as it led to "*melting*" of vegetables *(NQ 7)*. Some thought that DFS made their food bitter, but one participant mentioned that this could be a perception that "*settles in the mind*" after seeing the food discoloration *(NQ 7)*. Another participant mentioned that DFS makes her family "*unhealthy*" *(NQ 10)* and two 'naysayer' households reported that everyone in their family, *"even our little child",* suffered from rashes *(NQ 8, NQ 9)*. Unlike 'thrifter' households, 'naysayers' believed that it was DFS use that caused rashes, and completely discontinued its use. In spite of non-use, these participants had to continue purchasing DFS due to PDS bundling *(NQ 3)*. As DFS stock accumulated in their homes, they mixed DFS in cattle feed *(NQ 11)* and/or scattered it in agricultural fields to address worm infestations.

3.5. Discussion

Establishing the fidelity of implementation (14, 26-29) prior to impact assessments by proactively assessing perceived product quality and measuring program coverage/use are essential. Our documentation of the FOI in the UP DFS program revealed important differences between what was intended as per design in the PIP and what was actually implemented in the program districts. Using the PIP, the FOI in the UP DFS program was monitored across 1) product quality, 2) the distribution mechanism, 3) awareness creation, and 4) consumer perspectives. Applying the ISN framework as an analytic guide, we explored why there was low utilization of DFS (20), and observed three emerging typologies of DFS users who had varied experiences with the program.

DFS quality compromises affected the overall fidelity of implementation, and resulted in low utilization levels, with only a small proportion of DFS purchasers – 'believers' – continuing to use DFS in most or all foods, and adopting mitigation strategies to overcome discoloration issues. The scale-up of DFS interventions in India was emboldened by the successful implementation of universal salt iodization (16). The latter's accomplishment was mainly due to it being a passive intervention, requiring minimal behavior change to switch to using iodized salt. While the DFS formulation used in the UP program was designed to remain equally passive in theory, DFS that was eventually produced at scale, procured and distributed through the PDS had conspicuous premix particles. Cooking with DFS led to food discoloration, therefore making it a less desirable product for consumers of the UP program.

Bundling of DFS was a cost-recovery strategy adopted by FPS owners to cope with low product demand, where the sale of all other subsidized rations were made conditional upon DFS purchase. This bundling, coupled with food discoloration issues, led consumers to perceive DFS as an inferior product. With several households purchasing DFS only to obtain the other subsidized PDS rations, purchase rates stayed high but failed to translate to equally high utilization. This highlights a missed opportunity, because the DFS program did manage to effectively reach the most vulnerable consumers but did not convert 'thrifters' and 'naysayers' into regular DFS users. Some FPS owners suggested alternate distribution of DFS through retail markets, perhaps due to the difficulties faced by them to recover DFS costs. Although similar market-based strategies have shown to be successful in other contexts (30), an expansion of DFS distribution though private markets might be premature unless there are improvements in the product quality.

Training of frontline staff was originally designed to be a one-time activity, requiring low time and resource investments. This would have been sufficient had the premix maintained high quality. However, DCs had to quickly adapt their training sessions to better suit implementation realities. FPS owners and ASHAs were trained to proactively address the DFS-led food discoloration and encourage behavior change to minimize discoloration, in addition to reiterating the safety and benefits of using DFS. However, our results suggest that there were differences in attitudes, perceptions, motivations and self-efficacy levels in FPS owners and ASHAs, which argue for a segmented training approach with these two frontline implementers to ensure that the needs and motivations of each are addressed.

DFS promotion efforts had limited success in creating awareness around product benefits/safety and increasing product demand/desirability. Best practices in nutrition behavior change highlight how successful interventions integrate strong promotion campaigns (31). These interventions demonstrate the need to conduct multiple home visits (32), or incentivize ASHAs (33-35), organize interactive cooking demonstrations (28) and tasting sessions (36) or provide supportive supervision (27, 34) and refresher training sessions. DFS promotion strategies did not originally plan or budget to do this and consequently, these efforts did not increase utilization levels. It is important to acknowledge here that while DFS promotion efforts are important to normalize food discoloration experienced in UP, they can only be a short-term solution in improving implementation outcomes. The sustainable solution would be to improve product quality, and the DFS production technology is continuously evolving (16, 37, 38) to attain this – perhaps future programs will not face the discoloration challenges observed in UP.

Although we demonstrate the use of the ISN framework as an analytic tool in this paper, using it as a design framework to rigorously assess program implementation and/or design more effective delivery may have additional utility. It is important to also highlight that the sampling of interview participants for this qualitative research was restricted to rural areas, and several stakeholders linked to the program may not have been interviewed.

3.6. Conclusion

The UP DFS program faced implementation challenges that were identified and addressed, to the extent possible, during routine program monitoring and the midline evaluation. However, some bottlenecks remained unresolved, and continued to influence the FOI of the program –product quality improvements were essential, frontline staff needed incentives and streamlined training, and promotion efforts (albeit a stop gap measure) required higher investments in the interim. With the UP DFS program documenting a low FOI, subsequent impact assessments were conducted only in a sub-sample of intervention districts where the potential for impact was higher, based on DFS utilization estimates from the midline quantitative survey, carefully designed to maintain objectivity and evaluation rigor.

As new fortification programs are implemented in multiple contexts, our approach of using the ISN framework to document program fidelity can be replicated or modified to evaluate implementation outcomes and support rigorous program design to achieve sustainable impact. We hope this use of implementation research to course correct programs can maximize their potential in addressing the anemia burden, and ensure that DFS programs are worth their salt.

Chapter 3: References

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Table 3.1: Thematic analysis of Domains 1-3, using the adapted analytic framework of Implementation Science in Nutrition

Domain 1 - Objects of Implementation		
Theme	**Sub-theme**	**Quote**
Product	Iron premix quality	DFS consumer: *Something is mixed which looks black in colour. When you open it [the DFS packet] you will see the black granules which when dissolved makes food black.*
Price	Quantity and costs	FPS owner: *No one wants to take DFS on his own will... since we are getting the allotment, we have to helplessly tell them to take it. From that salt we don't get any commission…sometimes we find torn salt packets, and we have to bear the amount of those because no one takes torn packets. In a family even if one person is there, he is also given with one kg of salt in a month…so in total, he/she is given 12 kg of salt in a year…so how will one person use those 12 packets of salt in a year?"*
	DFS bundling	FPS owner: *They will have to take the salt…they at least have to take one packet of salt….those who don't take 2 packets, they take one. [But if they refuse to take even one] then I won't give ration.*
		FPS owner: *There was a meeting by the FPS owners to tell [higher authorities] that we won't take DFS. But then he [the official] said that it is compulsory to take DFS, we were bound to take that. They say if DFS is not taken, then don't give them the ration. They tell us to distribute it [DFS] anyhow… distribute it to even to those people who do not have a [PDS] card. First we try to convince them [PDS cardholders], but if they do not agree we have to put in a condition that we will not give the ration.*
Promotion	Intensity	DC: *There is only one weapon of IEC [information, education & communication]*
		DC: *ASHAs do this [DFS promotion], but they have a heavy work load…they are working for DFS, but can't focus much*. During ration distribution, *they [FPS owners] communicate with those who have some complaints. [But] because they have to collect the money, maintain the PDS card, fill out forms...they already have a high work load…if we expect that he will make each and every one understand [about DFS benefits and safety], then it can't be possible…we can't force them too, because they already have lots of work.*
	FPS owners training	FPS owner: *Some officers had come at the block-level and had conducted a training session…they were telling us that we have to enforce this thing [DFS], and we have to [create] awareness [among] the people about this salt.. In that training, they had given us a lunch packet, a diary, and a pen. After that, all formalities were completed. They had said, 'We will come to your village, we will do meeting and street-plays through which we will make people aware about DFS'. It has been seven to eight months since they said that, but* no one has come *till now*
	ASHA training	ASHA: *We were informed that it is an iodized salt and the people should eat this. In the training they said this salt is very good, it increases the stamina of ours, so we must eat it. This is a salt with small particles and it contains iodine, calcium, etc. I was given the responsibility that we have to inform by doing door to door campaign. We tell households that they should eat this salt because it contains black elements and provides strength to the body, "If you will eat this salt then it will give more benefits to your health, it will give strength to your body". Most of the people might be knowing about this. They might be eating it…but we don't know because we only tell them [about DFS] but don't go inspect whether they eat it or not."*

Domain 2 - Implementing Organization and Staff		
Theme	**Sub-theme**	**Quote**
Motivation	DC motivations	DC: *This is a nice program and it should continue…It is really a good program as it is concerned with eradicating anemia. If this will continue in a proper manner, then the problem of anemia will definitely be solved.*
	DC vision	DC: *For improving the implementation of this DFS program more time and manpower is needed …and the second thing is incentives for FPS owners…incentives also for community health workers. Look, ASHA is an incentive-based worker and without any incentive she will not do anything.*
	FPS owners' (lack of) motivation	FPS owner: *If the main focus of this program is to eradicate anemia, then DFS should have been distributed by community health centers and ASHAs. The only work of a FPS owner is to distribute the rations to the public. Who uses DFS and who doesn't -* *we have no business with that.*
Knowledge & Skills	Successful awareness creation	FPS owner: *I told them that the black content is iron and that it will address anemia in our bodies. Some agreed, some did not. At the start, even my family members said the curry becomes black. I asked them to cook in iron utensils using any other salt, 'You will know why it becomes black. Cook in iron utensils using any salt and keep it for some time'. So we removed people's apprehensions by saying that you make food in iron utensils and keep it there for some time. It will also become black. Then the people got to know that it [food darkening] is because of iron. Almost 50% households are using [DFS]…those who see that we are eating [DFS] and that we are not having any side-effects.*
	Unsuccessful awareness creation	FPS owner: *We also tell people to put this salt after the dal or curry is done…so that the color of the curry or dal does not turn to black, but they don't obey our instruction…so what can we do with this?*
		FPS owner: *It is only black in color, who looks in the evening? Eat it. What is the problem?*
Self-efficacy	Low confidence	FPS owner: *There should be awareness campaigns for the public, doctors from government hospitals should be present and teams should be stationed in villages to spread the information. We, FPS owners, will support it completely. The benefits of DFS should be explained and the general public should be informed. If we, FPS owners, tell about its benefits nobody will trust us. If others put in [DFS promotion] efforts, then it will be successful. Since I own and operate my shop, I will always tout my products as good…the public will think that since DFS is coming to us, we have to sell it somehow...they will think that I am trying to sell or get rid of DFS.*
	High confidence	*ASHA: Sometimes the people also question us, "why do you tell us these things?", but we explain everything to them after which they understand. Among 10-12 people there are 1 or 2 who don't want to understand our words, but when they see that the people near them are using DFS they also start to use it. There are some people [with whom] if we explain a little, they understand it, but there are others [for whom] it is very hard to explain about DFS. When we explain to them repeatedly, they understand everything…that DFS contains iron and iodine. To prevent anemia, it is essential that the people should eat green vegetables…we tell them "if you will eat all this, then anemia can be prevented", but the problem is that due to the economic condition of poor people they can't eat all this. We have made them aware about DFS when we visited their homes, and the FPS owners also tell them. But there are some rich people who are not ready to eat DFS…For them, it does not matter that we explain or not…Some people are totally rigid that DFS is not good, so they don't eat it. They are*

		not ready to accept DFS no matter what. They eat the iodized salt which is available in the [retail] market. Otherwise, all other people eat DFS.
Domain 3 - Implementation Context & Enabling Environment		
Theme	**Sub-theme**	**Quote**
Governance	Bureaucratic process	DC: *We assure the FPS people that discussions are going on in the administration and it [change] will come as soon as it is implemented*
	PDS vs. Retail	FPS owner: *People think that the government is giving a sub-standard thing… it is given at the FPS for free or INR 2 or 3, and they think that it is rubbish*
		FPS owner: *If DFS is also sold at INR 20 in the market, then the people will riot to buy it from me... it has come directly to me, people don't understand the value. If it is sold in the market, then the public will think it is a very good salt*

