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Rang-Din Nutrition Study: Assessment of Participant Adherence to Lipid-Based Nutrient and Iron-Folic Acid Supplements among Pregnant and Lactating Women in the Context of a Study on the Effectiveness of Supplements in Bangladesh

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Abbreviations and Acronyms

BCC	behavior change communication
BMI	body mass index
CHDP	Community Health and Development Program
CHW	community health worker
CF	community facilitator
CI	confidence interval
cm	centimeter(s)
FANTA	Food and Nutrition Technical Assistance III Project
FC	field coordinator
g	gram(s)
GA	gestational age
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
IFA	iron/folic acid
IRB	Institutional Review Board
LNS	lipid-based nutrient supplement(s)
µg	microgram(s)
mg	milligram(s)
MNP	micronutrient powder(s)
MUAC	mid-upper arm circumference
NIPORT	National Institute of Population Research and Training
PE	process evaluation
PEPA-PLW	process evaluation participant adherence among pregnant and lactating women
PET	process evaluation team
PLW	pregnant and lactating women
RDNS	Rang-Din Nutrition Study
SBA	skilled birth attendant
SD	standard deviation
SDU	safe delivery unit
SOP	standard operating procedure
SRC	self-report of consumption
U.S.	United States
UCD	University of California, Davis
UL	tolerable upper intake level
USAID	U.S. Agency for International Development
VHV	village health volunteer

Executive Summary

Overview

The Rang-Din Nutrition Study (RDNS) is a collaborative effort of the U.S. Agency for International Development Agency (USAID)-funded Food and Nutrition Technical Assistance II and III Projects (FANTA); the University of California, Davis (UCD); the International Centre for Diarrhoeal Disease Research, Bangladesh (ICCDR,B); and the LAMB Project (formerly known as Lutheran Aid to Medicine in Bangladesh).

The objective of RDNS is to evaluate the effect of lipid-based nutrient supplements (LNS) provided to pregnant and lactating women (PLW) and their children on nutrition and health outcomes through a cluster-randomized, partially blinded effectiveness trial, which is being implemented in rural northwest Bangladesh. As part of the effectiveness trial, the research team is conducting a process evaluation (PE) to thoroughly evaluate the implementation of the community health and development program (CHDP) of LAMB. The CHDP provided PLW with either LNS designed for PLW (through 6 months postpartum) or iron/folic acid (IFA) tablets (through 3 months postpartum), starting at the time the woman was identified as being pregnant (at or before 20 weeks gestation). The women's children receive LNS-child, micronutrient powder (MNP), or no supplement, starting at 6 months of age and continuing until they are 24 months old.

According to the LAMB CHDP protocol, community health workers (CHWs) visited women monthly to distribute a month's supply of supplements. The CHWs provided standard messages regarding the supplements (Appendix 1). Women receiving LNS were advised to consume one supplement per day through 6 months postpartum and were told that is was best if they mixed it with rice. IFA recipients were advised to consume one tablet per day throughout pregnancy and one tablet every other day after the child was born until 3 months postpartum and were told to consume it with water between meals.

This report presents a summary of the findings of the RDNS process evaluation participant adherence among pregnant and lactating women (PEPA-PLW) assessment. The PEPA-PLW assessment aimed to evaluate several aspects of the LAMB CHDP supplement distribution to PLW, and specifically to assess adherence to the formulation of LNS being distributed at the time of the interview (LNS-regular) and IFA among women participating in the LAMB CHDP, with particular interest in assessing whether the type of supplement (LNS versus IFA) affects adherence and whether adherence to LNS is sustained through 6 months postpartum.

Assessment Methods

The PEPA-PLW assessment was a cross-sectional survey of a random sample of RDNS participants between 28 weeks gestation and 6 months postpartum. To ensure that we had adequate sample sizes across pregnancy and postpartum groups, we stratified sampling by gestation or postpartum week to represent three phases defined as pregnant (P, > 28 weeks gestation until birth), early lactation (EL, 6 weeks postpartum until 3 months postpartum), and late lactation (LL, 3 months postpartum until 6 months postpartum). Thus, there were five groups

sampled, defined by the supplement provided and pregnancy and postpartum status (LNS_P, IFA_P, LNS_{EL}, IFA_{EL}, and LNS_{LL}). In total, 360 women were interviewed for the PEPA-PLW assessment, approximately 72 women per PEPA-PLW group. Women were interviewed in their homes regarding acceptability and intake of LNS or IFA and their experience with the community health center that provided the supplements.

The questionnaire consisted predominantly of open-ended questions. Adherence was assessed through a self-report of consumption (SRC) during the previous week. From SRCs, several variables were derived based on supplement intake recommendations: adherence as recommended (SRC = 100% of the recommended doses), high-adherence (SRC ≥ 75% of the recommended doses), and non-adherence (SRC = 0% of the recommended doses). Data on shared, lost, destroyed, and sold supplements were collected based on the participant's report. Women were also asked about how they received their first and most recent supply of supplements, how they typically consumed their supplements, and what their supplement preferences were, and to explain the reasons that they consumed the number of supplements that they did in the previous week. Supplement acceptability was assessed using a Likert-type scale.

Interruption of LNS supply

Prior to the PEPA-PLW assessment, but while the overall RDNS was ongoing, we were informed by the producer of the LNS that some batches of the formulation for PLW tested positive for the bacterium *Cronobacter sakazakii*. Although no adverse effects were reported, after consultation with the ICDDR,B Ethics Committee and Data Safety Monitoring Board, the decision was made to suspend distribution of LNS and provide those women with IFA instead, until new product that tested negative could be procured. When the new batch of LNS was available, remaining IFA tablets were collected from the homes and distribution of LNS sachets resumed. The nutrient composition of LNS did not change, but there were subtle differences in ingredients, resulting in differences in the taste of the LNS provided before the PEPA-PLW assessment (LNS-cumin) and the peanut LNS that was distributed at the time of the PEPA-PLW assessment (LNS-regular).

Depending on when a woman was enrolled in the study and at what stage of pregnancy or lactation she was in when the LNS-cumin distribution was suspended, her exposure to LNS-cumin, IFA, and LNS-regular varied. Thus, some women in the PEPA-PLW assessment in the LNS arm had experience with both LNS-regular and IFA and some women had experience with LNS-cumin, IFA, and LNS-regular. Those exposed to multiple supplements were asked about the acceptability of each supplement and were asked to compare LNS-regular and IFA.

Results

The sample selected for the maternal adherence evaluation did not differ significantly from the total RDNS population (n = 4,011), apart from gestational age (GA) at enrollment, which was slightly lower in the RDNS population compared with the PEPA-PLW sample ($p = 0.035$). Among the five subgroups defined for the PEPA-PLW sample, baseline characteristics were similar, with the exception of the prevalence of underweight at enrollment, which was lower among the LNS_{EL} group than among the IFA_P group ($p = 0.02$).

Mean SRC did not differ significantly by physiological status (pregnancy, early lactation, and late lactation) among LNS recipients ($p = 0.39$) or between LNS and IFA recipients during pregnancy ($p = 0.086$). However, the percentage of women who reported not consuming any supplements in the past week differed significantly between LNS and IFA recipients during pregnancy (22% and 6%, respectively; $p = 0.039$) and between IFA recipients who were pregnant compared with those in the early lactation period (6% and 19%, respectively; $p = 0.026$).

When asked about mode of supplement consumption in the previous week, LNS participants most often reported that they consumed LNS alone without adding it to any other food or liquid (63.6%), despite the message about mixing it with rice. Others mixed LNS with food (19.1%) or with water (9.8%). The majority of women who reported that they consumed LNS mixed with food took LNS-regular mixed with rice (66.7%) or puffed rice (24.2%).

Overall acceptability scores for both LNS and IFA were high, as were acceptability scores for organoleptic properties of LNS. Acceptability of LNS-cumin, the product provided to LNS recipients in the first part of the RDNS, was low however, with the majority of LNS recipients reporting that they 'disliked it a lot'. When asked what could make taking LNS-regular or IFA easier or more challenging for other women, LNS recipients suggested that specific preparation techniques (taking it with or without certain foods) could make it easier, while the smell could make it more challenging. IFA recipients suggested that taking it with water or specific routines of taking the tablet could make it easier, and that taking the tablet without water would make it more challenging.

Over half of the women who received both LNS and IFA (67.3%) stated that IFA was easier to consume than LNS, and approximately half (47.2%) preferred IFA while the other half (52.4%) preferred LNS.

More LNS recipients (18.0%) compared with IFA recipients (3.0%) reported that they shared some of the supplements from their most recent supplement supply ($X^2 = 33.33$; $P < 0.0001$), and more IFA recipients (9.0%) compared with LNS recipients (4.0%) reported that they lost or destroyed some of the supplements from their most recent supplement supply ($X^2 = 3.76$; $P = 0.05$). There were no reports of supplements from the most recent supply being sold or exchanged. Overall, 15% of women reported that they had run out of supplements at least once since starting to receive supplements; this was not associated with duration of RDNS participation and did not differ significantly by supplement type.

Women were asked to give the reasons for the number of supplements they consumed in the previous week. Among women who reported consuming the supplements ≥ 75% of the recommended times, common reasons were the benefits they perceived, either personally ('good for me', 'made me feel healthy', 'made me feel strong'), for their baby ('good for my baby', 'impacts my breast milk'), or in general ('contains nutrition'). These reasons were similar by supplement type. Reasons reported among low-adherers (<75%) were less consistent between supplement types. Both LNS and IFA low-adherers reported that they 'forgot' or 'ran out' of the supplements. They also reported benefits of the supplements, even though they were low-adherers. LNS low-adherers also reported the 'bad smell of the supplement', 'not being at home',

and ‘feeling nausea or vomiting’ as reasons for their consumption pattern. Both ‘bad smell of the supplement’ and ‘feeling nausea or vomiting’ were reported most commonly among pregnant LNS low-adherers in comparison to other low-adherers receiving LNS or IFA.

Conclusions

In summary, average SRC during pregnancy was similar between women given LNS-regular and those given IFA, although a statistically significantly higher percentage of the former reported “zero” consumption during the previous week. Adherence to LNS was not significantly different across physiological periods, suggesting sustained adherence through 6 months postpartum. For IFA, the percentage reporting “zero” consumption during the previous week was higher postpartum than during pregnancy. The findings suggest that beneficiaries make their own adaptations in terms of how and how often to consume the supplements.

The findings summarized in this report will allow us to better interpret and understand the results of the other components of the process evaluation as well as the results from the impact evaluation. They may also be useful to others considering the use of LNS in a programmatic setting, as the RDNS is the first effectiveness trial to be conducted with small-quantity LNS for pregnant and lactating women.

1. Introduction

1.1 The Rang-Din Nutrition Study

1.1.1 Background

The U.S. Agency for International Development (USAID)-funded Food and Nutrition Technical Assistance II and III Projects (FANTA), in collaboration with the University of California, Davis (UCD), initiated the Rang-Din Nutrition Study (RDNS), a cluster-randomized, controlled effectiveness study to evaluate the use of lipid-based nutrient supplements (LNS) for the prevention of chronic malnutrition in children and the improvement of nutritional status among pregnant and lactating women (PLW) in Bangladesh.

The RDNS is being implemented in partnership with the International Centre for Diarrhoeal Disease Research, Bangladesh (ICCDR,B) and the LAMB Project (formerly known as Lutheran Aid to Medicine in Bangladesh). LAMB provides an ideal programmatic context in which to test these interventions, as it provides services to approximately 10 million people in Bangladesh with a staff of more than 1,000 individuals employed in multifaceted health and development activities, such as primary health care, poverty alleviation, and a special focus on maternal and child health/welfare. The LAMB Project that is being used as the product and information delivery platform for the RDNS is the Community Health and Development Program (CHDP). The CHDP provides a host of services to the community, including maternity services at the home and at safe delivery units (SDUs) and behavior change communication (BCC) sessions on a wide variety of health topics. CHDP staff include community facilitators (CFs) and field coordinators (FCs), skilled birth attendants (SBAs) cum paramedics, community health workers (CHWs), and village health volunteers (VHVs).

1.1.2 Study Area

Bangladesh is divided into seven administrative divisions, which are further divided into districts. There are 65 districts in Bangladesh, each further subdivided into subdistricts (*upazila* or *thana*); there are a total of 507 subdistricts across the country. The rural areas of subdistricts are divided into approximately 7–10 unions, with each union consisting of multiple villages, and roughly 30,000 people. Unions are the lowest administrative units in the rural areas of Bangladesh.

The RDNS is being implemented in six unions (Auliapukur, Fateajangpur, Nasratpur, Saintara, Satnala, Tentulia) of the Chirirbandar subdistrict (**Figure 1**) of the Dinajpur district (**Figure 2**) and five unions (Bishnupur, Damodorpur, Lohanipara, Madhupur, Ramnathpur) of the Badarganj subdistrict (**Figure 3**) of the Rangpur district (**Figure 4**) in northwest Bangladesh. The LAMB Project and the RDNS offices are located in the Rajabashor union of the Parbatipur subdistrict of the Dinajpur district.

Figure 1. Map of Chirirbandar Subdistrict

Figure 2. Map of Dinajpur District

Figure 3. Map of Badargani Subdistrict

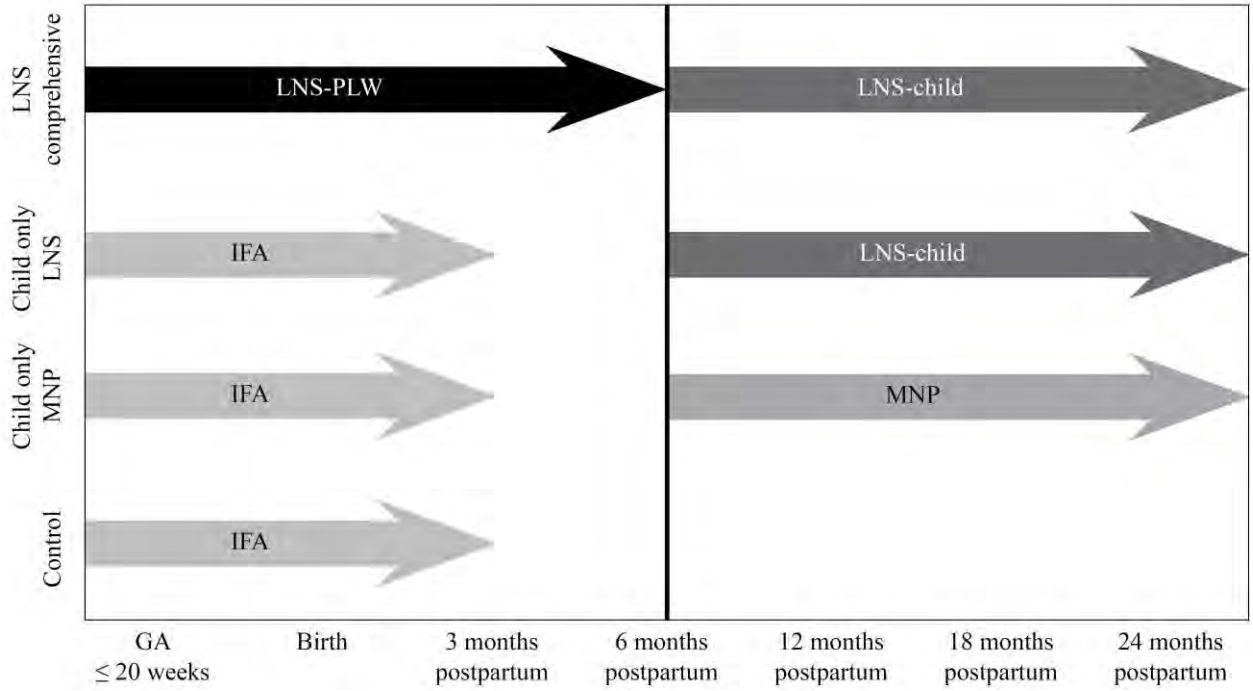
Figure 4. Map of Rangpur District

1.1.3 The RDNS Design

The RDNS involves four study arms (**Figure 5**):

1. **LNS comprehensive:** LNS for women during pregnancy and the first 6 months postpartum, plus LNS for their children starting at 6 months of age and continuing to 24 months
2. **Child only LNS:** Iron/folic acid (IFA) for women during pregnancy and the first 3 months postpartum, and LNS for their children starting at 6 months of age and continuing to 24 months
3. **Child only MNP:** IFA for women during pregnancy and the first 3 months postpartum, and multiple micronutrient powder (MNP) for their children starting at 6 months and continuing to 24 months
4. **Control:** IFA for women during pregnancy and the first 3 months postpartum and no additional supplement for their children

Figure 5. Timeline of Supplementation Intervention by Study Arm



The RDNS uses a longitudinal, cluster-randomized design. In this design, "clusters" (by definition, the work areas of specific CHWs and the population served within these work areas), rather than individual PLW, were randomly assigned to one of the treatment arms. The women were enrolled during the first or second trimester of pregnancy (≤ 20 weeks gestation), followed through pregnancy to 6 months postpartum, and their children are being followed from birth to 2 years, with health/growth assessments being conducted at several time points. The specific intervention arms evaluated as part of the study are depicted in Figure 5 above.

The standard of care in Bangladesh calls for women to consume IFA tablets containing 60 mg iron and 400 µg folic acid daily during pregnancy and for 3 months postpartum; thus, women not

receiving LNS were provied IFA tablets. In the current study, postpartum women were advised to consume IFA tablets containing 60 mg iron and 400 µg folic acid only every other day because the recommended dietary allowance for iron for lactating women is only 9 mg per day, compared to 27 mg during pregnancy. IFA tablets containing less than 60 mg of iron were unavailable in Bangladesh at the time the RDNS was starting, so the decision was to recommend consuming the standard IFA tablets every other day during the first 3 months postpartum to avoid excess iron intake.[1]

CHWs were identified as the key field-level CHDP staff members who could implement the RDNS interventions. According to LAMB CHDP protocol, women pick up their first supply of supplements at the LAMB SDU, after which the CHWs carry supplements from the SDUs to the women's homes. Along with distributing supplements, as per LAMB CHDP Supplement Distribution Protocol, CHWs were to give women a card with key messages about the supplements (Appendix 1) and to read the card aloud to the women.

1.2 The RDNS Process Evaluation

The RDNS evaluates the impact of the four interventions depicted in Figure 5 on the nutrition, health, and development outcomes of participating children up to 24 months of age and on the health and nutrition outcomes of their mothers. To understand the operational aspects of delivering these types of supplements through community-based programs, and to assess the feasibility, efficiency, and scalability of adding LNS to the current LAMB CHDP activities, FANTA and UCD are conducting a process evaluation (PE) to assess barriers and constraints to optimal delivery and uptake of the LNS and MNP interventions.

The PE involves the use of indicators coupled with qualitative assessments that reflect how well interventions are delivered and at what cost and how well they are received. As part of the RDNS PE, the personnel, financial, and other changes associated with adding LNS and MNP to the existing set of products, services, and messages already being delivered by the LAMB CHDP to women/caregivers in rural Bangladesh will be evaluated. The two primary objectives of the RDNS PE are to:

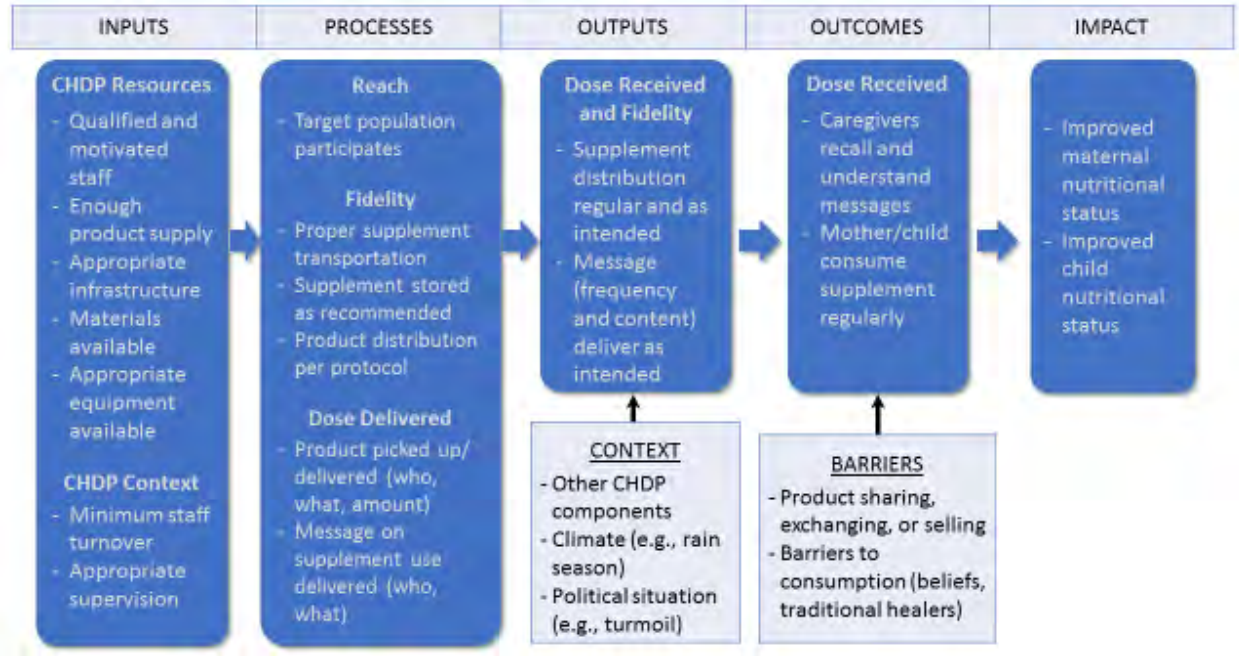
- Document and evaluate the resources (human, capital, financial, and informational) and processes needed for implementation of interventions that provide a nutrient supplement such as LNS or MNP in the context of the CHDP

[1] Stoltzfus, R.J. and Dreyfuss, M.L. 2003. "Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia." Available at: http://www.ilsi.org/ResearchFoundation/Publications/iron_guidelines_revised2003.pdf. These guidelines recommend that pregnant women receive 60 mg of iron daily for 6 months in pregnancy and continue daily supplementation through 3 months postpartum if the prevalence of anemia among pregnant women is < 40% in the population. This recommendation is based on the Bangladesh Demographic and Health Survey, which reports that the prevalence of anemia among pregnant women between the ages of 15 and 49 years was 49.6% (Bangladesh Demographic and Health Survey. 2011. Available at: http://dhsprogram.com/pubs/pdf/FR265/FR265.pdf). However, this does not reflect the prevalence of iron deficiency anemia, which is part of the anemia cases. A recent National Micronutrients Status Survey report states that 5% of non-PLW women had iron deficiency anemia (National Micronutrients Status Survey 2011–12: Final Report. 2013. Available at: http://www.icddrb.org/publications/cat_view/10043-icddrb-documents/10058-icddrb-reports-and-working-papers/14275-survey-reports).

- Use the PE findings to explain and interpret program effectiveness results and identify important facilitators and barriers to the success of the nutrition intervention, which can be used to improve the performance of current (CHDP) and future programs in the scaling up of LNS or MNP distribution

A key component of the RDNS PE is the assessment of expected program outcomes based on the expected inputs, processes, and outputs (**Figure 6**). The PE assesses what is needed to successfully initiate and implement supplement distribution. This assessment includes documentation of conditions before, at, and after the time of supplement distribution to beneficiaries. As part of a successful community supplementation program, one would expect the target population to receive the correct quantity of supplements and the correct messages on how to consume the supplements on time, and thereafter to both consume the supplements as recommended and recall and understand the related messages. Careful assessment of the dose received and utilized by the target population and the timing of supplement delivery should allow for a more informed explanation and interpretation of the overall study findings, as well as aid in identifying barriers and facilitators to participation of women in the program that could affect program success.

Figure 6. RDNS PE Model



Detailed information on the program as it is being implemented, along with the responses of the target beneficiaries to the program, will be valuable in assessing which activities along the program impact pathway worked well and which did not. The RDNS PE as a whole will aid in devising a guide to improve the replicability and success of this intervention program and to detail requirements for scaling up the intervention, if it is found to be effective.

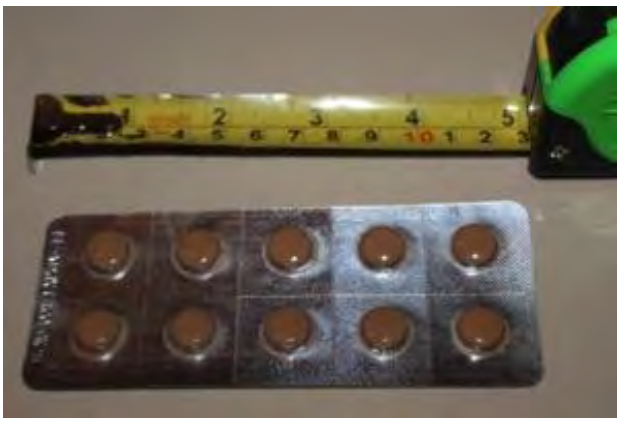
1.3 Process Evaluation Participant Adherence among Pregnant and Lactating Women Assessment

As part of the PE, the PE team (PET) conducted an assessment of adherence to maternal supplementation after the supplement distribution was established and had been operating for more than 1 year (the process evaluation participant adherence among pregnant and lactating women [PEPA-PLW] assessment). This report describes the main results of this assessment. Further analyses of maternal adherence, including an assessment of factors associated with adherence and a qualitative evaluation of acceptability and perceptions of LNS among participants and other key informants, will be presented elsewhere. This report is focused on adherence to maternal supplements and does not include evaluation of child supplementation adherence, which will be presented separately. Other components of the RDNS PE, and the implications of maternal adherence with regard to effects of the supplements on nutrition and health outcomes, are beyond the scope of this report, but will be included in another, more comprehensive report on the RDNS PE.