Table 3.2.1: Descriptive characteristics of DFS end-users, by typology

Characteristics	'Believers' (n=4)	'Thrifters' (n=10)	'Naysayers' (n=9)
District-wise distribution(n)			
Auraiya (4)	1	3	-
Etawah (7)	1	4	2
Faizabad (4)	1	1	2
Mau (4)	-	-	4
Moradabad (4)	1	2	1
Average age (years)	25.9	26	25.2
Education level			
No schooling	-	2	1
Primary school	2	3	4
Secondary school	-	3	-
High school	-	-	2
Graduate level	2	2	2
Average # of children	2.8	2.8	1.9
Average HH size	7	7.3	7.1

Table 3.2.2: Thematic Analyses of Domain 4 - Target of Implementation (Individuals/Households/Communities)

Theme	**Typologies of DFS users**		
(Sub-theme)	'Believers' (n=4)	'Thrifters' (n=10)	'Naysayers' (n=9)
Perception about DFS (Trust in the program)	Believer Quote (BQ) 1: *Everyone in our neighborhood is eating that salt. We think that the government is doing it for our benefit. We just don't know what is in it.*	Thrifter Quote (TQ) 1: *We have to use it since we are getting it. We hope that it is for our benefit. And that is why we eat it.*	Naysayer Quote (NQ) 1: *If something like the Tata salt [retail brand] comes, then everyone will eat it. We don't know what is being mixed in DFS.* NQ 2: *Only money matters to them. They [FPS owners] bring DFS for money only.*
Motivation for DFS purchase (Bundling of DFS with PDS rations)	BQ 2: *We are eating it just because the government is providing it. [We are using] DFS and we haven't used crystal salt since then. I don't like DFS...[we still consume] maybe because it is available at a cheaper rate. We cannot just throw it because we are purchasing it with our money.*	TQ 2: *They give it [DFS] to us forcefully, they tell that if you don't take this salt then we don't give you kerosene also. So, how can we refuse for the salt? Kerosene is essential for our fuel. They [FPS owners] give this [kerosene] to the rich people only, but they force the poor people to take the salt. They are telling that these packets are coming for you…so we have to give these packets to you.*	NQ 3: *They give us forcefully. If they'll give us forcefully, then what can we do? They say if you'll not take salt, then we'll not provide you ration.*
Awareness about DFS (DFS contents and its benefits)	BQ 3: *My mother in law says that DFS is beneficial to health*	TQ 3: *It has iron. Maybe because of the tiny black crystals which is there. Because of it only the vegetables become black. They [public] don't understand this and many houses throw it. It is written over here [in the DFS packet]...if you read it you will know.*	NQ 4: *When I used it, it settled down and only the powder portion came up. So once I put it in a glass of water, it floated on the top and some red colored element settled down in the bottom. By eating that, people have stone in their stomach.*
	BQ 4: *There are least chances of getting diseases from its use. It is a good salt…pure salt… The doctor said that it is good for health and digestion.*	TQ 4: *It feels as if there is 'Nirma' [local detergent] in the salt...it looks blue black.*	NQ 5: *It gets black because something is mixed in it. I don't know what it is but DFS has vitamins and iodine. These all things are mixed in it but because of the taste and colour no one eats it. It is written on the packet that iodine is mixed in it, it is good for health and the body. But then no one likes to eat it in the family….when you open it*

Theme (Sub-theme)	Typologies of DFS users 'Believers' (n=4)	'Thrifters' (n=10)	'Naysayers' (n=9)
			you will see the black granules which when dissolved makes it black.
Experience of DFS: (Organoleptic issue – Color)	BQ 5: *It [DFS] has something of black colour in it that darkens the dishes. It is just that the colour of the curry turns black…slight dark in colour*	TQ 5: *It destroys the food...the food color becomes black due to DFS. So people do not eat this...If it remains normal then everyone will eat this salt.* TQ 6: *When any relative comes over, it is an embarrassment to serve a black vegetable. It won't look good, and it doesn't even feel good. When you make potatoes then even the cauldron even becomes black.*	NQ 6: *It makes the vegetable black …completely [black]…If we make DFS fine by grinding with jeera [cumin seeds] and ajwain [carom seeds], then also it becomes black. In any pulses or anything when you put it then the colour of the turmeric vanishes and only black is left. So it is not all good to see…At home they say, "the vegetable is not good, it is black what have you done?!"*
Experience of DFS: (Organoleptic issue – Taste)	BQ 6: *The taste is not that bad. We have been using it for so long, nothing has happened to us yet, and its taste is overall good.* BQ 7: *This salt tastes something when the dish is freshly prepared and tastes something else after the dish has cooled down*	TQ 7: *When we add this salt in our food, our spices become watery instead of thick. It seems like something fell in it. When we add this salt in our curry we don't get the taste of any ingredients, meaning we don't get the taste of vegetables or spices - everything became tasteless.*	NQ 7: *When you see that the vegetable is black...so you don't like it and it settles in the mind that the vegetable is not good in taste…When you put it [DFS] in vegetables, it tastes like water - bland. The vegetables start melting, [as in] it gets overcooked, and if you just serve it in the plate then water releases because of the use of this salt. The iodized [Tata] salt doesn't make the vegetable bland, we use that salt from the very start so we are accustomed to its taste.*
Experience of DFS: (Perceived side effects)	BQ 8: *It's been around a year since DFS is being given…we have been using it since then. Other people complain that it*	TQ 8: *It causes itching. This salt doesn't suit me. When I eat this salt, I start itching. Everyone doesn't get itching. Just that it suits someone and doesn't suit someone else. My*	NQ 8: *Everyone had that itchiness; even our little child had rashes.*

Theme (Sub-theme)	Typologies of DFS users 'Believers' (n=4)	'Thrifters' (n=10)	'Naysayers' (n=9)
	caused rashes and such. But me and my kids are using it since then and don't have any complaints about it	*brothers-in-law and my father-in-law eat it. Nothing happens to them. It doesn't suit only me. May be I got [rashes] due to [an] allergy. He [the doctor] said it's due to allergy and to protect myself from sun and water...I eat DFS, but in a very low quantity. I use crystal salt [in dishes] and if more is needed then a bit of that salt [DFS].*	NQ 9: *When they gave that salt to us, we used it but when it started causing rashes, we stopped using it. The whole village suffered from rashes. Nobody is using that. If it suits them, they eat and if it doesn't, they don't eat. When we used that salt, rashes appeared and when we stopped using it, then rashes also disappeared.*
Regularity of DFS use (Usage in food)	BQ 9: *There are two ways of using salt. For wet food I use crystal salt after cleaning it. For dry food I use the government's [DFS].* BQ 10: *We use DFS when the salt is less in food [to sprinkle on top].*	TQ 9: *We don't like DFS but sometimes we eat it when crystal salt gets finished. Because DFS contains very small particles, we can't wash it. If we will wash it then it will get dissolved with the water. In some packets of salt we find some particles which look like stone.*	NQ 10: *That salt [DFS] makes us unhealthy...We don't like this. About 2 to 3 months ago, we were eating DFS, but now we are not eating it.*
Regularity of DFS use (Usage other than food)	BQ 11: *We eat DFS, we also add it to buffalo feed and still have some DFS remaining*	TQ 10: *We wouldn't throw it. We use it sometimes in the fodder that we feed the buffaloes.* TQ 11: *Because this salt is turning the food black, people throw this salt in agricultural fields…Once seven packets of salt were left over in our home for a long time, so we also threw those DFS packets in the field like other people. We put it in the field because the paddy is affected by insects.*	NQ 11: *If they [other villagers] have buffaloes, then they feed it to their buffaloes. But we don't have any cattle; we don't have agricultural land, so we don't have any cattle…We just throw it away in the pond…6- 8 packets.*
Mitigation strategies (Overcoming	BQ 12: *It blackens the food when added. It blackens the yellow colour of dal. But still we use it…for yellow colour we*	TQ 12: *We have to use the filter to get the pure salt. We put it in water, the black thing settles down and becomes like lime…tight…it is not*	NQ 12: *Dal becomes less black and the vegetables becomes more blackish in colour. It is visible in the curry with spices. If we consider palak [spinach] curry, it does not become black*

Theme (Sub-theme)	Typologies of DFS users 'Believers' (n=4)	'Thrifters' (n=10)	'Naysayers' (n=9)
organoleptic experiences)	*add more turmeric so that it hides the blackness of salt*	*able to mix fast….and we use the salt that remains.*	*because it is already dark in colour. But in curry with spices which are yellow in colour, they become black. The program should take such a step so that the food will look good...it shouldn't look black. There is no problem in the taste.*

Figure 3.1: Theory based Program Impact Pathway: DFS program in Uttar Pradesh, India
(A simplified version)

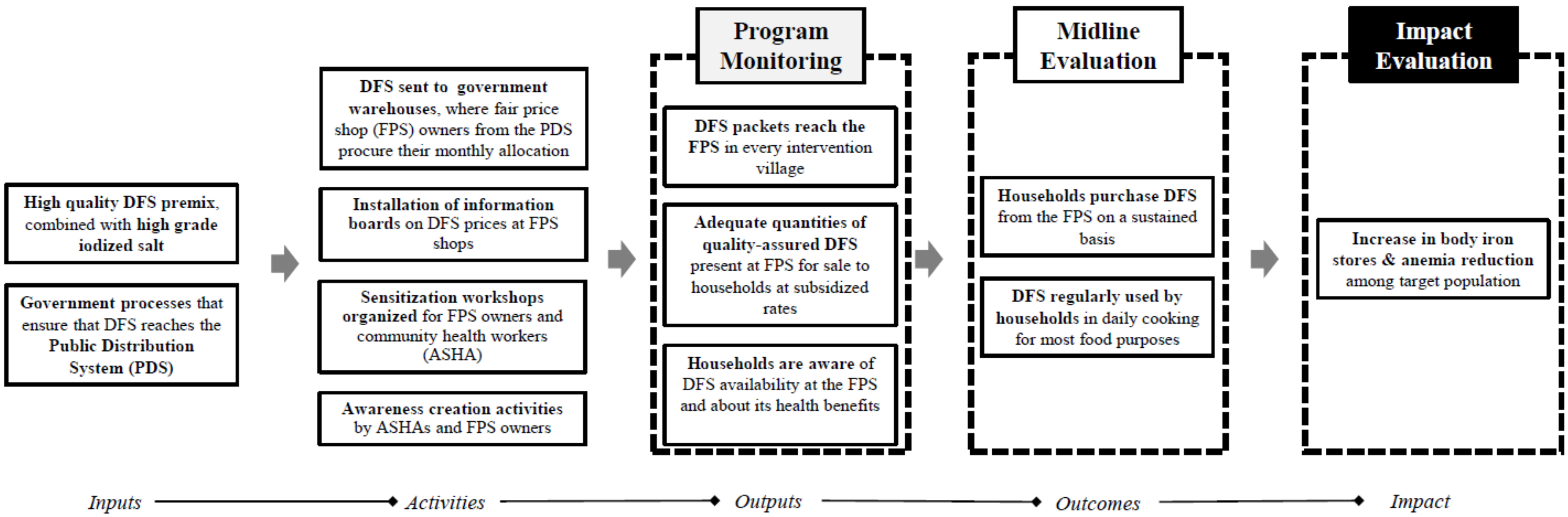
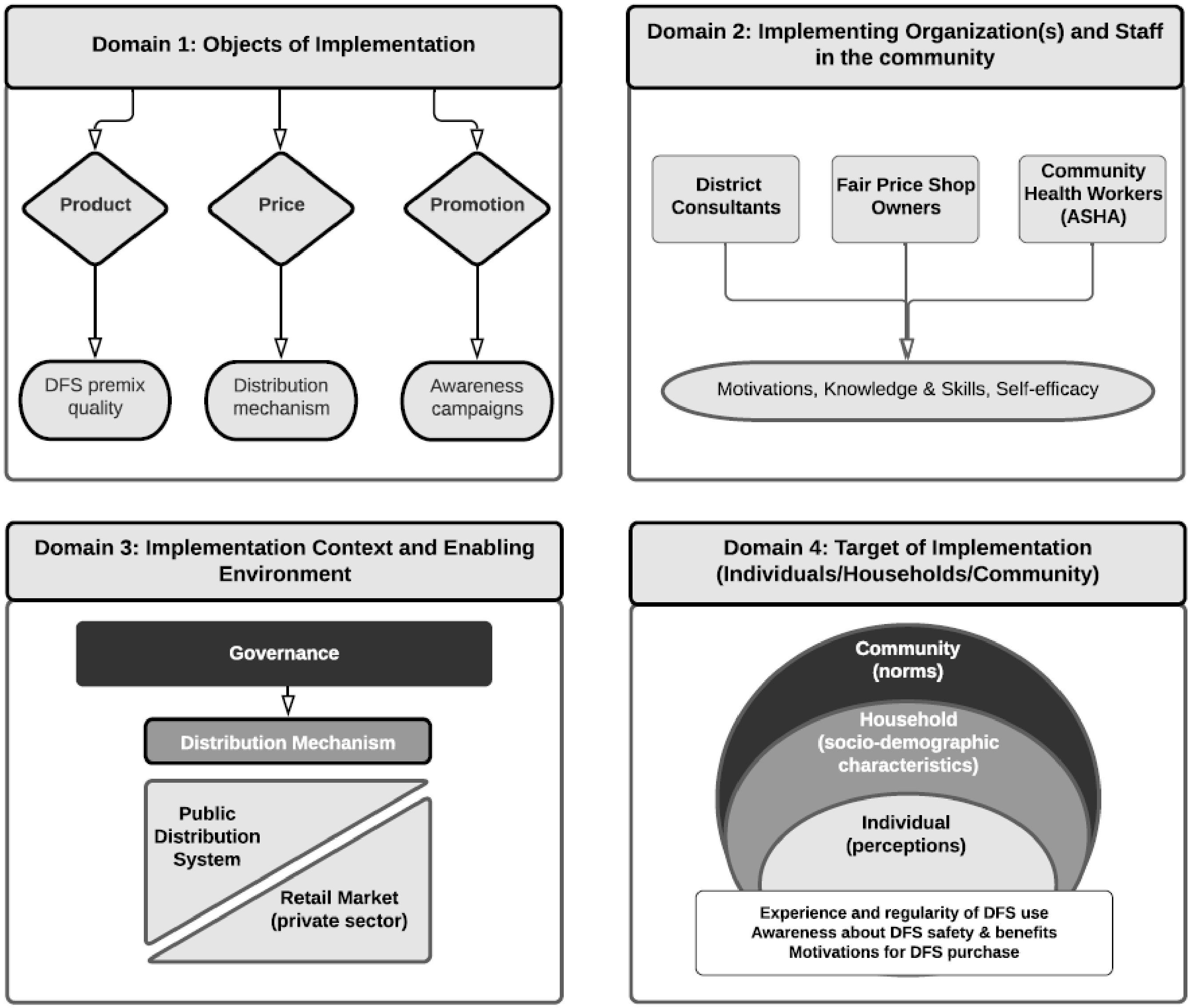


Figure 3.2: The adapted analytic framework of Implementation Science in Nutrition



CHAPTER 4: Modeling the potential impact of the Double Fortified Salt Program on iron intake levels of non-pregnant women of reproductive age in Uttar Pradesh, India

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4.1. Abstract

Background: Fortification programs differ in the extent to which they deliver adequately fortified foods to all targeted households (i.e. effective coverage). Predictive modelling techniques utilizing observed effective coverage data can examine their potential impact and prioritize interventions.

Objectives: We assessed the potential impact of a double fortified salt (DFS) intervention in addressing the risk of inadequate iron intakes, in women of reproductive age (WRA), using observed effective coverage data of the Uttar Pradesh DFS program.

Methods: Repeat cross-sectional surveys at program baseline and midline collected 24-hour dietary recall data (N= 526 WRA) and DFS purchase and utilization data (N= 1202 households) respectively. We computed the usual iron intakes using baseline data, and examined associations in the midline data for DFS effective coverage and household socio-demographics. Using midline regression equations, we predicted DFS utilization for baseline households, and simulated increases in WRA iron intake through DFS consumption (including hypothetical scenarios of improved (50% and 100%) DFS effective coverage). Using the probability approach, we assessed the prevalence of inadequacy of iron intake (below Estimated Average Requirement (15mg/day)) and risk of excess iron intakes (above Tolerable Upper Level (45 mg/day)) for this WRA population.

Results: At baseline, 66% of the WRA population were at risk of inadequate iron intakes, and this dropped to 53% at observed DFS effective coverage. However, with improved effective coverage, only 26% (hypothetical scenario: 50% effective coverage) and 2.5% (hypothetical scenario: 100% effective coverage) of the population remained at a risk of inadequate iron intake. There was no risk of excess iron intakes for WRA in any scenario.

Conclusions: At current levels of effective coverage, the DFS program is only partially successful but the hypothetical scenarios helped determine likely effects of DFS program improvements. This approach can help ascertain the need for improving program implementation and/or complementary interventions that addresses iron deficiency in populations.

Keywords: Predictive modelling, effective coverage, iron intakes, nutrient adequacy, scenario modelling

4.2. Introduction

Large-scale food fortification programs (LSFF) add specified amounts of nutrient 'premixes' to staple foods to shift the average distribution of nutrient intakes towards levels that can be considered adequate (1). Numerous countries have mandated national-level LSFF programs, such as universal salt iodization (USI), to achieve this population-level nutrient adequacy. While USI programs have decreased iodine deficiency levels globally (2), several countries struggle with effectively addressing persisting micronutrient deficiencies. Iron deficiency is one such, where it's deleterious effects manifest in various conditions, including anemia. It has a complex multi-causal etiology and affects nearly 1.93 billion people, with more than 89% of the disease burden falling on low- and middle-income countries (3). Although we commonly assume that nearly half of all anemia cases are due to iron deficiency, the proportion of the disease that is directly attributable to iron deficiency is not uniformly 50%, and varies among geographies (4).

In India, the largely cereal-based diet has a low concentration of iron (5) and poor bioavailability, and nutrient-dense diets are often unavailable, inaccessible or unaffordable, especially in rural settings (6). India contributes to almost one quarter of the global anemia burden (7), with more than half of women of reproductive age (WRA) being anemic (8, 9). However, India's social safety net programs (SSNPs) are set up to distribute subsidized staple foods to marginalized populations, and using this as a platform to distribute iron-fortified foods is a promising solution to address its anemia burden. Leveraging USI's success, a new program in the state of Uttar Pradesh (UP), distributes iron-fortified salt (or double fortified salt (DFS) i.e. salt fortified with iron and iodine) through a SSNP called the Public Distribution System (PDS).

While important to leverage SSNPs, iron fortification interventions in these contexts should consider 1) the magnitude of iron deficiency, 2) baseline distribution of population-level iron intakes, 3) potential sources of dietary iron (habitual foods, iron supplements, bio-fortified/targeted foods) and 4) all suitable fortification vehicles (10). While LSFF programs aim to address the lower intake levels of the more disadvantaged population groups, context-specific predictions are required to ensure safe intakes of those groups who are at the higher end of their intake distribution curves (11, 12). Modelling tools can be leveraged to improve such predictions, evaluate the risks and benefits of various interventions (13) and identify an optimal LSFF strategy that can address iron deficiency and anemia.

In this paper, we demonstrate the use of such modelling exercises in the context of the UP DFS program in India. We measured the current dietary iron intake levels among WRA and DFS utilization across households from varying socio-demographic strata, and used these data to model the change in dietary iron intakes in pre- and post-fortification scenarios. We also modeled hypothetical scenarios of improved program implementation to generate a range of simulated outcomes (14, 15), that can inform DFS program staff and policy makers about the potential impact of such investments.