The PEPA-PLW assessment aimed to evaluate several aspects of the LAMB CHDP supplement distribution among PLW. The specific outcomes include beneficiary's recall of messages regarding supplement use and consumption of supplements as per supplement recommendations, as well as supplement acceptability among PLW. IFA tablets have been readily available in the Dinajpur and Rangpur markets for more than 20 years. In contrast, LNS for PLW is a novel product being distributed only by LAMB in these regions; it could be met with interest, enthusiasm, apathy, skepticism, or rejection. As it is an unfamiliar product, it is important to assess its acceptability among beneficiaries and influential persons, and to evaluate whether the product is being used as intended by the target population. The form of LNS (a daily dose of a 20 g sachet of fortified paste [**Figure 7**]) is also unfamiliar in this context and different from that of IFA, which in the RDNS context consists of one flat tablet approximately 1 cm in diameter (**Figure 8**) daily during pregnancy and every other day for 3 months after birth.

Figure 7. Local LNS Supplement, "Jononi"

Figure 8. Local IFA Tablet, "Alic"



Even if the processes and outputs of a program function properly, outcomes may not meet expectations for any number of reasons. For example, the supplements may not be consumed by the targeted individual or may be consumed by the targeted individual but not as prescribed. To identify shortfalls in outcomes shown in Figure 6 and to understand factors associated with these

shortfalls, thorough evaluations of adherence throughout the supplementation period (i.e., during pregnancy and postpartum) are needed, with special attention paid to uses of the supplements beyond those intended, barriers to adherence, and recollection of supplement use messages by the beneficiaries.

The main objective of the PEPA-PLW assessment was to evaluate adherence to LNS-regular, the LNS for PLW being provided at the time of the PEPA-PLW assessment, and IFA among women participating in the LAMB CHDP, specifically:

- Assessing whether adherence differs between LNS-regular and IFA
- Assessing sustained adherence to LNS-regular through 6 months postpartum by comparing adherence during pregnancy, early lactation, and late lactation
- Assessing sustained adherence to IFA through 3 months postpartum by comparing adherence during pregnancy to adherence in early lactation

Furthermore, we aimed to summarize the uses of the supplements beyond those intended, barriers to adherence, supplement consumption practices, supplement acceptability and preferences, and recall of supplement use messages by the beneficiaries.

2. Methodology

2.1 PEPA-PLW Design and Sample

The PEPA-PLW assessment is a cross-sectional survey of a random sample of RDNS participants to assess women's adherence to maternal supplementation from enrollment through 6 months postpartum. Although the RDNS design consists of four arms (depicted in Figure 1, page 6), there is no difference in the treatment in three of these arms from enrollment through 6 months postpartum (all women in those three arms received IFA from enrollment until 3 months postpartum) because child supplementation does not begin until 6 months postpartum. Therefore, because adherence to maternal supplementation is the focus of the PEPA-PLW assessment, the "Child only LNS," the "Child only MNP," and the "Control" arms were collapsed into one arm before sampling.

The PEPA-PLW assessment was conducted during December 2012 and January 2013. Supplement distribution had begun 16 months earlier, and the RDNS enrollment of 4,011 women had been completed. Of the 4,011 women, 2,945 had given birth and 838 were still pregnant. (The remaining 228 women were lost to follow-up due to either loss of pregnancy [miscarriage] or some other reason.) Conducting the PEPA-PLW assessment at this time allowed for pregnant and postpartum women to be interviewed concurrently. It also allowed ample time for the LNS distribution to be fully integrated into the program and to avoid problems likely to be encountered in the program's first few months.

The target population for the PEPA-PLW assessment included women who were pregnant (> 28 weeks gestation) or within the first 6 months postpartum who were enrolled in the RDNS. Some women participating in the RDNS had been randomly selected for participation in various RDNS substudies; those women were excluded from the PEPA-PLW to minimize the burden on participants. We hypothesized that adherence to maternal supplementation and factors affecting adherence may differ between pregnancy and the postpartum period and that postpartum adherence may differ over time in the LNS group. To ensure that we had adequate sample sizes across pregnancy and postpartum groups, we stratified sampling by gestation or postpartum week to represent three phases, defined as pregnant (P, > 28 weeks gestation until birth), early lactation (EL, 6 weeks postpartum until 3 months postpartum), and late lactation (LL, 3 months postpartum until 6 months postpartum). Thus, there were five groups (PEPA-PLW groups) sampled, defined by the supplement provided and pregnancy and postpartum status, referred to throughout the rest of this report as LNS_P, IFA_P, LNS_{EL}, IFA_{EL}, and LNS_{LL} (**Table 1**).

Table 1. PEPA-PLW Subgroup Definitions

Name	Definition
LNS_P	Pregnant LNS recipients between 28 weeks gestation and birth
IFA_P	Pregnant IFA recipients between 28 weeks gestation and birth
LNS_{EL}	LNS recipients in the early postpartum, defined as 6 weeks to 3 months postpartum
IFA_{EL}	IFA recipients in the early postpartum, defined as 6 weeks to 3 months postpartum
LNS_{LL}	LNS recipients in the later postpartum, defined as 3 to 6 months postpartum

Our sample size target was 72 women randomly selected for each of these five groups (total n = 360). This sample size was chosen to allow detection of a difference in adherence between two groups of ≥ 1 dose of supplement per week, using the standard deviation (SD = 2.03 doses of supplement per week) from preliminary adherence data collected at 42 days postpartum (n = 98), with 95% confidence and 80% power, while also accounting for an intra-cluster correlation of 0.01. The original sample size calculation included only three groups (LNS_P, IFA_P, LNS_{EL}).

To ensure that we had data from each of the CHWs' areas, sampling was stratified by cluster. As there are 16 clusters in which women were provided LNS, four or five women per cluster were sampled per LNS PEPA-PLW group. One or two women were randomly selected in each of the 48 IFA clusters for each of the pregnancy and early lactation PEPA-PLW groups.

Each of the 16 LNS clusters was assigned a number 1 through 16. Using a random number generator, eight numbers corresponding to the LNS cluster numbers were selected, and five LNS_P-eligible women from each of these clusters were randomly selected using a similar process (i.e., assigning numbers 1 through n and randomly selecting five). Two additional random numbers corresponding to eligible participants were generated for the back-up sample and used only if one of the first five selected women was unable or unwilling to participate. Four women were randomly selected from the remaining eight clusters, with two additional women preselected as back-ups. If there were not enough eligible women in a cluster to yield the four or five needed, another cluster with enough eligible women was randomly selected and an additional participant was randomly selected from that cluster. A similar process was carried out for the other four groups.

2.2 Data Collection Methods

The PEPA-PLW questionnaire was administered by the PET enumerator at the participant's home and consisted of questions related to the topics in **Table 2**. The PET is part of the RDNS evaluation team, and is independent from LAMB. Participant contact information was collected from the RDNS data management center, and enumerators tried to call each participant on the day of the interview before the enumerator arrived at her home. Women who were not home or unavailable on the assigned interview date were rescheduled for the interview on a later date, provided they were available within the data collection period.

Table 2. Components of the PEPA-PLW Questionnaire

Distribution of supplement	Messages related to supplement use
Adherence to supplement regimen	Supplement storage[a]
Method of supplement ingestion	Supplement acceptability
Sharing of supplements	Loss and destruction of supplements
Selling and exchanging of supplements	Running out of supplements
Supplement preferences	Beneficiary's evaluation of CHDP staff[1]
Utilization of CHDP services[a]	

[a] Not included in this report. These domains reflect other aspects of the PE and will be included in subsequent reports.

The questionnaire consisted predominantly of open-ended questions. Adherence was assessed through a self-report of consumption (SRC) from the previous week and a physical inventory of the participant's supplement supply. However, due to the many assumptions that are required to

make the physical inventory data interpretable, as well as other limitations to these data, results from these data are not presented in this report, with the exception of reporting the proportion of women who did not have any supplements in storage at the time of the interview.

Supplement acceptability was assessed using a Likert-type scale. The enumerator asked the participants what they thought about the supplement or about a specific property of the supplement. Using a pictorial face scale (Appendix 2), the enumerator then read the response options: "Dislike it a lot," "Dislike it a little," "Neither like nor dislike it," "Like it a little," and "Like it a lot."[2]

Data on baseline characteristics were collected from all RDNS participants at the women's homes and at the SDU at the time of enrollment, ≤ 20 weeks gestation. Information regarding socioeconomic characteristics was collected at the home, and medical history and anthropometric data were collected at the SDU. These data are used to describe the PEPA-PLW sample population. In particular, characteristics were compared among the five PEPA-PLW groups, and the participant characteristics of the overall PEP-PLW sample were compared to those of the overall study population.

2.2.1 Interruption of LNS Supply

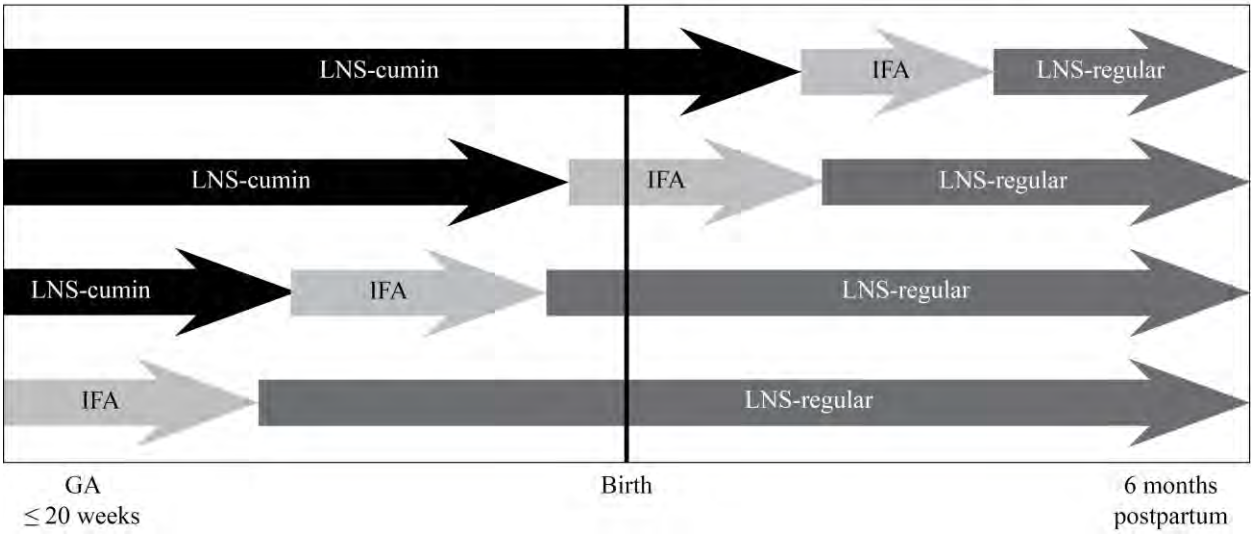
In early August 2012, we were informed by the producer of the LNS that some batches of the formulation for PLW tested positive for the bacterium *Cronobacter sakazakii*. Although no adverse effects were reported, after consultation with the ICDDR,B Ethics Committee and Data Safety Monitoring Board, the decision was taken to suspend distribution of LNS-PLW and provide those women with IFA instead, until new product that tested negative could be procured. The RDNS field team and LAMB CHDP collected all LNS sachets on August 8–9, 2012, and provided women in LNS clusters with IFA tablets for 10 consecutive weeks. Women were told that there was a new quality assurance test required for the Jononi (LNS) supplements and that until a new batch of Jononi was ready they should take the Alic (IFA) provided.[3] When the new batch of LNS (LNS-regular) was available, remaining IFA tablets were collected from the homes and distribution of LNS sachets resumed between October 15 and 20, 2012. The nutrient composition of LNS did not change, but there were subtle differences in ingredients that affected the taste of the supplement. The initial LNS used in the study contained cumin and soy (LNS-cumin), while LNS-regular, used after LNS supplementation resumed, did not contain these two ingredients and contained more peanut to compensate for the lack of soy.

[2] A similar method was used during the supplement acceptability trial (Mridha et al. 2012). That trial was conducted within the RDNS region from December 2009 through January 2010 as formative research for the RDNS. During Phase 1, Test Feeding, of the acceptability trial, women were asked to rate the color, consistency, odor, taste, and overall degree of liking of LNS mixed with rice using a similar pictorial scale.

[3] The exact wording that was developed to be disseminated to participants during the recall is as follows: "There is a new quality assurance test recommended for nutrient supplements like Jononi. The company that produces Jononi will have to conduct the new test to ensure quality and safety. We have sent samples of our current products to be tested, but we don't have all the results yet in. No adverse effects have been observed from the use of Jononi, but as a precautionary measure, we are temporarily suspending distribution of Jononi. We expect to have the test results soon and will be able to resume Jononi distribution."

Depending on when a woman was enrolled in the study and at what stage of pregnancy or lactation she was in when LNS-cumin was recalled, her exposure to LNS-cumin, IFA, and LNS-regular varied (**Figure 9**). The interruption in the LNS supply—although unfortunate—did provide a unique opportunity for women to compare their experiences with IFA and LNS-regular and between the initial LNS (LNS-cumin) and the replacement LNS (LNS-regular). Women who received LNS were asked to rate the acceptability of LNS-regular, IFA, and LNS-cumin. LNS recipients were also asked to compare the ease of use and overall preference between LNS-regular and IFA. All LNS recipients included in the PEPA-PLW assessment were receiving LNS-regular and not LNS-cumin at the time of data collection for the PEPA-PLW. Therefore, the LNS adherence data in this report are specific to LNS-regular.

Figure 9. Illustration of Categories of Supplement Exposure for Women in the PEPA-PLW



This diagram provides an overall illustration of the periods of exposure (pregnancy vs. postpartum) to the different supplements for women in the PEPA-PLW. It should be noted that the interruption could have occurred at any time during pregnancy or postpartum.

2.2.2 Questionnaire Development

The questionnaire was developed in English and translated into Bangla by bilingual staff. Questions regarding supplement acceptability were adapted from the acceptability trial that had been conducted prior to the start of the study (Mridha et al. 2012). Questions developed to assess beneficiaries' evaluation of CHDP staff were based on the "Head, Heart and Hand" scoring system developed by Shankar and colleagues (2009). The majority of the questions were open-ended and coded according to responses. The topics included in the questionnaire are listed in Table 2 (page 13). For questions that could have multiple responses, enumerators were instructed to ask the women "anything else?" two to three times or until the women responded "no."

The questionnaire was initially piloted by the PET staff in January 2012 and, after several revisions, was finalized in December 2012. PEPA-PLW groups were interviewed sequentially: First, the samples of pregnant women (LNS_P and IFA_P) (n = 144) were interviewed, followed by the LNS_{EL} sample (n = 72), the IFA_{EL} sample (n = 72), and finally the LNS_{LL} sample (n = 72).

2.2.3 Training PET Personnel

Field staff of the PET underwent training for the PEPA-PLW data collection. Training consisted of thoroughly discussing the questionnaire, standard interviewing techniques, research fundamentals, research ethics, ensuring data quality, standard operating procedures (SOPs), and obtaining informed consent. Staff members conducted mock interviews with each other and in the field with women who were beneficiaries of the LAMB CHDP supplement distribution, but not RDNS participants. To evaluate the knowledge level of the staff who underwent training, pre- and post-training quizzes were administered.

2.3 Ethical Approval

The PEPA-PLW assessment was approved by the UCD Institutional Review Board (IRB) on August 23, 2012; by the ICDDR,B Ethics Committee on December 3, 2012; and by the LAMB Ethics Committee on December 23, 2012. Each participant was read the IRB-approved consent form in Bangla. All participants provided consent prior to being interviewed. If a participant was under 18 years old, her guardian was also asked to provide consent. Participants who could not write were asked to provide consent with a thumbprint.

2.4 Data Management and Analysis

All completed questionnaires were submitted to the PET Research Investigator at the end of each day. Quality control procedures consisted of repeating 10% of the interviews to back-check responses and carrying out supervisor observations of an additional 10% of interviews to ensure that interviews were conducted as instructed in the SOPs. The PET Research Investigator or supervisors reviewed questionnaires and consent forms within 24 hours (or 72 hours, after weekends) of data collection, after which all forms were scanned and filed in a soft copy archive. The original forms were stored in a locked file cabinet in the PET archive before and after data entry.

Data were entered into a Microsoft Access 2010 template, which was designed to flag unreasonable and incorrect values. The data collector was asked to respond to queries raised by the supervisor or data management team. When data queries could not be resolved in the office, the data collector returned to the participant's home to re-collect data when appropriate. All data were double-entered. A UCD co-investigator cross-checked the first and second entries and performed additional data verification and cleaning. All data cleaning and analysis was done in SAS 9.3.

Baseline characteristics were compared between the PEPA-PLW sample and the overall study population and among PEPA-PLW groups using a generalized linear model that accounted for the random cluster effect. The Rao-Scott chi-square test, which also accounted for the design effect, was used to evaluate the difference in categorical variables among groups.

2.4.1 Adherence Analysis Methods

The recommended supplement dosage for LNS and pregnant IFA recipients was one supplement per day (or a total of 7 per week) and for postpartum IFA recipients was one supplement every other day (or a total of 3.5 per week) (**Table 3**). Maternal self-report of intake during the

previous 7 days (SRC) refers to the number of times the woman reported consuming the supplements in the previous week and does not account for the quantity consumed. Thus, a woman who consumed half of a sachet of LNS daily would have the same SRC as a woman who consumed a whole sachet of LNS daily. From this variable, variables for "adherence as recommended," "high-adherence," and "non-adherence" were created (**Table 4**). "Adherence as recommended" was defined as women reporting that they consumed the recommended number of supplements in the previous week (versus less than the recommended number) (Table 3**)**. "High-adherence" was defined as reporting the consumption of ≥ 75% of the recommended number of supplements (versus < 75%), and "non-adherence" was defined as reporting no supplements consumed in the previous week (versus any supplement consumption).

Table 3. Recommendations for Frequency of Supplement Intake

Supplement	Pregnant	Postpartum
LNS	Consume one sachet each day throughout pregnancy (7 per week)	Consume one sachet each day up to 6 months after birth (7 per week)
IFA	Consume one tablet each day throughout pregnancy (7 per week)	Consume one tablet every alternate day up to 3 months after birth (3–4 per week)

Table 4. Adherence Variables Defined by PEPA-PLW Group

PEPA-PLW Group	Adherence as Recommended	High-Adherence	Non-Adherence
LNS_P	SRC = 7	(SRC / 7) * 100 ≥ 75	SRC = 0
IFA_P	SRC = 7	(SRC / 7) * 100 ≥ 75	SRC = 0
LNS_{EL}	SRC = 7	(SRC / 7) * 100 ≥ 75	SRC = 0
IFA_{EL}	SRC = 3, 3.5, or 4	(SRC / 3.5) * 100 ≥ 75	SRC = 0
LNS_{LL}	SRC = 7	(SRC / 7) * 100 ≥ 75	SRC = 0

Thus, an LNS recipient or pregnant IFA recipient was considered a "high-adherer" if she consumed 6 or more supplements in the previous week, and a postpartum IFA recipient was considered a "high-adherer" if she consumed 3 or more tablets in the previous week.

Generalized linear models were used to evaluate differences in adherence among groups, using appropriate link functions for the various ordinal, binary, and continuous adherence variables. All models accounted for the design effect.

3. Results

3.1 Final Sample Baseline Characteristics

A total of 360 women were interviewed for the PEPA-PLW assessment (**Table 5**). Table 5 outlines the sample size and mean gestational age (GA) in weeks or weeks passed since birth by supplement provided and physiological status (PEPA-PLW groups).

Table 5. Average Gestational or Postpartum Age at Time of Interview, including Final Sample, by Supplement and Physiological Status

Supplement	Pregnant (P)[a]	Early lactation (EL)[b]	Late lactation (LL)[b]
LNS	n = 73 34.7 ± 2.6	n = 72 9.6 ± 1.9	n = 72 19.9 ± 3.2
IFA	n = 71 34.3 ± 2.8	n = 72 9.4 ± 1.9	n = 0

[a] Mean ± SD GA in weeks at the time of the interview
[b] Mean ± SD weeks since birth at the time of the interview

Of the 360 women originally selected for the PEPA-PLW sample, 45 were not interviewed and replacements were assigned (**Table 6**). Women were not interviewed if they had moved out of the study area and would not be returning until after the PEPA-PLW assessment was completed or if they chose not to participate in the interview. In the case of the LNS_P and IFA_P samples, women were not interviewed if they had already given birth at the time of the interview, as they were no longer eligible. Nineteen of the replacements were from a different cluster than the originally selected woman, and nine were from a different union.

Baseline characteristics of the PEPA-PLW sample did not differ significantly from those of the RDNS population (**Table 7**), with the exception of GA at enrollment: The women in the PEPA-PLW sample were enrolled on average approximately 3 days earlier in their pregnancy than those in the overall RDNS population ($p = 0.035$). It is possible that this is due to the timing of the cross-sectional PEPA-PLW survey. The PEPA-PLW sample occurred 16 months into the project, and it did not capture women enrolled in the first 9 weeks of enrollment. The mean GA at enrollment among participants enrolled in those first 9 weeks was 13.7 ± 3.5 weeks, a bit higher than for the RDNS sample as a whole (13.0 ± 3.4 weeks). At the start of the enrollment period, women with a wide range of GA were identified through the CHDP's active surveillance for new pregnancies. As the new pregnancy active surveillance and RDNS became established, pregnant women were identified more promptly, i.e., at an earlier GA.

Table 6. Summary of Reasons for Not Interviewing Originally Selected Women, by PEPA-PLW Group

	Reason			
PEPA-PLW Group	**Gave birth[a]**	**Moved**	**Refusal**	**Total**
LNS_P	8	5	1	14
IFA_P	6	2	3	11
LNS_{EL}	0	7	0	7
IFA_{EL}	0	4	0	4
LNS_{LL}	0	8	1	9
Total	**14**	**26**	**5**	**45**

[a] Three women who were selected as replacements were visited by field staff and found to be ineligible because they had given birth. These cases are not included in the table.

Table 7. Baseline Characteristics of Overall PEPA-PLW Sample Compared to RDNA Population

Characteristic	**PEPA-PLW (n = 360)**	**RDNS (n = 4,011)**	**p value[g]**
GA at enrollment (weeks)	12.6 ± 3.1[a]	13.0 ± 3.4	0.035
Age (years)	21.6 ± 4.8	22.0 ± 5.0	0.23
Primiparous[b] (%)	37	35	0.69
Previous stillbirth[b] (%)	5	6	0.53
Current smoker[b] (%)	0.00	0.05	–[c]
Tobacco use[b] (%)	4	5	–[c]
Early pregnancy body mass index (BMI)[b] (kg/m^2)	20.3 ± 2.6	20.4 ± 2.8	0.99
BMI[b] < 18.5 (%)	27	27	–[d]
Height[b] (cm)	150.7 ± 5.6	150.5 ± 5.6	0.49
Short stature[b,e] (%)	15	16	0.47[h]
Mid-upper arm circumference[b] (MUAC) (cm)	25.0 ± 2.5	24.9 ± 2.6	0.69
Formal schooling completed[f] (years)	6.3 ± 3.1	6.2 ± 3.3	0.92
Did not attend any school (%)	6	8	0.32
Formal schooling completed by household head[f] (years)	3.9 ± 4.0	4.1 ± 4.1	0.18
Household head did not attend any school (%)	30	30	0.83
Husband's occupation (%)			0.84[i]
Farmer	16	16	
Business owner	17	19	
Transport worker	14	15	
Day labor	36	33	
Other	17	18	
Religion (%)			0.39[i]
Islam	78	80	
Hindu	21	19	
Christian	1	1	
Buddhism	0	< 1	

[a] Mean ± SD for all similar variables.
[b] Missing 16 PEPA-PLW participants and 159 RDNS participants
[c] The values were too small to detect a difference; model would not converge
[d] Model would not converge
[e] Height < 145 cm
[f] Includes those who never attended school as 0 grades completed
[g] Generalized linear models that account for the cluster design
[h] The random effect of cluster was removed because the model would not converge otherwise
[i] The Rao-Scott chi-square test with a random effect of cluster

Table 8. Comparison of Baseline Characteristics among PEPA-PLW Groups

Characteristics	LNS_P (n = 73)	LNS_{EL} (n = 72)	LNS_{LL} (n = 72)	IFA_P (n = 71)	IFA_{EL} (n = 72)	p value[f]
GA at enrollment (weeks)	12.6 ± 3.0[a]	13.2 ± 3.3	12.3 ± 3.1	12.2 ± 2.8	12.8 ± 3.2	0.27
Age (years)	20.8 ± 5.2	22.2 ± 4.7	21.3 ± 4.7	21.8 ± 5.2	21.8 ± 4.2	0.52
Primiparous[b] (%)	47[A]	24[A]	44[A]	40[A]	29[A]	0.025
Previous stillbirth[b] (%)	0	7	6	7	6	–[c]
Tobacco use[b] (%)	2	6	3	9	3	–[c]
Early pregnancy BMI[b] (kg/m^2)	20.0 ± 2.7	20.6 ± 2.3	20.8 ± 2.5	20.1 ± 3.0	20.3 ± 2.5	0.29
BMI < 18.5[b] (%)	32[A,B]	17[B]	18[A,B]	39[A]	30[A,B]	0.02
Height[b] (cm)	149.8 ± 5.1	150.3 ± 5.7	151.5 ± 5.8	151.0 ± 5.4	150.7 ± 5.7	0.49
Short stature[b,d] (%)	15	24	14	7	13	0.10
MUAC[b] (cm)	24.5 ± 2.5	25.0 ± 2.3	25.6 ± 2.3	24.8 ± 2.8	24.8 ± 2.3	0.085
Formal schooling completed[e] (years)	6.8 ± 3.3	6.5 ± 3.1	6.4 ± 2.6	6.0 ± 3.2	6.0 ± 3.4	0.56
Did not attend any school (%)	7	6	6	3	10	0.57
Formal schooling completed by household head[e] (years)	4.0 ± 4.1	4.4 ± 4.0	3.2 ± 3.7	3.6 ± 4.2	4.0 ± 4.1	0.50
Household head did not attend any school (%)	27	25	38	34	25	0.38
Husband's occupation (%)						0.47[g]
Farmer	21	18	19	11	11	
Business owner	18	13	19	13	22	
Transport worker	16	13	17	13	13	
Day labor	36	38	33	44	31	
Other	10	19	11	20	24	
Religion (%)						0.17[g]
Islam	73	74	83	76	85	
Hindu	23	25	17	24	15	
Christian	4	1	0	0	0	