4.3. Materials and Methods

The UP government used its PDS network, which provides subsidized rice, wheat and kerosene to eligible households, as a distribution platform for the DFS program, introducing the fortified salt as an additional commodity in 10 intervention districts. An external consortium of partners led by the Global Alliance for Improved Nutrition, and including St. John's Research Institute (SJRI), Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI), Cornell University, Emory University and The India Nutrition Initiative, evaluated this UP DFS program.

4.3.1. Study design and sampling

Five out of the 10 intervention districts were randomly selected for the evaluation, and a baseline cross-sectional household survey was conducted in these selected districts and in five matched control districts between October – December 2016. These baseline survey districts were part of a larger state survey, conducted simultaneously, that included 25 districts (10 baseline survey districts + additional 15 state survey districts). A repeat cross-sectional household survey was conducted at program midline between November – December 2018, focusing only on the five intervention districts. Twenty clusters of villages or urban wards were selected using stratified random sampling and population proportion to size for the baseline/state survey, and revisited (if in the five intervention districts) during the midline survey. Within each urban ward, one Census Enumeration Block (CEB) was randomly selected using Indian census data (16). From every village or CEB, a total of 5 to 8 households were selected for the baseline/state survey, and 12 households were selected for the midline survey.

All surveys selected the non-pregnant women of reproductive age (WRA) in the household as the primary respondent. The total baseline survey sample was 1284 WRA (647 intervention; 637 control) and the total midline survey sample was 1202 WRA (intervention only). The eligibility criteria for all surveys required that the WRA had to be between 18 to 49 years, and had to have at least one child between 6-59 months of age. The midline survey also required WRA's households to have a PDS card.

4.3.2. Biomarkers

During the baseline survey, trained phlebotomists collected 10 mL venous blood samples from WRA after obtaining their written informed consent. A drop of whole blood from this sample was used by the phlebotomist to test the hemoglobin (Hb) concentration using the Hemocue Hb 201+ analyzer (Hemocue AB), and a cut-off of Hb <120 g/L was used to assess the prevalence of anemia. Serum ferritin and markers of inflammation – C-reactive protein (CRP) and alpha1-acid glycoprotein (AGP) – were also measured. For estimating the prevalence of iron deficiency, we used inflammation-adjusted serum ferritin values and applied a cut-off of <15mg/L (17). Ferritin was measured using sandwich electrochemiluminescence immunoassay (ECLIA) ELECSYS 2010 (ROCHE Diagnostics, Mannheim, Germany). CRP and AGP were measured using immunoturbidimetry: Cobas Integra 800 and Hitachi 902 (ROCHE Diagnostics, Mannheim, Germany) respectively (9).

4.3.3. Dietary intakes at baseline

For the baseline household survey (N=1284), a random sub-sample of eligible WRA in intervention (N=263) and control (N= 264) districts were administered a multi-pass 24-hour dietary recall. For this recall, WRA reported all foods and beverages consumed in the previous day, including those consumed outside their homes. After a first round of recall, interviewers used the aid of pre-calibrated local utensils and geometric food models to capture an accurate assessment of portion sizes and used specific probes to help the respondent recall the intake. They probed based on the timing of a reported meal, around specific activities of the respondent, and about more details on already reported foods. We then used a food composition database, developed at SJRI, containing nutrient values for raw foods and local recipes to convert the 24-hour dietary recall data into nutrient intake for each WRA.

Using the National Research Council (NRC) method (18, 19) for estimating the usual nutrient intakes, the within- and between-person variability was computed. These computations used data from a repeat 24-hour recall, collected on a non-consecutive day, from a sub-sample of 100 WRA in the 25 baseline/state survey districts. We computed a shrinkage factor (ratio of between-person standard deviation (SD) to the sum of within- and between-person SD), and applied this to our analytic sample (N=527) to estimate distributions of adjusted (usual) intake. After examining the usual distribution of iron intakes, we adopted a list-wise deletion approach for one outlier observation in the intervention recall data, to obtain our final analytic sample (N=526).

The distribution of usual intakes of iron was used to estimate the prevalence of inadequacy of iron intake in WRA, using the Estimated Average Requirement (EAR) value of 15mg/day. The EAR value is the average nutrient intake needed to meet the requirements of 50% of healthy Indian WRA population. It is the current requirement specified by the Indian Council of Medical Research (ICMR) for non-pregnant and non-lactating WRA (20). Using the probability approach (21) the risk of inadequate iron intake in WRA, i.e. the probability of inadequacy, where individual usual intake of iron is less than 15mg/day was determined. WRA iron requirements are not normally distributed and, therefore, we considered the lognormal distribution of iron for our probability estimations. To examine the probability of excess iron intakes in WRA, we used 45mg/day as the Tolerable Upper Level (TUL) for iron, i.e. the intake above which adverse effects are likely.

4.3.4. Validity of dietary data

Dietary assessments have an inherent problem of validity as they may either under- or over-estimate the energy intake by a person, and provide inaccurate estimates of the prevalence of inadequate intake the population level. A method frequently used to assess such misreporting is the Goldberg cut-off (22, 23), where when weight-stable, energy intake of an individual is assumed to be equal to their energy expenditure requirements. The individual energy requirements are expressed as a multiple of the mean basal metabolic rate (BMR), or the physical activity level (PAL). The ratio of reported energy intake (EI_{rep}) and BMR

(EI_{rep}:BMR) is compared with the expected physical activity level (PAL) for the specific population, and confidence limits (cut-offs) of the agreement between EI_{rep}:BMR and PAL is determined using updated Goldberg equations (23, 24). The cut-offs are then compared with each individual's EI_{rep}:BMR ratio – if EI_{rep}:BMR is less than the 95% lower cut-off, then energy intake has been under-reported by the individual; if EI_{rep}:BMR is greater than the 95% upper cut-off, then energy intake has been over-reported by the individual (23-25).

We applied this method to assess the validity of our baseline dietary data, adjusted for usual intakes, by first using age-specific predictive equations (26) to estimate the basal metabolic rates (BMR_{est}) of the WRA in our sample. We then compared the ratio of reported energy intake and BMR (EI_{rep}:BMR_{est}) to light physical activity level (PAL=1.4), assuming that this is a sedentary population (based on ICMR guidelines (20)). We used the Goldberg cut-offs to identify under-, over-, and plausible reporters of energy intake in our sample, and subsequently ran separate models (for all reporters and plausible reporters) of pre- and post-fortification scenarios in addition to hypothetical scenarios of improved implementation.

4.3.5. DFS utilization at midline

The midline assessment, focusing on DFS program implementation in the five intervention districts, provided insights on DFS purchase and utilization levels. In the midline survey, DFS program 'coverage' was measured as those who had "ever seen/heard" and "ever purchased" the product. DFS 'utilization' was measured as adherence to the intervention, i.e. whether respondents used DFS in their household cooking. 'Effective coverage' (27) is defined as households receiving the intervention (100% coverage) and indicating full adherence i.e. using DFS for all cooking needs (100% utilization). In this definition of effective coverage, we assume that DFS has high fortification compliance i.e. the mandated or stipulated levels of iron and iodine were added and maintained in the salt.

Previous analyses (28) of the midline data showed that effective coverage among surveyed households (N=1202) was only 23%. Several midline survey respondents had low awareness about DFS benefits. They found DFS to be of poor quality, indicating that it often led to food discoloration. Some respondents selectively using DFS in food preparation where discoloration was minimal. Overall, the midline survey showed effective coverage to be higher among households of lower wealth quintiles and those located in rural areas, as PDS access and use was higher among these groups.

We used these insights from the midline survey to simulate pre- and post-fortification scenarios that predict the change in baseline iron intakes of the WRA population, consequent to DFS consumption. Additionally, we considered hypothetical scenarios of 50% and 100% effective coverage of DFS. The first will be a scenario where DFS demand creation efforts boost consumer awareness (about DFS benefits and mitigation strategies to minimize food discoloration) and thereby improve DFS consumption. The second hypothetical scenario would arise when an improved product that addresses food discoloration and product quality concerns is used in place of the current one.

Using principal component analysis, conducted separately for rural and urban areas, on data of household ownership of assets and housing characteristics, we created a household wealth index, and then computed wealth quintiles (29). We used survey-weighted multivariable logistic regression models (using reported DFS utilization at midline) to examine the association of DFS effective coverage and socio-demographic variables, including household wealth quintiles and location. The regression equation thus identified (30) from the midline data was used to predict household utilization of DFS based on the baseline sample, to simulate effective coverage of DFS and subsequently simulate increases in their iron intake through DFS consumption.

4.3.6. Simulating post-fortification iron intakes

At an assumed usual salt consumption level of 10g/day for the Indian population (31), the UP DFS program aims to add 10mg iron per day (1mg for each gram of salt consumed) to an individual's diet (32), provided there is 100% effective coverage. Using data of observed effective coverage at midline, we estimated (for the baseline sample) the expected iron intake in the post-fortification scenario. We calculated this using the targeted intake (10mg) from the DFS program times the probability of DFS utilization (10mg x the predicted probability). We used the expected iron intake from DFS consumption and baseline recall of usual iron intake to obtain post-fortification iron intake. Following this, we computed the dietary iron inadequacy and risk of excess in the pre- and post-fortification scenarios as described earlier.

Simulating iron intakes for hypothetical scenarios

In the first hypothetical scenario, we assumed that, irrespective of household characteristics, all purchased DFS (100% coverage) and use it for 50% of household cooking (i.e., excluding dishes where the food discoloration is severe, estimated at 50%). For this scenario, all household were assigned a uniform 0.5 probability of DFS utilization independent of household characteristics. All individuals (assuming they consume salt at 10g/day) therefore would increase their iron intake by 5mg/day (10mg x 0.50), in this hypothetical scenario, compared to their usual intake of iron at baseline.

In the second hypothetical scenario, where DFS would become a passive intervention like iodized salt, we apply a uniform 1.0 probability of DFS utilization, independent of household characteristics. All individuals purchase and use DFS exclusively for consumption (i.e. 100% utilization), increasing their iron intakes by 10mg/day (10mg x 1.00), in this 100% effective coverage scenario, compared to their usual iron intake of iron at baseline.

4.4. Ethics

The evaluation is registered with 3ie's Registry for International Development Impact Evaluations (RIDIE-STUDY-ID-58f6eeb45c050). Ethical approval for the evaluation was obtained from institutional review boards at SJRI, SGPGI and Emory University.