[a] Mean ± SD for all similar variables

[b] Missing 7 participants from LNS_P, 1 from IFA_P, 2 from each LNS_{EL} and IFA_{EL}, and 4 from LNS_{LL}

[c] The values were too small to detect a difference; model could not converge

[d] Height < 145 cm

[e] Includes those who never attended school as 0 grades completed

[f] Characteristics were compared among groups using generalized linear models that accounted for the cluster design and adjusted for multiple comparisons using the Tukey-Kramer test for multiple comparisons; if the differences among groups were statistically significant ($p \leq 0.05$), then between-group differences at $p \leq 0.05$ are indicated by different uppercase letter superscripts

[g] The Rao-Scott chi-square test with a random effect of cluster

Within the PEPA-PLW sample, the baseline characteristics did not differ significantly between groups, with the exception of prevalence of underweight at enrollment (**Table 8**), defined as a body mass index of < 18.5 kg/m^2. This differed significantly between LNS recipients in the early lactating and pregnant IFA recipients. The percentage of primiparous women also differed significantly among groups (perhaps because primiparous women are more likely than multiparous women to return to their parents' home in the early postpartum period, resulting in a lower percentage of primiparous women being at their residence at the time of the early postpartum interview), but after adjustment using the Tukey-Kramer test for multiple comparisons no significant differences were detected between any two groups.

3.2 Distribution of Supplements and Related Messages

3.2.1 Supplement Distribution

Based on women's reports, initial supplement distribution occurred mostly at the SDU (71.7%), while 17.8% of the women reported receiving the first supply of supplements at their home from CHDP staff (CHW, VHV, or CF/FC), and 7.5% reported receiving the first supply by a CHW at a satellite session where LAMB CHDP provides antenatal, postnatal, child health, and family planning care. Some women also reported that they received their first supply from an RDNS office, at a BCC session, or from a CHW on the side of the road (3.1%). In contrast, 92.2% of women reported receiving the most recent supply of supplements at home from CHDP staff, while 2.5% reported gathering them from the SDU, 2.8% received them from a CHW at a satellite session, and 2.5% received them through other methods. Supplements recently received at the home were delivered by CHWs (76.4%), VHVs (12.2%), or CHWs together with VHVs (3.6%) (total of 92.2% of all respondents). This appropriately reflects the CHDP protocol to provide the first supplement distribution at the SDU and subsequent distributions at the woman's home.

Table 9. Methods of Supplement Distribution

	Supplement Provisions, % (n)		
Method	**Initial (n = 360)**	**Most recent (n = 360)**	**Preferred (n = 357)**
Pick up from SDU	72 (258)	3 (9)	< 1 (1)
Drop off at home by CHDP staff	18 (64)	92 (332)	99 (354)
CHW[a]	86 (55)	83 (275)	82 (289)
VHV[a]	8 (5)	13 (44)	12 (43)
CF/FC[a]	2 (1)	0 (0)	< 1 (1)
CHW and VHV[a]	5 (3)	4 (13)	6 (21)
Pick up from CHW during satellite session	8 (27)	3 (10)	< 1 (1)
Pick up from RDNS office	3 (9)	0 (0)	0 (0)
Pick up from VHV at VHV's home	0 (0)	1 (3)	0 (0)
Other	1 (2)	2 (6)	< 1 (1)

[a] Percent (n) out of drop off at home from CHDP staff

When asked what the preferred distribution method is, 98.9% of women responded that the best distribution method is to receive supplements from CHDP staff at their homes and 1.1% reported other preferred methods of receiving supplements. Specifically, 80.7% of the women would prefer to receive supplements from CHWs at the home, 12.0% from VHVs at the home, 5.9% from the CHW and VHV at home, and 0.3% from CF/FC at home.

3.2.2 Supplement Consumption Messages at First Supplement Distribution

All women reported receiving instruction on supplement consumption at the time of the first supplement distribution. Overall, the most common message women recalled about supplement use during the first distribution was to take one supplement per day. **Table 10** and **Table 11** summarize messages women remembered receiving during initial supplement distribution. Apart

from the standard supplement messages developed by LAMB and RDNS (Appendix 1), women reported receiving a number of other instructions. Only 3% of all women reported being instructed that it is fine to take more than one supplement per day (which contradicts the standard supplement messages). Women were also advised regarding specific times of day to take the supplements, such as in the evenings or after dinner. This advice was reported more commonly among IFA recipients. Six percent of LNS recipients reported being advised to mix the supplement with sugar or molasses. Some of these unexpected messages that women reported receiving, such as mixing with sugar or the timing of when to take the supplements during the day, may have been the CHWs' responses to hearing about challenges women were facing when they consumed the supplements as recommended or may reflect the participant's suggestions for making consumption of supplements easier. There were also women provided with LNS who reported receiving conflicting messages to both "take the supplement mixed with food" and to "take it without any foods or liquids." It is possible that CHDP staff advised women to either mix the LNS or consume it alone. Similarly, some women said that they received advice to "take it as [she] like[s]/as [she] can." Among the IFA recipients, there were reports of being advised to "take one supplement per day" and that it was "okay to take more than one supplement per day [or to] take more than one a day."

Table 10. Supplement Consumption Messages Received during First Supplement Distribution Reported by Women Receiving LNS

Messages	Beneficiaries received (%)[a] (n = 217)
Standard LAMB CHDP messages	
Take one supplement per day	95.4
Take the supplement mixed with food	82.9
Do not take more than one supplement per day	22.1
Messages that are not part of the standard LAMB CHDP messages	
Take it without any other foods or liquids	27.2
Take the supplement with water	12.0
Mix the supplement with sugar or molasses	6.0
OK to take more than one supplement per day/take more than one a day	3.2
Advice about what time of day to eat it	2.8
Take it as you like/as you can	2.3
Take it with hot or cold foods specifically	1.8
Take the supplement between meals	0.9
Take it like a pickle	0.9
Do not heat it	0.9
Take it at any cost/no matter what	0.9
Take one packet of LNS throughout the day	0.5

[a] Numbers add up to more than 100% because the question was open ended and respondents could list more than one message.

Table 11. Supplement Consumption Messages Received during First Supplement Distribution Reported by Women Receiving IFA

Messages	Beneficiaries received (%)[a] (n = 142)
Standard LAMB CHDP messages	
Take one supplement per day	98.6
Take the supplement with water	55.6
Do not take more than one supplement per day	23.9
Take the supplement between meals	16.9
Take sachet/tablet every other day	1.4
Take supplement on a full stomach	1.4
Messages that are not part of the standard LAMB CHDP messages	
Advice about what time of day to eat it	12.7
OK to take more than one supplement per day/take more than one a day	3.5
Take the supplement mixed with food	0.7

[a] Numbers add up to more than 100% because the question was open ended and respondents could list more than one message.

3.2.3 Supplement Consumption Messages at Most Recent Supplement Distribution

There was a significant difference between supplement groups in the percentage of recipients who reported receiving instruction on supplement consumption when they received their most recent supplement ration: LNS = 46% vs. IFA = 69%, p = 0.0001 (LNS_P = 52%; LNS_{EL} = 36%; LNS_{LL} = 50%; IFA_P = 53%; IFA_{EL} = 85%). This was no longer significant when postpartum IFA recipients were excluded (p = 0.31). Fewer pregnant IFA recipients (53%) were provided instruction compared with postpartum IFA recipients (n = 85%). Because the supplement use directions changed for IFA in the postpartum period, we speculate that CHWs were more inclined to provide the new instructions to postpartum women, and less inclined to reiterate the same instructions for pregnant IFA recipients and LNS recipients. In addition, women receiving new instructions may have been more inclined to remember receiving advice, compared to women receiving the same advice as before. According to the LAMB supplement distribution protocol, women should have received supplements every month. Since the women were on average 9.6 ± 1.9 weeks postpartum in the LNS_{EL} group and 9.4 ± 1.9 weeks postpartum in the IFA_{EL} group, we would expect the majority of the women in the early lactation groups to have received more than one visit from the CHW since birth. However, we did not ask about the number of visits women had received since birth.

Table 12. Supplement Consumption Messages Reportedly Received during the Most Recent Supplement Distribution by Women Receiving LNS (among those who reported receiving messages at the most recent supplement distribution)

	Beneficiaries received (%)[a] (n = 100)			
Messages	LNS_P (n = 38)	LNS_{EL} (n = 26)	LNS_{LL} (n = 36)	All LNS (n = 100)
Standard LAMB CHDP messages				
Take one supplement per day	81.6	69.2	91.7	82.0
Take the supplement mixed with food	68.4	57.7	77.8	69.0
Do not take more than one supplement per day	10.5	7.7	5.6	8.0
Take the supplement with water	7.9	0.0	0.0	3.0
Messages that are not part of the standard LAMB CHDP messages				
Take it without any other foods or liquids	5.3	30.8	25.0	19.0
Consume it as you have been taking it/as instructed before	13.2	0.0	2.8	6.0
Take it as you like/as you can	7.9	0.0	0.0	3.0
Take the supplement between meals	2.6	0.0	2.8	2.0
Mix the supplement with sugar	2.6	0.0	2.8	2.0
OK to take more than one supplement per day/take more than one a day	0.0	3.8	0.0	1.0
Take one sachet throughout the day	2.6	0.0	0.0	1.0

[a] Numbers add up to more than 100% because the question was open ended and respondents could list more than one message.

Table 13. Supplement Consumption Messages Reportedly Received during the Most Recent Supplement Distribution by Women Receiving IFA (among those who reported receiving messages at the most recent supplement distribution)

	Beneficiaries received (%)[a] (n = 99)		
Messages	IFA_P (n = 38)	IFA_{EL} (n = 61)	All IFA (n = 99)
Standard LAMB CHDP messages			
Take tablet every other day	0.0	96.7	59.6
Take one supplement per day	94.7	4.9	39.4
Take the supplement with water	42.1	18.0	29.3
Take the supplement between meals	10.5	4.9	7.1
Do not take more than one supplement per day	10.5	3.3	6.1
Messages that are not part of the standard LAMB CHDP messages			
Advice about what time of day to take it	0.0	1.6	1.0
Consume it as you have been taking it/as instructed before	2.6	0.0	1.0

[a] Numbers add up to more than 100% because the question was open ended and respondents could list more than one message.

The most common instructions given at the time of the most recent supplement distribution were those regarding frequency of intake. Ninety-five percent of pregnant IFA recipients were instructed to take one supplement per day and 97% of postpartum IFA recipients were told to take one tablet every other day. This correctly reflects the LAMB CHDP messages, which state

that women should take one IFA tablet per day during pregnancy and one tablet every other day after birth until 3 months postpartum.

3.3 Adherence

The adherence results based on SRCs showed that 51% of participants consumed the correct supplement dose in the previous week. The mean percentage adherence (i.e., the number of times consumed as a percentage of the recommendation) among all participants was 77%. Four percent of women reported consuming more than the recommended dose, and 17% did not consume any supplements in the previous week.

The average SRC during the previous week did not differ significantly by supplement group (e.g., LNS_P vs. IFA_P) or by pregnancy or postpartum status (e.g., LNS_P vs. LNS_{EL} vs. LNS_{LL}) (**Table 14**). The average number of LNS-regular sachets reportedly consumed by the target population of pregnant and postpartum women in the previous week was five (95% CI: 4.6, 5.4) out of the recommended seven sachets. Pregnant women receiving IFA reported consuming an average of six tablets per week (95% CI: 5.5, 6.4), and postpartum women reported an average of three tablets per week (95% CI: 2.6, 3.4).

When SRCs were converted to percentages and dichotomized into low adherence (< 75% of recommended) and high-adherence (≥ 75% of recommended), there was a significant difference in high-adherence between LNS and IFA women in the early postpartum period (LNS_{EL} vs. IFA_{EL}): 71% of IFA_{EL} women were high-adherers compared to 51% of LNS_{EL} women ($p = 0.04$). High-adherence was similar across pregnancy and postpartum periods among LNS ($LNS_P = 56\%$, $LNS_{EL} = 51\%$, $LNS_{LL} = 63\%$; $p = 0.42$) and IFA ($IFA_P = 70\%$, $IFA_{EL} = 71\%$; $p = 0.82$) recipients, and was similar between LNS and IFA recipients during pregnancy ($LNS_P = 56\%$, $IFA_P = 70\%$; $p = 0.23$). There were nine cases (13%) in the IFA_{EL} group who consumed more than the recommended number (> 4 tablets per week) and two cases (3%) in the LNS_{EL} group who consumed more than the recommended number (> 7 sachets in a week). When these over-consumers were excluded from the analysis, there was no longer a significant difference between groups in the prevalence of high-adherence ($p = 0.26$). Thus, the difference in the prevalence of "high-adherers" seems to be due to a greater percentage of IFA_{EL} women consuming more than the recommended number of doses compared with the LNS_{EL} women. This is not surprising given that the IFA recommendations change from 7 tablets per week during pregnancy to 3–4 tablets per week in the postpartum period. While the prevalence of "high-adherers" was no longer significantly different between LNS_{EL} and IFA_{EL} after excluding over-consumers, there were significantly more women in the IFA_{EL} group (58%) than in the LNS_{EL} group (42%) who reportedly consumed supplements as recommended (i.e., 100% of recommended dose) in the previous week ($p = 0.050$). Among LNS groups, the percentages of women who reported consuming zero supplements in the previous week, "non-adherers," did not differ between pregnancy and postpartum (Table 14). However, the prevalence of non-adherers was significantly higher among pregnant women receiving LNS-regular (22%) and among postpartum women receiving IFA (19%) than the prevalence of non-adherers among pregnant women receiving IFA (6%). There was no significant difference in other measures of adherence among groups (Table 14).

Table 14. Adherence Comparisons among Supplementation Groups and Physiological Status

	LNS				IFA			LNS vs. IFA	
Adherence Definition	**LNS_P (n = 73)**	**LNS_{EL} (n = 72)**	**LNS_{LL} (n = 72)**	**p(a)**	**IFA_P (n = 71)**	**IFA_{EL} (n = 72)**	**p(b)**	**p(c)**	**p(d)**
SRC[a,b]	4.8 ± 3.0 6	4.9 ± 3.1 6	5.2 ± 2.6 7	0.39	5.9 ± 1.8 7	3.0 ± 1.8 3	NA[f]	0.086	NA[f]
Mean percent adherence based on SRC[b]	68.7 ± 42.4 85.7	70.2 ± 44.9 85.7	75.4 ± 37.4 100.0		84.9 ± 25.9 100.0	85.9 ± 52.3 85.7			
Adherence as recommended[c] (%)	45	42	53	0.39	56	58	0.72	0.29	0.050
Prevalence of non-adherers[d] (%)	22	21	17	0.76	6	19	0.026	0.039	0.94
Prevalence of high-adherers[e] (%)	56	51	63	0.42	70	71	0.82	0.23	0.040

p values for comparisons: p(a): LNS_P vs. LNS_{EL} vs. LNS_{LL}; p(b): IFA_P vs. IFA_{EL}; p(c): LNS_P vs. IFA_P; p(d): LNS_{EL} vs. IFA_{EL}

[a] Reported number of times supplement was consumed in the past week

[b] Mean ± SD; median

[c] Reported consuming seven supplements per week among LNS and IFA_P recipients and reported consuming three or four supplements per week among IFA_{EL} recipients

[d] Prevalence of women who reported consuming zero supplements per week

[e] Prevalence of women who reported consuming ≥ 75% of recommended supplements based on SRCs of the previous week

[f] Due to the difference in recommendations, these groups were not compared

3.4 Method of Supplement Consumption

Women who had consumed supplements in the previous week were asked to report the method by which they typically consumed their supplements in the previous week. While most women reported having been instructed to consume LNS-regular mixed with food, the majority of women consumed LNS-regular directly without any other food or drink. Of the 19% of women who typically consumed LNS-regular with food, 67% took the supplement mixed with cooked rice and 24% mixed the supplement with puffed rice. It was less common for women to consume LNS-regular with breads, biscuits, or other foods.

Table 15. Methods of Consumption among Women Who Reported Consuming LNS-Regular in the Previous Week, % (n)

Method	LNS_P (n = 57)	LNS_{EL} (n = 57)	LNS_{LL} (n = 59)	All LNS (n = 173)
Taken directly without anything	59.6 (34)	66.7 (38)	64.4 (38)	63.6 (110)
Mixed with food	15.8 (9)	24.6 (14)	16.9 (10)	19.1 (33)
Mixed with water	10.5 (6)	5.3 (3)	13.5 (8)	9.8 (17)
Mixed with sugar/molasses	8.8 (5)	3.5 (2)	1.7 (1)	4.6 (8)
Taken with water	5.3 (3)	0.0 (0)	0.0 (0)	1.7 (3)
Mixed with juice	0.0 (0)	0.0 (0)	1.7 (1)	0.6 (1)
Taken with milk	0.0 (0)	0.0 (0)	1.7 (1)	0.6 (1)

Table 16. Foods with which Women Generally Mixed LNS-Regular, % (n)

Food	LNS_P (n = 9)	LNS_{EL} (n = 14)	LNS_{LL} (n = 10)	All LNS (n = 33)
Rice	55.6 (5)	78.6 (11)	60.0 (6)	66.7 (22)
Puffed rice	33.3 (3)	14.3 (2)	30.0 (3)	24.2 (8)
Curry	11.1 (1)	0.0 (0)	0.0 (0)	3.0 (1)
Bread	0.0 (0)	7.1 (1)	0.0 (0)	3.0 (1)
Biscuits	0.0 (0)	0.0 (0)	10.0 (1)	3.0 (1)

IFA was consumed by swallowing it with water among 93.7% of women. As IFA is a tablet, it is expected that the majority of women would consume it in such a way. IFA recipients were advised to take the supplement with water between meals or after a meal (Appendix 1).

3.5 Acceptability

Women rated how much they liked the supplement using a 5-point Likert scale for each characteristic, with 1 = "Dislike it a lot," 2 = "Dislike a little," 3 = "Neither like nor dislike it," 4 = "Like it a little," and 5 = "Like it a lot." A picture scale of faces was used to guide the women in their responses (Appendix 2). Women rated their overall opinion of the supplements and additionally rated the organoleptic properties of LNS-regular.

The median Likert scores for the color and consistency of LNS-regular were not different from the overall acceptability of LNS-regular, all of which were 5 ("Like it a lot") (**Tables 17a–c**). Women in pregnancy, early lactation, and late lactation found the LNS-regular equally acceptable. Approximately 5% of women disliked the color, while 10% disliked the consistency, and 10% disliked LNS-regular overall. The median Likert scores for smell and taste were 4 ("Like it a little"), which are lower than that of the score for overall acceptability, but still acceptable. Twenty-eight percent of women disliked the smell of LNS-regular and 15% disliked the taste.

Table 17a. Acceptability of LNS-Regular Organoleptic Properties Reported Using a 5-Point Likert Scale, Pregnant Women (n = 73)

Characteristic	1	2	3	4	5	Do not know	Median score
Color (%)	4.1	5.5	2.7	28.8	58.9	0.0	5
Smell (%)	19.2	15.1	4.1	26.0	34.3	1.4	4
Taste (%)	13.7	5.5	5.5	27.4	48.0	0.0	4
Consistency (%)	4.1	8.2	8.2	20.6	58.9	0.0	5
Overall (%)	**8.2**	**6.9**	**5.5**	**19.2**	**60.3**	**0.0**	**5**

Table 17b. Acceptability of LNS-Regular Organoleptic Properties Reported Using a 5-Point Likert Scale, Women in Early Lactation (n = 72)

Characteristic	1	2	3	4	5	Do not know	Median score
Color (%)	0.0	4.2	2.8	25.0	68.1	0.0	5
Smell (%)	11.1	16.7	11.1	33.3	27.8	0.0	4
Taste (%)	5.6	9.7	8.3	29.2	47.2	0.0	4
Consistency (%)	5.6	5.6	2.8	27.8	58.3	0.0	5
Overall (%)	**5.6**	**5.6**	**0.0**	**27.8**	**61.1**	**0.0**	**5**

Table 17c. Acceptability of LNS-Regular Organoleptic Properties Reported Using a 5-Point Likert Scale, Women in Late Lactation (n = 72)

Characteristic	1	2	3	4	5	Do not know	Median score
Color (%)	1.4	0.0	4.2	23.6	70.8	0.0	5
Smell (%)	5.6	15.3	5.6	40.3	33.3	0.0	4
Taste (%)	2.8	6.9	4.2	36.1	50.0	0.0	5
Consistency (%)	2.8	4.2	8.3	23.6	61.1	0.0	5
Overall (%)	**2.8**	**2.8**	**5.6**	**34.7**	**54.2**	**0.0**	**5**

Overall, LNS-regular and IFA were acceptable to participants (**Table 18**). Due to a disruption in the LNS supply chain because of the problems described previously, women in the LNS clusters received LNS-regular, IFA, and LNS-cumin at different periods during pregnancy and postpartum. Among these women, there was no difference in the median Likert scores for LNS-regular vs. IFA; both were acceptable. However, women reported a strong dislike for the LNS distributed prior to the disruption, LNS-cumin (Table 18). Further informal discussion with participants and CHWs revealed that women found the smell and taste of LNS-cumin less acceptable than LNS-regular.

Table 18. Overall Acceptability of LNS-Regular and IFA Tablets Reported Using a 5-Point Likert Scale, Median Likert Scale (Interquartile Range)

Supplement	P	EL	LL	Acceptability among P, EL, and LL groups combined
LNS (LNS-regular) (n = 73, 72, 72, 217)	5 (4–5)	5 (4–5)	5 (4–5)	5 (4–5)
IFA tablets (n = 71, 72, NA, 143)	5 (5–5)	5 (5–5)	NA	5 (5–5)
Previous LNS provided to women in the LNS group (LNS-cumin) (n = 191)				1 (1–2)
IFA tablets provided to women in the LNS group (n = 212)				5 (4–5)

3.6 Supplement Preference

3.6.1 Easy and Challenging Aspects to Consumption

Women were asked to indicate one thing about LNS-regular or IFA that could make it easy for other women to take it and one thing that could make it challenging for other women to take it. Women provided IFA suggested that taking the tablet with water (76%), after meals (29%), or in the evening or before bed (35%) would make it easier for other women and that taking the tablet alone without water (41%) would be challenging. There were also some women who reported that the smell of the tablets made it challenging to consume (12%), and some women suggested that others might be concerned about having large babies or problems during childbirth as a consequence of taking IFA (9%).

Women provided LNS were less consistent in their responses. Women suggested that consuming LNS-regular without any food (36%), with rice (30%), with puffed rice (21%), with water (19%) or with sugar or molasses (9%) could make taking the supplement easy. However, 35% of women suggested that taking the supplement with rice would make it challenging, and 17% thought taking it without anything would make it challenging. Almost one-third of women (31%) stated that the smell could make consuming the supplement challenging.

3.6.2 Comparison of LNS to IFA

The women provided with LNS were also asked to compare LNS-regular and IFA in terms of ease of use and overall preference, as they had been exposed to both LNS and IFA during their supplementation period. Most said that IFA was easier for women to consume because they can swallow it easily with water (90%). They said that LNS was not as easy to take because it is time consuming (36%), the smell of the supplement is unpleasant (28%), and it is difficult to eat mixed with food (14%). While women found IFA to be easier to consume, there was no significant difference in overall preference between LNS and IFA when women were asked which supplement they liked more. Women who preferred LNS reported that they preferred LNS because it is nutritious (14%), it allows them to produce more breast milk for their child (15%), it is good for the health of mother and/or child (31%), or they like some property of the supplement or the supplement overall (61%). Women who preferred IFA overall reported that the supplement is easy to take with water and requires little time (70%), does not smell (23%), is good for the health of mother and/or child (8%), contains nutrition (7%), and "increases blood" (6%).

Table 19. Preference for LNS or IFA among Women Who Had Taken Both during Different Time Periods

Characteristics of supplement comparison % (n)	Exposed to only LNS-cumin during pregnancy[b] (n = 8)		Exposed to LNS-cumin and IFA during pregnancy[c] (n = 75)		Exposed to LNS-cumin, IFA, and LNS-regular during pregnancy[d] (n = 103; 102)		Not exposed to LNS-cumin (n = 26)		Overall		χ2 (p value)[a]
Easy to use (n = 212)											
LNS	25.0	(2)	24.0	(18)	21.4	(22)	30.8	(8)	23.7	(50)	222.45 (< 0.0001)
IFA	75.0	(6)	60.0	(45)	71.8	(74)	65.4	(17)	67.3	(142)	
Both	0.0	(0)	16.0	(12)	5.8	(6)	3.9	(1)	9.0	(19)	
Neither	0.0	(0)	0.0	(0)	1.0	(1)	0.0	(0)	0.5	(1)	
Preferred supplement (n = 211)											
LNS	50.0	(4)	60.0	(45)	45.1	(46)	61.5	(16)	52.4	(111)	0.52 (0.47)
IFA	50.0	(4)	40.0	(30)	54.9	(56)	38.5	(10)	47.2	(100)	

[a] Rao-Scott chi-square for overall values
[b] Women received IFA and LNS during the postpartum period
[c] Women could have received IFA and LNS or only LNS in the postpartum period
[d] Women received only LNS in the postpartum period

3.7 Sharing Supplements

Participants were asked whether they shared any of the supplements since the last distribution date, how many supplements were shared, with whom supplements were shared, and the main reason the supplements were shared. Sharing was more prevalent among LNS recipients than IFA recipients (**Table 20**). LNS recipients also tended to share a greater number of supplements than women receiving IFA. Twenty-six percent of women shared 10 or more sachets of LNS-regular since the last distribution date, while the greatest number of IFA tablets shared was 6.