4.5. Results

Characteristics of the baseline (N=1284) and midline (N=1202) survey participants were mostly comparable (**Table 4.1**). The midline sample had a higher proportion of WRA with secondary or graduate education, and a higher proportion of rural households compared to the baseline sample. The midline sample also had a higher proportion of households accessing and utilizing the PDS (due to the additional survey eligibility criteria), but household wealth and salt purchase levels were similar across both surveys. From the total baseline sample, 1090 WRA had complete data on venous hemoglobin, ferritin and markers of inflammation. After removing the single observation for outlier iron intake, we found that 36% of all sampled WRA were anemic (**Table 4.2**), with the majority having either mild or moderate anemia. Among sampled WRA, 47% were iron deficient and 25% had iron deficiency anemia (IDA). Since dietary data was available only for a sub-sample, we pooled all baseline districts (intervention and control) for further analyses, after establishing comparability of these districts based on the prevalence of anemia, iron deficiency and IDA (Table 4.2). We then ascertained the representativeness of the dietary data sub-sample by stratifying the total biomarker sample based on the availability of dietary data. We found that all values except iron deficiency prevalence were comparable in groups with and without diet data. The iron deficiency prevalence for WRA was higher in the subsample with diet data (52%) than the sample with no diet data (43%), highlighting a potential limitation with the small sample size for the dietary recalls and, therefore, the need for a more careful interpretation of the modelling results.

Logistic regression models estimated the probability of observed DFS effective coverage in different households and the association with socio-demographic predictors (**Supplemental Table 4.1**). Using these probabilities, our comparisons of the distribution of iron intakes in the pre- and post-fortification scenarios (**Figure 4.1**) showed an improvement in iron intakes among WRA, based on observed DFS effective coverage. With predicted DFS consumption-led increases in iron intake, the post-fortification distribution shifts to the right of the baseline distribution and, using the EAR value at 15mg/day, we find a lower proportion of the population to be at a risk of inadequate iron intake. The hypothetical scenarios of 50% and 100% effective coverage (**Figure 4.2)** also showed a positive shift in iron intake distributions in Panel A and Panel B respectively. While observed effective coverage and 50% hypothetical effective coverage led to iron intake increases, it is only in the hypothetical 100% effective coverage scenario that most of the entire distribution shifts to the right of the EAR line.

Among all reporters (N=526) under the baseline pre-fortification scenario, 66% were at a risk of inadequate iron intakes (**Table 4.3,** Column (1)). The risk steadily decreased for the post-fortification scenario and the two hypothetical scenarios, with 97.5% of the total population having sufficient intakes of dietary iron in the 100% effective coverage scenario. Our validity assessments of the diet data showed nearly 75% of dietary recalls to be plausible reports of energy intake, assuming a PAL of 1.3 (**Supplemental Table 4.2**). Subsequently, comparisons of the distribution of iron intakes at baseline and all three scenarios (**Figure 4.3**) for all reporters (Panel A) and plausible reporters (Panel B) showed similar results for the risk of inadequate and excess iron intakes. Compared to the baseline (pre-fortification scenario), all three scenarios showed (Table 4.3) that the risk of inadequate iron intakes decreased, with no risk of excess intake of iron for all reporters and plausible reporters. When we consider only the population with plausible reporters (N=392), the risk of inadequate iron intakes at baseline is 57% (Table 4.3, Column (2)) and this reduced to 42% in the post-fortification scenario, at observed DFS effective coverage. In the hypothetical scenarios of 50% and 100% effective coverage, the risk of inadequate iron intake decreased to 16% and 1% respectively. There was no risk of excess iron intakes (i.e. crossing the TUL of 45mg/day) in any of the scenarios.

4.6. Discussion

With a population of nearly 204 million, and an anemia prevalence that remains high across all population groups assessed (8), UP stands to particularly benefit from population-level approaches that are part of a comprehensive anemia prevention and control strategy. Our analyses of baseline biomarker data indicate that iron deficiency and IDA are high among WRA, pointing to a demonstrable need for anemia prevention interventions that aim at increasing the iron intakes of this population. One such intervention was the large-scale implementation of the UP DFS program. Using effective coverage data from this program, we applied predictive modelling techniques that assessed UP DFS program's potential impact on WRA iron intakes. Our models showed that at current levels of effective coverage, the DFS program in UP is only partially successful in reducing the risk of inadequate iron intake – the baseline risk of inadequate iron intake drops by 13-15 percentage points in the post-fortification scenario. Nevertheless, our hypothetical scenarios indicated that if effective coverage levels improve to 50% or 100%, the DFS program could reduce the risk of inadequate iron intake by 40-41 percentage points or 56-63 percentage points respectively, with no risk of any WRA crossing the TUL.

When effective program coverage data are available, predictive models can inform fortification decisions, as it affords the ability to estimate, under certain assumptions, the change in outcomes of interest consequent to a program's implementation. If effect sizes of fortification interventions on biological outcomes are available from meta-analyses, we can also model the potential impact of these programs on the disease burden without having to collect endline biomarker data. For example, a recent meta-analyses of DFS efficacy studies documents a pooled mean difference of 0.44g/dL in hemoglobin concentrations (33). We use this effect size to model the potential impact of 100% effective coverage in the UP DFS program – a best-case scenario comparable to efficacy trials. In this hypothetical scenario, increasing hemoglobin concentrations of WRA by the effect size of 0.44g/dL decreases anemia prevalence among WRA from 36% at baseline to 28% post-DFS intervention (at the hypothetical 100% effective coverage scenario). The actual change in anemia prevalence for other scenarios are likely to be much lower.

These findings have several implications. First, it demonstrates the true potential of the DFS program in addressing iron deficiency, provided implementation challenges are overcome. This warrants a re-focus on improving the DFS product quality and investing in demand creation activities, giving program practitioners a roadmap on what to expect at different levels of program performance. Second, it shows that the potential for impact at current levels of effective program coverage remains modest. Therefore, impact assessments of this intervention require an adaptive methodological approach, which can first assess effective program coverage to establish a high potential for impact, prior to investing in assessments of hemoglobin concentration and iron status. Finally, the hypothetical scenario of 100% effective coverage shows how the risk of inadequate iron intake among WRA can be completely addressed with a single iron-fortified food intervention – the caveat here being that the DFS program is implemented as planned, compliance (to fortification standards) is maintained, and all challenges are addressed. If additional iron-fortified foods or iron supplementation programs for WRA are introduced in this scenario, some of the WRA who are at the higher end of the distribution intake may risk consuming an excess amount of iron.

While conducting such modelling exercises in other contexts, it is important to note that our projections of program effective coverage and its' impact in reducing the risk of inadequate iron intake depend on the chosen EAR cut-off. Until recently, the risk of inadequate intake of iron for Indian populations was determined using the Recommended Dietary Allowance (RDA) – the average nutrient intake that would put individuals at a 2.5% risk of inadequate nutrient intake. Previously, the Indian Council of Medical Research and National Institute of Nutrition (ICMR-NIN) had proposed using a value of 21mg/day for iron as the RDA for non-pregnant WRA – this compares to a value of 18mg/day, set by the Institute of Medicine as the RDA for this population group. However, a recent report by the Indian Council of Medical Research has released updated values for the Estimated Average Requirement (EAR) of iron at 15mg/day (20), to determine the risk of inadequate iron intake for non-pregnant, non-lactating WRA. We use these updated EAR values to determine the prevalence of inadequate intake in our sampled WRA. If we use the IOM values of 18mg/day or the previous ICMR-NIN value of 21mg/day, the risk of inadequate iron intake would be much higher than currently estimated in the different scenarios presented in this paper.

Finally, there were several assumptions made in our analyses and we discuss all the caveats below. By using the midline observed effective coverage data to predict DFS consumption-led increases of baseline usual iron intakes, we assume that two survey samples are comparable in spite of the minor differences in some socio-demographic characteristics. Secondly, for the dietary analyses of WRA iron intakes, we pool intervention and control baseline districts to obtain a larger analytic sample assuming 1) that dietary intake is comparable across all baseline districts 2) the sub-sample with dietary data is representative of the entire baseline WRA sample. While we established comparability of iron deficiency and IDA prevalence across baseline intervention and control districts, the analytic sub-sample with dietary data had a higher prevalence of iron deficiency and therefore may not be representative of the entire baseline WRA sample. Therefore, generalizing the findings of our scenario models to the entire baseline sample is not possible. Thirdly, the scenario models in this paper assume that the average individual level consumption of salt is 10g/day. However, the dietary data from the subsample suggests that average consumption of salt is much lower at 5.3 ± 4.1g/day and therefore the intake of iron from DFS will be much lower than what is modelled here. Finally, the impact of this DFS program is examined only on non-pregnant WRA. It is important to examine how population level interventions such as this DFS program can affect iron intake levels in men, who have the same threshold of 45mg/day as the TUL for indicating a risk of excess intake. With lower intakes of salt among PSC, it is likely that this population group will have a lower benefit from this program, and will need more targeted interventions to address their anemia burden.

In spite of these limitations, scenario modelling of the potential nutrient contribution from fortification program outcomes has been an important gap in program planning, and in their evaluation. Multiple modelling techniques have informed fortification priorities in the past (34-36). However, most studies that use fortification optimization models assume there is 100% effective coverage (37) to model the potential impacts on dietary inadequacy (36, 38, 39). Economic optimization models (35, 40), that evaluate the cost-effectiveness of various fortification interventions, use simulated effective coverage levels that fail to factor in the costs of implementation during their assessments. However, with low-cost, rigorous and timely assessments of fortification coverage possible (41, 42), the use of predictive models that leverage coverage data may be particularly useful in improving the accuracy of the estimates from these optimization models. Using these estimates, evaluators and implementers can make informed decisions on the need and timing of an impact evaluation. Finally, policy makers can simulate predicted effects of varied food fortification strategies, and make decisions on whether they need to be strengthened or scaled back. For the UP DFS program, the availability of data, both on dietary intake as well as effective coverage, enabled us to 1) predict the impact of the program, based on coverage estimates, and 2) model the potential impact of the program if better effective coverage can be achieved (13).

This paper provides actionable insights to policy and/or program practitioners to facilitate strategic decision-making on whether to scale up the DFS program in UP and/or make investments in complementary nutrition interventions that can address the high prevalence of iron deficiency and IDA in the state. Building a context-specific evidence base, that can guide programmatic decisions for anemia prevention, is often difficult or expensive, and there is limited data that can guide the choice of a tailored mix of interventions at a disaggregated level (15). With the growing political and private sector momentum to scale up fortification programs in several LMIC contexts, such modelling exercises may enable better management of subnational- and national-level fortification programs.