Reported sharing of supplements from the most recent supply was not associated with the number of days that had passed since the last supplement delivery, with an average of 21.9 and 21.2 days passed among women who reported sharing and not sharing respectively (p = 0.85). Furthermore, number of days passed since the last supplement delivery did not differ significantly among the five PEPA-PLW groups (p = 0.73).

Table 20. Supplement Sharing by Supplement Type since the Last Distribution Date

	Percent of women[a]	Number of supplements shared since last distribution date[b]	χ2 among physiological statuses (p value)[c]	χ2 between supplement type (p value)[c]
LNS (n = 217)	18.0 (38)	3 (2–10)	2.12 (0.35)	33.33 (< 0.0001)
LNS_P	11.0 (8)	4 (2–28)		
LNS_{EL}	19.4 (14)	2.5 (2–7)		
LNS_{LL}	22.2 (16)	3 (1–12)		
IFA (n = 143)	3.0 (4)	6 (4–6)	1.11 (0.29)	
IFA_P	4.2 (3)	5 (2–6)		
IFA_{EL}	1.4 (1)	6 (6–6)		

[a] Percent (number)
[b] Median (interquartile range)
[c] Rao-Scott chi-square for prevalence of sharing

LNS-regular was shared primarily with the participant's children (32%) and relatives or household members *other than* the participant's children and husband (58%). Among 8% of the women who reported sharing, the husband was given some supplement, and 11% of women reported that they shared LNS-regular with other pregnant women. The novelty and palatability of LNS-regular accounted for 58% of the cases of sharing LNS-regular. When women were asked why they shared the supplement, they explained that other people were curious to try LNS-regular and liked to consume the fortified paste.

There were four reported cases of sharing IFA, in three of which women reported sharing with other household members. There was one report of sharing IFA with the participant's child. IFA tablets were shared for the health of the other person, as IFA "contains vitamins" and "provides blood." As IFA is in the form of a tablet, which is typically swallowed rather than eaten, we speculate that there was less interest in sharing. In addition, there may be less curiosity surrounding IFA because the tablets have been available in the local markets previously and the community is more familiar with this product compared to LNS.

While the number of cases of reported sharing of supplements with children was not large, it is still a potential concern given that the doses of micronutrients in LNS and IFA are targeted for PLW. One LNS sachet contains copper (4 mg), folic acid (400 µg), manganese (2.6 mg), niacin (36 mg), vitamin A (800 retinol activity equivalents), and zinc (30 mg) at levels greater than the tolerable upper intake level (UL) (the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population) for children 12–35 months old, and one IFA tablet contains iron (60 mg) and folic acid (400 µg), which exceeds the ULs for children 12–35 months old (Chaparro and Dewey 2010). For copper, folic acid, manganese, vitamin A, and niacin, the risk of toxicity from one or even two sachets of LNS is small (Chaparro and Dewey 2010). Two sachets of LNS would provide a potentially toxic dose of zinc to small children (46 mg), based on extrapolating from toxic doses of zinc for adults (Chaparro and Dewey 2010). A toxic dose of iron for children 6–11 months old and children 1–3 years old is 180 mg and 260 mg, respectively. These doses would not be reached with one or two sachets of LNS or with one or two IFA tablets, but could be reached with three IFA tablets.

3.8 Loss or Destruction of Supplements

Women were asked about any supplements lost or destroyed from their most recent supply of supplement. The number of supplements and reason for the supplement loss or destruction were recorded. Overall, there were 22 cases of supplement destruction and loss. The prevalence of supplement loss or destruction was greater among IFA recipients (**Table 21**).

As reported previously (Section 3.7), days passed since last supplement delivery did not differ significantly by PEPA-PLW group. In addition, days passed since last delivery was not significantly associated with reports of lost or destroyed supplements, with an average of 23.1 and 21.2 days passed among women who reported lost or destroyed supplements and no lost or destroyed supplement, respectively (p = 0.72).

The largest number of IFA tablets lost or destroyed since the most recent distribution period was 30 tablets, and three participants reported that 10 or more tablets were lost or destroyed. The greatest number of LNS-regular sachets lost or destroyed since the most recent distribution period was six.

Table 21. Supplement Loss and Destruction by Supplement Type since the Last Distribution Date

	Percent of women[a]	Number of supplements shared since last distribution date[b]	χ2 among physiological statuses (p value)[c]	χ2 between supplement type (p value)[c]
LNS (n = 217)	4.0 (9)	1 (1–2)	2.5 (0.29)	3.76 (0.05)
LNS_P	4.1 (3)	2 (1–2)		
LNS_{EL}	1.4 (1)	1 (1–1)		
LNS_{LL}	6.9 (5)	1 (1–2)		
IFA (n = 143)	9.0 (13)	4 (3–10)	0.94 (0.33)	
IFA_P	11.3 (8)	4 (3–10)		
IFA_{EL}	6.9 (5)	5 (1–30)		

[a] Percent (number)
[b] Median (interquartile range)
[c] Rao-Scott chi-square for prevalence of sharing

Among LNS recipients, 22% of lost or destroyed supplement cases were a result of losing the sachets (2 cases). In 67% of the cases (6 cases), the supplements were opened but not consumed and were considered wasted. There was one case of LNS-regular being intentionally discarded (11%). The woman threw the sachets away because the smell was unpleasant to her.

For 46% of the cases of lost or destroyed IFA (6 cases), the woman reported that she misplaced the IFA and could not recall where it was. There were six cases (46%) of crushed or broken tablets. There was one case (8%) of supplements being discarded by the woman.

3.9 Exchanging Supplements for Other Commodities or Capital

Because LNS is a new product in Dinajpur and Rangpur, it is possible that the novelty of the product could result in the sachets being sold or exchanged for other commodities. The concept of selling or trading LNS is a sensitive topic, as selling or exchanging the supplements may be done by poor families to gain cash or commodities for the family. As a result, there may be negative connotations to selling or exchanging supplements. This question was approached cautiously and sensitively. There were no reports of selling or trading LNS-regular or IFA.

LAMB is also monitoring the exchange and sale of supplements and has not detected any cases of these activities. In one incident, a woman provided with LNS gave two sachets to a woman receiving IFA. The women receiving IFA provided 12 taka for the sachets. Upon further investigation, it became clear that the woman who received LNS gave the money as a courtesy to the provider to thank her for sharing, and not as an arranged purchase. While this was not considered a case of selling, it does indicate that some women place monetary value on the supplements, a concept that is being explored through the willingness-to-pay component of the RDNS.

3.10 Running Out of Supplements

A component of program evaluation and a factor that directly affects participant adherence to supplementation is a functioning supplement distribution channel. As an evaluation of this channel, women were asked if they had ever run out of their supplement supply. Overall, 15% of women reported that they had run out of supplements at least once since they first received supplements. Running out of supplements was not associated with duration of enrollment in the study ($p = 0.80$) as expected, and similarly, there was no significant difference in the reported prevalence of running out of supplement by physiological status within each supplement group (LNS, $p = 0.11$, and IFA, $p = 0.48$) (**Table 22**).

Data collectors' field notes from the interviews indicated that women ran out of supplements because:

- They moved to another home that the CHW did not visit
- The CHW missed or was late to a scheduled supplement distribution visit
- The CHW had stopped going to their home
- The woman refused to take the supplements so the CHW had stopped bringing them

Seven percent of women did not have any supplements in their stores at the time of the interview, and, for another 7% of women, the supplement supplies could not be observed because the woman was at a different home and did not have her supplements with her or refused to show the enumerator her supply.

Table 22. Prevalence of Running Out of Supplements since the Woman Started Receiving Supplements, by Supplement Type and Physiological Status

	Percent of women[a]	Enrollment duration in days[b]	χ2 among physiological statuses (p value)[c]	χ2 between supplement type (p value)[c]
LNS (n = 217)	15.0 (33)		4.38 (0.11)	0.26 (0.61)
LNS_P	9.6 (7)	154.8 (23.2)		
LNS_{EL}	22.0 (16)	246.5 (37.2)		
LNS_{LL}	14.0 (10)	328.6 (38.0)		
IFA (n = 143)	13.0 (19)		0.50 (0.48)	
IFA_P	11.3 (8)	154.9 (24.3)		
IFA_{EL}	15.5 (11)	246.9 (34.3)		

[a] Percent (number)
[b] Median (interquartile range)
[c] Rao-Scott chi-square for prevalence of sharing

3.11 Reasons for Consuming and Not Consuming Supplements

Understanding women's adherence to supplement regimens requires understanding why women take or do not take supplements. After women reported the number of supplements they consumed in the previous week, they were asked the reasons they consumed that number of supplements. The following four tables (**Tables 23a, 23b, 24a,** and **24b**) display the reasons given by ≥ 10% of women. Tables 23a and 24a display the reasons reported by high-adherers (SRC ≥ 75% of recommended intake) and **Tables 23b** and **24b** display reasons reported by low-adherers (SRC < 75% of recommended intake) for taking the number of supplements reported. The primary reasons provided were similar between LNS and IFA recipients, although there were some differences in the reasons provided by supplement type. IFA high-adherers reported that they consumed IFA because it increased their blood (19%), while only 1% of LNS-regular high-adherers provided this reason. The unpleasant smell of the LNS-regular was a reason non-adherers reported for their consumption pattern (15% of LNS-regular low-adherers), but was not commonly reported by IFA low-adherers (2%).

Table 23a. Reasons High-Adherers Consumed the Number of LNS-Regular Sachets They Did in the Previous Week, % (n)

Reason	LNS_P (n = 41)	LNS_{EL} (n = 37)	LNS_{LL} (n = 45)	Total (n = 123)
Good for my baby	98 (40)	81 (30)	82 (37)	87 (107)
Good for me	83 (34)	84 (31)	80 (36)	82 (101)
Made me feel healthy	34 (14)	59 (22)	53 (24)	49 (60)
Made me feel strong	29 (12)	19 (7)	31 (14)	27 (33)
Contains nutrition	37 (15)	14 (5)	4 (2)	18 (22)
Impacts my breast milk quantity	2 (1)	11 (4)	24 (11)	13 (16)

Table 23b. Reasons Low-Adherers Consumed the Number of LNS-Regular Sachets They Did in the Previous Week, % (n)

Reason	LNS_P (n = 32)	LNS_{EL} (n = 35)	LNS_{LL} (n = 27)	Total (n = 94)
Good for me	41 (13)	49 (17)	48 (13)	46 (43)
Good for my baby	38 (12)	54 (19)	44 (12)	46 (43)
Made me feel healthy	13 (4)	23 (8)	37 (10)	23 (22)
Forgot	9 (3)	20 (7)	22 (6)	17 (16)
Ran out of supplements	3 (1)	26 (9)	15 (4)	15 (14)
Bad smell of supplement	22 (7)	14 (5)	7 (2)	15 (140
Made me feel strong	13 (4)	17 (6)	11 (3)	14 (13)
Not at home	6 (2)	14 (5)	7 (2)	10 (9)
Feeling nausea or vomiting	16 (5)	3 (1)	11 (3)	10 (9)

Table 24a. Reasons High-Adherers Consumed the Number of IFA Tablets They Did in the Previous Week, % (n)

Reason	IFA_P (n = 50)	IFA_{EL} (n = 51)	Total (n = 101)
Good for my baby	100 (50)	67 (34)	83 (84)
Good for me	72 (36)	82 (42)	77 (78)
Made me feel healthy	46 (23)	61 (31)	53 (54)
Made me feel strong	30 (15)	39 (29)	35 (35)
Increased my blood level	16 (8)	22 (11)	19 (19)
Impacts my breast milk quantity	0 (0)	24 (12)	12 (12)

Table 24b. Reasons Low-Adherers Consumed the Number of LNS-Regular Sachets They Did in the Previous Week, % (n)

Reason	IFA_P (n = 21)	IFA_{EL} (n = 21)	Total (n = 42)
Good for me	43 (9)	38 (8)	40 (17)
Good for my baby	62 (13)	14 (3)	38 (16)
Made me feel healthy	38 (8)	19 (4)	29 912)
Ran out of supplements	5 (1)	38 (8)	21 (9)
Made me feel strong	29 (6)	5 (1)	17 (7)
Forgot	14 (3)	14 (3)	14 (6)

We expected women who did not take the supplements as recommended (every day or every other day for postpartum IFA recipients) to provide the reason they did *not* take the supplement the recommended number of times. However, many of these women provided reasons for *taking* supplements, which could indicate a flaw in the way the question was asked or understood by the participants, or a belief that the supplements were beneficial for them and their children even though they did not take the supplements as instructed.