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Table 4.1: Descriptive Analysis of Individual- and Household-level socio-demographic characteristics, stratified by type of survey (Baseline vs. Midline)

Characteristic	**Baseline N=1284**	**Midline N=1202**	**p-value**
Age of children (in months): Mean ± SD	31.1 ±13.9	-	-
Age of women : Mean ± SD	27.5 ±5.0	27.9± 4.6	0.08
WRA Education level:			
No schooling	29.9	28.4	0.43
Primary or middle school	30.0	28.1	0.29
Secondary School	24.5	32.1	**<0.0001**
Graduate	15.6	7.5	**<0.0001**
Rural location	64.9	71.6	**0.001**
Religion (Hindu)	89.1	84.5	**0.01**
Caste (General or OBC category)	75.2	76.3	0.52
Average household size (Mean (SD))	7.2 ±3.1	7.1± 3.0	0.30
Extended family household	60.5	60.7	0.91
Primary Income source			**<0.0001**
Agriculture	24.0	19.9	
Non-agriculture	56.5	67.2	
Both	19.6	12.9	
Primary light source: Electricity	81.2	94.9	**<0.0001**
Primary fuel source: LPG/Natural Gas	28.4	39.4	**<0.0001**
Primary water source: Improved	98.2	98.3	0.93
Non-permanent Housing structure	11.6	6.9	**<0.0001**
Separate room for cooking	35.9	50.1	**<0.0001**
Owns agricultural land	62.4	59.1	0.09
Wealth Quintile	b	m	
Lowest Quintile	19.9	20.0	0.99
Low Quintile	20.0	20.0	0.98
Middle Quintile	20.1	20.1	0.98
High Quintile	20.0	20.1	0.98
Highest Quintile	19.9	20.0	0.99
PDS access (cardholder & uses the PDS)	71.5	80.2	**<0.0001**
Type of PDS card: Priority household	41.9	60.6	**<0.0001**
Frequency of PDS purchase: monthly	65.8	78.5	**<0.0001**
Decision of PDS purchase by male head	70.2	55.7	**<0.0001**
Salt Purchase			
Purchase frequency: Bi-weekly or more often	21.0	20.4	0.72
Purchase frequency: Monthly	62.3	58.7	0.06

Table 4.2: Prevalence of Anemia, Iron Deficiency and Iron Deficiency Anemia in Women of Reproductive Age, baseline sample with biomarker data, stratified by availability of diet data

Characteristic	Total Baseline N=1089	Intervention N= 541	Control N= 548	p-value	Biomarker sample without diet data N=623	Biomarker sample with diet data N=466	p-value
Hemoglobin (Mean ± SD)	12.3±1.7	12.3±1.8	12.2±1.6	0.68	12.2±1.7	12.3±1.6	0.22
Anemia prevalence							
Any Anemia (Hb < 12g/dL)	35.9 (390)	35.3 (191)	36.5 (200)	0.68	36.0 (224)	35.8 (167)	0.97
Mild Anemia (11 g/dL ≤ Hb < 12 g/dL)	17.4 (189)	15.7 (85)	19.0 (104)	0.15	16.2 (101)	18.8 (88)	0.25
Moderate Anemia (8 g/dL ≤ Hb < 11 g/dL)	16.7 (182)	17.4 (94)	16.1 (88)	0.56	17.3 (108)	15.9 (74)	0.52
Severe Anemia (Hb < 8 g/dL)	1.8 (20)	2.3 (12)	1.5 (8)	0.35	2.4 (15)	1.1 (5)	0.10
Iron Deficiency (inflammation-adjusted Ferritin (< 15 ug/L)	46.8 (510)	45.7 (247)	48.0 (263)	0.44	43.0 (268)	52.0 (242)	0.04
Iron Deficiency Anemia (inflammation-adjusted Ferritin < 15 ug/L & Hb < 11 g/dL)	25.3 (275)	25.5 (138)	25.0 (137)	0.85	24.6 (153)	26.2 (122)	0.54

Table 4.3: Estimates of risk of dietary iron inadequacy and risk of excess iron intake among non-pregnant women of reproductive age in Uttar Pradesh, at pre- and post- fortification scenarios

	Risk of inadequate[1] iron intake (%)		***Risk of excess[2] iron intake (%)***	
Sample → All (1) vs. Plausible (2) reporters	*(1) N=526*	*(2) N=392*	*(1) N=526*	*(2) N=392*
Pre-fortification (Baseline): Usual iron intake levels	*66*	*57*	*0*	*0*
Post-fortification (observed effective coverage): Usual intakes + predicted DFS use	*53*	*42*	*0*	*0*
Hypothetical Scenario: 50% Effective DFS Coverage: +5mg	*26*	*16*	*0*	*0*
Hypothetical Scenario: 100% Effective DFS Coverage: +10mg	*2.5*	*1*	*0*	*0*

[1]Risk of inadequacy calculated using an Estimated Average Requirement value of 15mg/d

[2]The risk of excess intake calculated using the Tolerable Upper Level cutoff of 45mg/d

Supplemental Table 4.1: Logistic regression coefficients of predictors of effective DFS coverage, midline household survey (N=1202), adjusted for survey weights

Variables	**Categories**	**Unadjusted OR**	**Adjusted* OR**
Wealth Quintiles	*Lowest quintile*	*Reference*	*Reference*
	Low quintile	*1.5 (0.8, 2.6)*	*1.5 (0.9, 2.7)*
	Middle quintile	*1.0 (0.6, 1.8)*	*1.2 (0.6, 2.2)*
	High quintile	*0.5 (0.3, 0.9)**	*0.5 (0.3, 1.1)*
	Highest quintile	*0.4 (0.2, 1.0)*	*0.5 (0.2, 1.1)*
Location	*Urban*	*Reference*	*Reference*
	Rural	*2.5 (1.5, 4.1)**	*2.8 (1.2, 6.6)**
Religion	*Non-Hindu*	*Reference*	*Reference*
	Hindu	*1.7 (0.6, 4.6)*	*1.6 (0.6, 4.2)*
Caste	*SC/ST*	*Reference*	*Reference*
	General/OBC	*0.7 (0.4, 1.4)*	*0.8 (0.4, 1.4)*
Schooling	*No schooling*	*0.6 (0.1, 6.3)*	*0.5 (0.1, 5.7)*
	Primary or middle school	*1.0 (0.1, 10.6)*	*0.7 (0.1, 9.0)*
	Secondary School	*0.8 (0.1, 8.9)*	*0.7 (0.1, 8.0)*
	Graduate	*0.5 (0.1, 5.8)*	*0.5 (0.1, 7.0)*
Age of WRA (y)		*1.0 (1.0, 1.1)*	*1.0 (1.0, 1.2)*

Supplemental Table 4.2: Validity of dietary data using Goldberg cut-offs, Physical Activity Level = 1.3

Reporting category	**PAL = 1.3**
Acceptable reporters	392 (74.5%)
Under reporters	130 (24.7%)
Over reporters	4 (0.8%)
Total	526

Figure 4.1: Pre- and post-fortification iron intakes for baseline intervention and control districts (N=526)

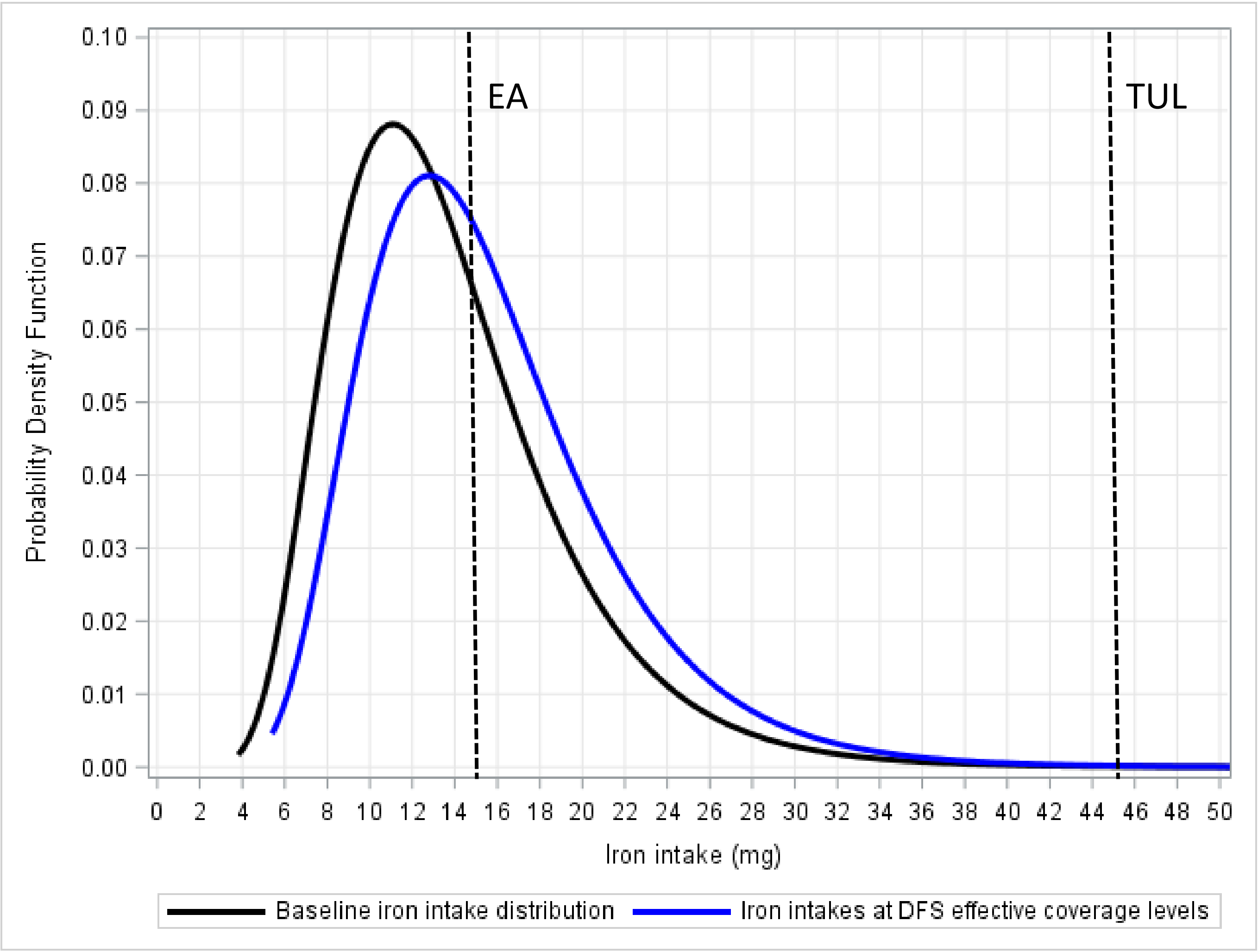


Figure 4.2: Hypothetical scenarios of improved DFS program coverage and effect on baseline iron intake levels

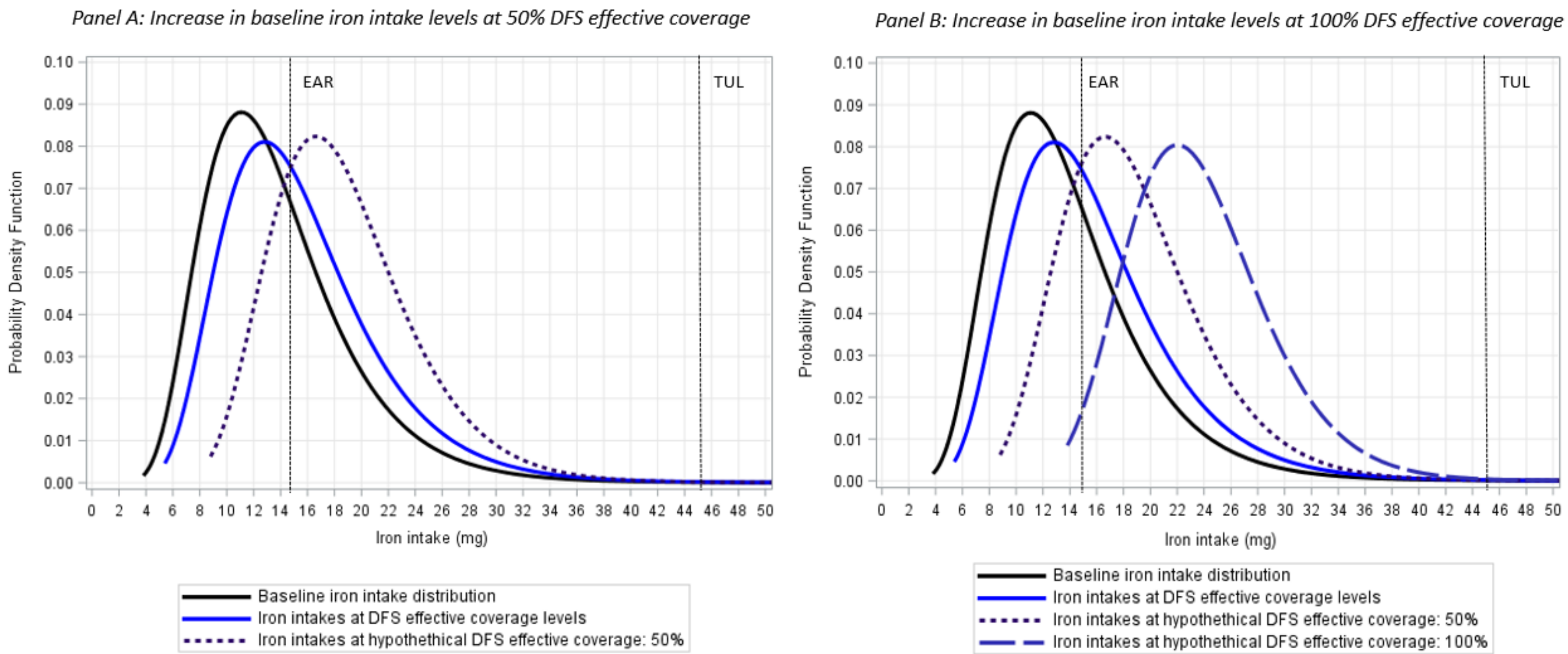
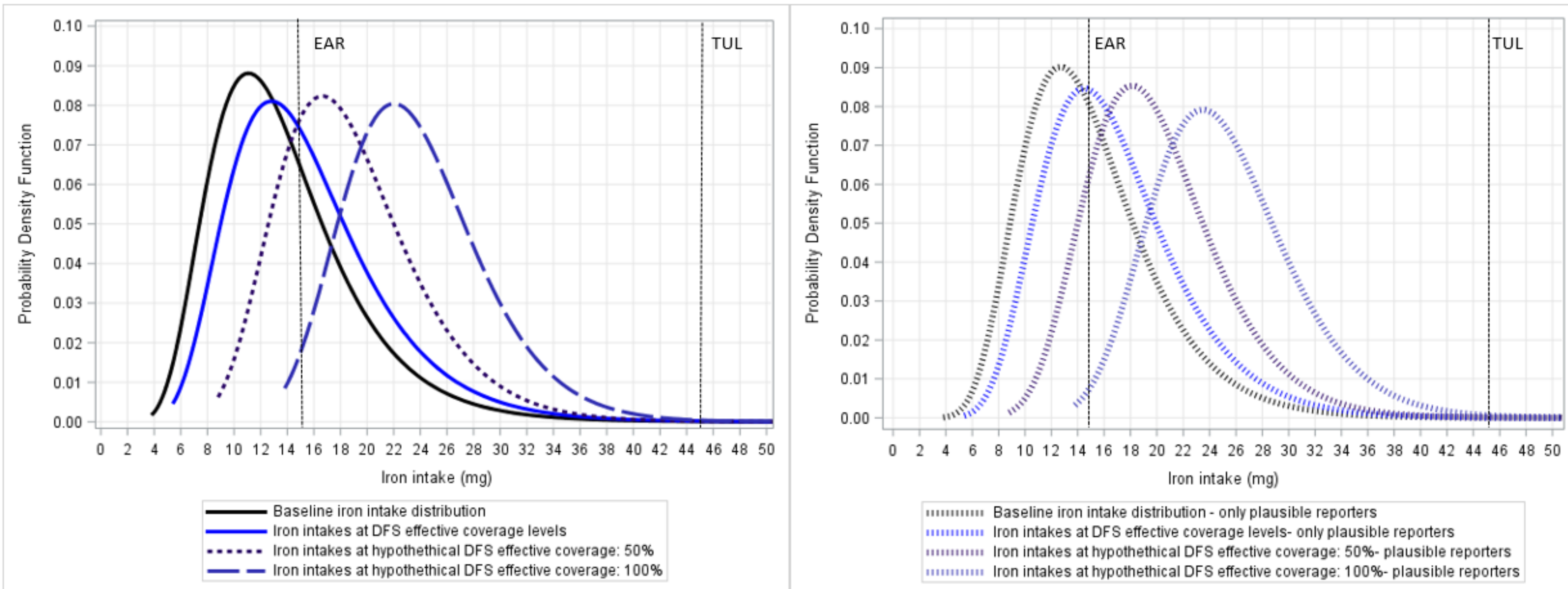


Figure 4.3: All scenarios with full dietary sample and subsample (plausible reporters only)

Panel A: All reporters (N=526) *Panel B: Plausible reporters (N=392)*



CHAPTER 5: DISCUSSION

This dissertation research was conducted within the context of an ongoing assessment of the UP DFS program. Households that were part of the PDS social safety net could purchase subsidized iron-fortified iodized salt i.e. DFS, from their local FPS. Guided by a PIP analysis (1), our research aimed to determine the program's potential for impact on iron deficiency anemia in UP. In our analyses, I 1) described the coverage and utilization levels of the DFS program in a sample of intervention districts, 2) examined the fidelity of DFS program implementation, and 3) modeled the predicted impact of DFS use, using observed effective coverage data, on the risk of inadequate iron intake among WRA. To the best of our knowledge, this large-scale, state-run program is the one of first to use the DFS intervention in India as an iron deficiency anemia prevention strategy, and our findings are particularly important because of its implications on future DFS programs in India, and abroad.

5.1. Key findings

5.1.1. What influenced DFS utilization in Uttar Pradesh?

In Aim 1, we assessed the UP DFS program coverage and utilization levels. Overall, DFS coverage was high but regular use remained low, especially in urban areas. We found that nearly two-thirds of households did not replace the use of their regular salt with DFS. Quality concerns about DFS coupled with poor awareness about the iron premix contents, its safety and benefits among consumers were significant bottlenecks identified in the program. These needed to be addressed to improve the program's potential for impact.

Using the PDS as a DFS delivery platform was effective in reaching food-insecure households. Household access and use of the PDS – the sole distribution platform for DFS – was a primary driver of DFS utilization. However, our findings suggest that urban households relied less on the subsidized commodities that were sold at the PDS, and therefore self-selected themselves out of the distribution platform. Rural and lower wealth households, on the other hand, were more likely to access the PDS and in turn utilize DFS exclusively, in place of any other salt used in their kitchens.

5.1.2. How did DFS program implementation affect coverage and utilization?

Further, we examined how the DFS program was implemented, and analyzed why there was high DFS coverage but low utilization at the household level. Findings from Aim 2 showed that the actual implementation of the DFS program in the intervention districts varied significantly from what was originally intended in the PIP **(Figure 3.1)**. The DFS product quality was compromised due to inadequacies in premix production, and this affected the overall fidelity of implementation. It was challenging for FPS owners to sell DFS and recover their investment costs due to the product quality concerns. Therefore, they adopted cost-recovery strategies such as bundling of DFS with other highly desired PDS rations – many sold the subsidized PDS commodities as a single package instead of the separate sale of individual items. This resulted in the high purchase rates of DFS but failed to translate to equally high utilization.

While Aim 1 findings showed that only about one-third of the sampled households used DFS, our Aim 2 analyses suggest that these households were primarily of two types – '*believers*' and '*thrifters*'. Caregivers in *'believer'* households completely replaced their usual salt intake with DFS. Due to the product quality concerns, those in *'thrifter'* households selectively used

DFS only in certain foods where organoleptic issues, such as food discoloration, were minimal. The overall utilization levels of the DFS program remained low because a majority of households were *'naysayers'* who continued to use their regular salt – either packaged iodized salt or crystal salt – even if they were compelled to purchase DFS through bundled PDS sales.

Although motivation levels were high among the mid-level program implementers, i.e. DCs, FPS owners remained unmotivated to promote DFS use. Without adequate improvements in product quality, the awareness creation efforts by FPS owners and community health workers (ASHAs) only had limited effectiveness in converting the *'thrifters'* and *'naysayers'* to *'believers'*.

5.1.3. Why is understanding program coverage and utilization important?

Persistent inequities in the health and nutrition service delivery often impair the effective coverage of interventions (2). Yet, few programs factor intervention quality into their estimates of potential impact, and therefore often fail to provide a realistic estimate of their health benefits. Using insights from Aim 1 where we developed a DFS coverage cascade (3, 4), we examined the potential implications of DFS effective coverage levels (where households purchase *and* utilize DFS in all foods, i.e. *'believer'* households) in improving the dietary iron intake of our sampled population. We found that at current levels of effective coverage, the DFS program is only partially successful in reducing the risk of dietary inadequacy of iron for non-pregnant WRA in UP. At the same time, our hypothetical models of improved effective coverage showed that the risk of dietary iron inadequacy falls in scenarios of improved implementation outcomes. We did not find a risk of excess iron intakes for any WRA for the scenarios modelled. This highlights how investments in DFS product quality and demand creation are essential to improve the potential for impact, and increase the viability and sustainability of the UP DFS program.

5.2. Strengths and innovations

Several strengths of this research merit further discussion. This dissertation highlighted novel approaches that use implementation research in the context of food fortification, to examine program potential for impact. Specific to large scale food fortification (LSFF), our predictive modeling study demonstrates an innovative use of program coverage data which, in combination with dietary information, has the potential to be used to guide fortification priorities. To date, most studies that use fortification optimization models assume there is 100% effective coverage (2) to model the potential impacts on dietary inadequacy (5-7). However, with low-cost, rigorous and timely assessments of fortification coverage possible (8, 9), the use of predictive models that leverage coverage data may be particularly useful in improving the accuracy of the estimates. Using these estimates, evaluators and implementers can make informed decisions on the need and timing of an impact evaluation. Finally, policy makers can simulate predicted effects of varied food fortification strategies, and make decisions on whether they need to be strengthened or scaled back.

The rigorous design of this process evaluation, informed by close collaborations with program implementers, is another strength. We leveraged their experiential and tacit understanding, around all aspects of the DFS program, to inform this implementation research (10, 11). We used key insights from the routine monitoring data collected by program implementers, from household and PDS exit surveys, to strengthen our coverage survey questionnaire and in-depth interview guides for the midline assessment. This collaborative relationship enabled the evaluation team to quickly establish the adequacy (or lack thereof) of the program (12), and convey our findings to implementers for remedial actions and real-time course corrections.

Further, this dissertation adds to the evaluation literature by highlighting the importance of assessing implementation outcomes and designing an adaptive evaluation that meets the adequacy criterion for the intervention. To avoid a premature analysis of program impacts (13), we first determined whether the UP DFS program was moving in the expected direction. A resource-intensive summative evaluation, complete with biomarker data to determine impact, was conducted only after this important step of demonstrating the potential for impact (14-16). With the use of the adapted ISN Framework (17) to document the DFS program's fidelity of implementation, this dissertation also provides an illustrative example for other nutrition interventions to embrace context-specific implementation research. The ISN framework can also inform the design of future interventions, taking into consideration the different domains of implementation and understanding how they affect the fidelity of program.

5.3. Limitations

There are several limitations in this research, many of which were due to the nature of the DFS program, and the focused goals of the DFS process evaluation. Some of these caveats particularly relate to the local context of the DFS program. While we previously discussed some of the specific limitations related to analyses in Chapters 2-4, the general limitations of this research are discussed below to facilitate a nuanced view of the findings in this dissertation.

Although the process evaluation was guided by the PIP, we were unable to examine some of its upstream components – DFS production, procurement and transportation through the PDS

– in our mixed-methods analyses. State officials were primarily responsible for these upstream activities, and access to them was limited in this implementation context. Consequently, we were unable to adequately examine the reasons behind poor DFS product quality or understand the procurement of DFS through the PDS in greater detail. Nonetheless, our interviews with TINI DCs and FPS owners did provide some information on these upstream activities.

Another shortcoming of this dissertation is that our understanding of the implementation of the DFS program and its implications is limited by our evaluation sample. Firstly, we have a limited understanding of the urban context. The in-depth interviews participants – FPS owners, ASHAs and DFS consumers – were only selected from rural areas. In our path analyses, the urban model fit was poor indicating the possibility of an unmeasured mechanism and pointing to the need for more research in this setting. This is especially relevant in the context of rising urbanization in India, and the emerging nutrition transition where individual salt intake is rising with increased consumption of ready-to-eat foods and a shift towards 'westernized' diets that include processed foods (18). Secondly, we know little about salt intake levels in other population groups, such as men, who tend to have a higher intake of salt compared to WRA and therefore may be at a risk for excess iron intakes. The current sample for our baseline and midline surveys were restricted to non-pregnant WRA with a PSC (PSCs were included in the baseline sample), and where there were multiple eligible WRAs (or PSCs) one was randomly selected from the household. Since the UP DFS program is a population-level intervention, having additional information on usual iron intakes and the prevalence of iron deficiency among adolescent girls and men would have been beneficial for policy-makers to make decisions on the target population and delivery platform during program scale-up.

Finally, an assessment of implementation of programs in UP may be incomplete without considering the larger socio-political context, but we were unable to examine this in detail due to the highly focused nature of our process evaluation. Understanding the socio-political context in UP is critical because religious and caste-based identities are all-pervasive in the state (19, 20) and my field experience suggests that this may have influenced DFS utilization levels to some degree. However, a holistic assessment of these factors would have required a heavy focus on ethnographic methodology (21) which was beyond the scope of this process evaluation. Although our mixed-methods approach identified several important socio-political factors that affected program implementation, it is important to acknowledge there may be parts of the story that are not fully captured in this analysis.

5.4. Generalizability

The DFS program was piloted in 10 out of the 75 districts in UP, and the evaluation was conducted in five of the intervention districts. The findings of this research are representative of the pilot districts, but further generalization of our findings will need to factor in contextual differences. Nonetheless, our findings can be used to adapt policies to other contexts, and improve predictions of their effectiveness in those settings. There could be socio-political and structural factors that affect the applicability of our findings in a different setting, but evidence from this research can be a useful starting point to compare and analyze how any contextual differences matter for DFS interventions (22).

5.5. Implications of our findings

Given the public health success of universal salt iodization programs, the global nutrition community has shown tremendous interest in examining the potential of adding iron to iodized salt to produce DFS. The findings of this dissertation have important implications for implementers, researchers and policy makers who are keen to consider DFS programs as a potential strategy for the prevention of iron deficiency anemia.

First, it is important to highlight that, at current levels of effective coverage, the UP DFS program has a low potential for impact on iron deficiency anemia prevelance. Therefore, it would be premature to conduct an effectiveness evaluation that adopts an intention-to-treat approach, and measure impact at this early stage of the program. Instead, our findings were used to conduct course corrections in the program, and an adaptive evaluation (23) was conducted after six months, in two out of the five intervention districts that met an *a priori* evaluability criteria of 50% DFS utilization. Second, our qualitative findings demonstrate that there may have been a spill-over of the DFS intervention to non-PDS households, as FPS owners struggled with DFS sales and needed to recover their costs. This requires further investigation, and needs consideration while interpreting endline/adaptive evaluation results.

As it stands, our findings indicate that demand creation and improvements in product quality were fundamental requirements for DFS program to improve its potential for impact. This was reiterated in a systematic review and meta-analyses by Larson et al (24) of all published and grey literature on DFS efficacy and effectiveness trials. The authors state, “in a programmatic setting, particularly those with for-purchase DFS, DFS may fail to effectively substitute for alternative salt types if there is not an effective awareness creation campaign that informs consumers about its benefits or unless a product of adequate quality is provided at such a favorable price”. The varied experiences and perceptions of the three typologies of DFS consumers identified in our research can be utilized to develop a comprehensive awareness campaign and behaviour change communication strategy.

Although our findings show that the PDS social safety net was successful in reaching food-insecure, lower-wealth households in rural areas, there needs to be additional research on possible business models (25) related to the delivery of DFS, which can determine the sustainability of such programs in the long run. Secondly, while continued research on DFS formulations (26), and efforts to improve the product quality remain paramount (27), there also remains a critical need for programs to invest in adequate research capacities that can ensure continual tests of DFS product quality in field trials. The purpose of such field tests is to not only ensure that DFS contains adequate amounts or iron and iodine, but also to check for organoleptic issues due to poor color masking or improper encapsulation. Another recent review of iron-fortification in condiments highlighted that the most successful DFS efficacy trials were those that routinely tested the sensory characteristics of the fortified salt and considered the acceptability of the fortified product (28). Waller et al developed a novel paper-based sensor – that can help test DFS quality in field settings – to assess the iron content in fortified foods, but also acknowledge that “it is not a suggested replacement for the gold standard methods until a thorough field-validation study has been conducted in one of the LMICs” (29).

Finally, it is important to consider the public health implications of using salt as a fortification vehicle, especially due to the increasing prevalence of hypertension globally. In the current design of the DFS program, families with four or more members receive 2 kg of DFS every month. For the average family of seven members in our sampled population, this DFS allocation amounts to 9.5gms per family member, per day. If some of these family members are children, which is likely to be the case, then the allocation per adult is greater. This is much higher than the current WHO guidelines, which recommend adults to reduce their sodium intake and limit salt consumption to 5g/day (30). Recent evidence from India indicates that individual salt intakes are around 11g/day and the government has committed to a 30% reduction in salt intakes by 2025 to adhere to the WHO recommendations (18). In light of this, it is important for the UP program to work synergistically with the WHO recommendations and revise the present allocation of DFS. While the WHO has recommended a reduction in salt intakes, it has also recognized that salt iodization is an intervention that is compatible with salt-reduction goals, as formulations can be adjusted to be compatible with salt-reduction goals. As such, if higher fortification dosages are warranted due to a reduction in salt consumption levels, then DFS programs will need to consider its implications on the sensory quality and shelf life of the product. Additionally, demand creation efforts for fortified-salt need careful consideration such that they do not justify or encourage an increase in fortified-salt intakes (31). Alternative fortification vehicles could be considered, and our demonstration of the predictive models can be particularly useful in identifying an optimal range of context-specific fortification interventions that can safely and effectively address iron deficiency anemia.

5.6. Conclusions

Through the process evaluation of the UP DFS program, this dissertation demonstrates the use implementation science methods in the context of food fortification, to examine program potential for impact. Our process and findings provided important learnings for conducting and using implementation research to design and evaluate nutrition interventions at scale. Examining the DFS program in a real-world context and identifying inefficiencies in program delivery helped assess the adequacy of the program. Our work strengthens the evidence around the real-world implementation of DFS programs, and provides an analytic framework that can be applied to understand implementation of DFS programs in newer contexts. At this early stage of the UP DFS program, the potential for measurable benefits was constrained by low rates of utilization.

The production technology of DFS is an evolving field, and this large-scale implementation of the DFS program in UP highlight some of the operational challenges related to the quality and sensory aspects related to the product. Additional investments to improve DFS quality and boost demand creation efforts are required to ensure that the true potential of the program is realized. Findings from this dissertation have important implications related to the implementation and design of DFS programs, ensuring that their potential to address iron deficiency anemia is maximized, and that these programs are worth their salt.

Chapter 5: References

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