Among women who did not take any LNS-regular in the last week (n = 43), 27% stated that this was due to the bad smell of the supplement, 22% explained that they ran out of supplements, 22% explained that nausea or vomiting caused this, and not being at home accounted for 17% of cases. IFA recipients reported similar reasons for not taking any supplements (n = 18). Running out of supplements was the most common reason for not taking any IFA (33%), followed by not being at home (17%).

4. Summary and Lessons Learned

There were no significant differences in adherence, based on SRCs, by physiological status (pregnancy, early lactation, and late lactation) among LNS recipients ($p = 0.39$) or between LNS and IFA recipients during pregnancy ($p = 0.086$). However, during pregnancy, the percentage of LNS recipients who reported not consuming any supplements in the past week did differ significantly from the percentage of IFA recipients who reported not consuming any supplements in the past week (22% and 6%, respectively; $p = 0.039$). In addition, the percentages of IFA recipients reporting no consumption of supplement differed between pregnancy and the early lactation period (6% and 19%, respectively; $p = 0.026$). The reasons for the higher percentage of non-adherence to LNS-regular during pregnancy (compared to IFA) are not clear, but may be related to the less acceptable smell of LNS-regular, particularly among pregnant women (34.3% reported disliking the smell). In addition, 16% of low-adherent pregnant LNS recipients cited nausea and vomiting as the reason for taking the number of supplements reported; this was not a commonly cited reason by pregnant IFA recipients. Further research is needed to determine the causes of these differences.

LNS-regular and IFA were highly acceptable among participants, but the previously distributed LNS, LNS-cumin, was generally disliked. All organoleptic properties of LNS-regular received median acceptability scores of 4 ("Like it a little") or 5 ("Like it a lot"). The organoleptic properties of IFA were not evaluated.

The prevalence of sharing was greater among LNS recipients, while the prevalence of lost or destroyed supplements was greater among IFA recipients.

A substantial percentage of women in both LNS and IFA groups reported having run out of supplements at some point (14%), which did not differ by supplement group. However, running out of supplements was reported more commonly as a reason for low-adherence among IFA recipients in the early lactation period (38%) compared with pregnant IFA recipients (5%). This may account for the difference in percent of non-adherence to IFA between pregnancy and early lactation.

All women received instruction on supplement consumption at the time they received their first supply of supplements and approximately half received instructions at the time of their most recent supplement delivery.

Women tended to recall the expected supplement consumption messages provided by the CHDP staff. However, women reported several other messages that are not the CHDP standard messages. Most of the additional messages tended to reflect suggestions women gave during the interview when asked what could make LNS-regular or IFA easier to consume. Therefore, these unconventional messages could have been given to improve supplement adherence. It is also possible that the messages the women recalled were their interpretation of what the CHDP staff members said and not what the CHDP staff actually advised. These findings provide insight on how messaging and consumption recommendations may need to be revised for future supplementation programs.

Adherence to LNS-regular was lower in this study than that reported in the short-term acceptability trial in the same study area, during which women reportedly took 95% of the recommended supplement doses during a 2-week period (Mridha et al. 2012). This may be due in part to the difference in adherence measurement, as the acceptability trial used supplement count, and also in part to the different methodological design of the trials (short-term study with highly involved research team versus long-term effectiveness trial). However, median SRC and prevalence of women who consumed supplements as recommended were comparable to adherence values reported from similar contexts of maternal supplementation programs with IFA and MNP (Shankar et al. 2009; Aguayo 2004; Jasti et al. 2005; Kulkarni et al. 2010; Lutsey et al. 2008; Seck and Jackson 2008; Zavaleta et al. 2012; Barbour et al. 2012).

The prevalence of sharing was greater among LNS recipients than among IFA recipients. Sharing of LNS-regular took place because others liked the taste and because others wanted to try the supplements. As the novelty of LNS wanes, sharing may become less prevalent. Developing effective messages for the women and the community to emphasize the PLW-specific nature of the supplements may also reduce sharing. In the current program, the strategy has been to inform women: "Jononi is all for you, because women need special foods when they are pregnant and breastfeeding to be healthy and have strong babies." If the program were to be scaled up or used in other settings, it may be more effective to have a more specific standard message that discourages sharing LNS with non-PLW. Other programs may also consider the use of a targeted social marketing campaign that clearly positions Jononi in the market as a home fortificant for PLW.

Crushed and broken IFA tablets could account for the difference in the prevalence of destroyed supplements between IFA and LNS recipients. The broken and crushed tablets could be a result of the quality of the supplements, improper storage, or careless distribution.

The percentage of women who reported having run out of supplements (14%) and the percentage of women with zero supplements in their supply at the time of the interview (7%) were somewhat surprising. As field notes from the interviews suggest, there were a number of reasons cited for running out of supplements. A key reason is that a woman who moved to a different home, such as her father's home, may not have had access to the CHW from her new home, and thus may have had difficulty obtaining supplements. As per LAMB CHDP protocol, if a woman is not at home, the supplements should be given to her husband or other family member, who is instructed to take the supplements to the woman. Through the PEPA-PLW assessment, it is not clear where along this chain of events there were deviations. There were some reported cases in which the CHW failed to visit the woman's home. The reports of women running out of supplements emphasize the impact that supplement distribution can have on adherence, which has been highlighted previously in the literature (Shankar et al. 2009; Kulkarni et al. 2010; Seck and Jackson 2008; Galloway et al. 2002; Galloway and McGuire 1994; Zeng et al. 2009).

Deviations from planned supplement distribution comprise two types of issues: 1) deviations that are within the control of the program and 2) deviations that are *not* within the control of the program. The current report highlights both issues within the RDNS context, and the latter warrants further discussion. The supplement supplier, LAMB CHDP, and the field team's response to the LNS recall and resumption of distribution was as prompt as possible, but still

resulted in 10 weeks of participants not having access to LNS. Depending on when a woman in the LNS-comprehensive arm was enrolled, she was exposed to some period of supplementation with IFA, supplementation with LNS-regular, and, in most cases but not all, supplementation with LNS-cumin prior to the 10 weeks of IFA supplementation.

The LNS-cumin was the same as one of the two supplements tested in the acceptability trial (Mridha et al. 2012). However, the acceptability of LNS-cumin among participants in the main study differed substantially from that reported in the acceptability trial. In that trial, LNS-cumin received high median acceptability scores (5 = "Like it a lot"), whereas it received a median acceptability score of 1 ("Dislike it a lot") in the current population. In contrast, LNS-regular, the LNS distributed later in the trial without cumin and soy, received acceptability scores more compatible with those observed in the previous acceptability trial. The reasons for the low-acceptability of LNS-cumin were not explored formally in this assessment, but informal reports suggest that women strongly disliked the smell and taste of LNS-cumin.

While the median acceptability score for LNS-regular smell was 4 ("Like it a little"), 27% of LNS-regular non-adherers mentioned the supplement smell as the reason for not consuming the supplements. Approximately one-third of women who received the LNS-regular supplement reported that the smell could make the supplement challenging to consume, and 28% of women who thought IFA was easier to consume stated that the unpleasant smell of LNS made it more challenging to consume (19% overall). There was a similarly high acceptability of the smell reported in the previous acceptability trial (Mridha et al. 2012). Although the median Likert score suggested high acceptability, there was a significant number of women who found the smell unpleasant for various or unspecified reasons. This supports the findings of the *Oportunidades* program in Mexico, highlighting limitations to assessing supplement acceptability using Likert scales (Young et al. 2010), and may suggest that in this context acceptability scores of 4 ("Like it a little") should be assessed more critically and with more skepticism. There are limitations to using a Likert scale to assess supplement acceptability in cultural contexts where people are unwilling to provide negative feedback (Young et al. 2010). In addition, the low variability in the median Likert scores across supplements and organoleptic properties in the current study may be a reflection of using a face scale that was not validated in this context. It is possible that interpretations of smiling and frowning cartoon faces are inconsistent among women. While women were also read the response options for each question, their interpretation of the faces may have altered their responses.

The limitations to the current assessment of participant adherence should be noted. Approximately 13% of the originally selected sample was not interviewed. In the majority of cases (58%), this was because the woman had moved out of the study area. Field notes from the interviews suggest that women who shifted to a different home (e.g., a parent's home) tended to have low adherence because they either ran out of supplements and did not receive supplements at their new location or they did not bring their supplements with them to the new home. Therefore, it is likely that the adherence estimates in this report are slightly higher than would be found in the total RDNS population. Furthermore, not sampling women enrolled during the first 9 weeks of enrollment may have biased the adherence estimates. Discussions with CHWs suggest that in the beginning of the study women were skeptical of the supplements, and it took

time and seeing other supplement consumers giving birth to healthy babies for the supplements to gain social acceptability. This suggests that women enrolled in the study after the initial community sensitization period would have greater adherence. The limitation to using SRC as an estimation of adherence should also be noted. It is evident from the literature that individuals tend to over-report consumption; thus, SRCs are typically greater than adherence estimates from pill counts or Medication Event Monitoring Systems (Jasti et al. 2005).

A strength of the study is the evaluation of shared, lost, destroyed, sold, or exchanged supplements, which better informs the adherence assessment. While exclusion of the first 9 weeks of enrollment may have biased the estimation of adherence for the RDNS, it likely better reflects adherence within an established program, which is valuable when considering incorporating LNS distribution into other programs and understanding sustainability of supplement adherence. This report also provides a unique assessment of supplement preferences among women who were exposed to different supplement treatments. Among women exposed to both LNS and IFA, about half preferred LNS and half preferred IFA, but IFA was perceived as easier to consume than LNS. That half of women preferred LNS despite it being less easy to consume than IFA implies that scaling up LNS may be feasible; however, the higher percentage of non-adherers in the LNS group during pregnancy suggests that barriers to adherence need to be addressed in advance based on careful, context-specific evaluations of LNS acceptability in the target population.

These findings highlight the importance of devising ways to assess and interpret supplement acceptability. Future programs considering LNS distribution to PLW should consider acceptability assessment methods appropriate to the program's context. The importance of the program's distribution process must also be emphasized. Maintaining women's access to supplements directly influences adherence. In contexts similar to rural Bangladesh where women often move to their parents' home during pregnancy or early postpartum, access to supplements while away from home should be carefully considered and managed. As described previously, LAMB protocol instructed CHWs to provide supplements to women's family members if the woman was not at the home and to instruct the family member to ensure that the woman received the supply.

Overall, we found that women tended to value both the LNS-regular and IFA supplements and reported health benefits to both mother and child when asked why they consumed the supplements. The supplements had a high overall acceptability and approximately half of the women reported taking the supplements as recommended. While overall acceptability of LNS-regular and IFA was high in this context, the poor acceptability of the previous LNS (LNS-cumin) is informative. The PEPA-PLW assessment was conducted after LNS-cumin distribution was halted and therefore we did not collect data on adherence to LNS-cumin. Based on the low acceptability of LNS-cumin, it is possible that adherence during that phase of the study was low. Alternatively, it is possible that the low post-hoc reported acceptability of LNS-cumin was influenced by the ability of women to compare it to LNS-regular, and adherence during the LNS-cumin phase may have been adequate. Given the potentially low-adherence to LNS-cumin followed by a 10-week interval of interrupted access to LNS, this period in the project will need to be carefully considered in future data analyses.

Because adherence varies within the population and may be related to other factors, on both the program and individual levels, it will be necessary to consider adherence when evaluating the program impact. Access to supplements, the unpleasant smell of LNS-regular, nausea/vomiting (common during pregnancy and thus not necessarily related to supplement intake), and forgetfulness were barriers to supplement adherence. As many of the RDNS participants moved to their parents' home during pregnancy or soon after birth, it may be important to consider the impact of this movement on supplement access and adherence when assessing other outcomes and when designing food distribution programs.

In summary, average self-reported consumption during pregnancy was similar between women given LNS-regular and those given IFA, although a significantly higher percentage of the former reported "zero" consumption during the previous week. Adherence to LNS-regular was not significantly different across physiological periods, suggesting sustained adherence through 6 months postpartum. For IFA, the percentage reporting "zero" consumption during the previous week was higher postpartum than during pregnancy. Overall, the PEPA-PLW assessment suggests that several components of program implementation are being conducted as expected (e.g., method of supplement distribution), whereas other components may have deviated somewhat from the original protocols (e.g., additional messaging about supplements reported by participants). The findings also suggest that beneficiaries make their own adaptations in terms of how and how often to consume the supplements.

Within the context of the RDNS, the findings summarized in this report will allow us to better interpret and understand the results of the other components of the process evaluation as well as the results from the impact evaluation. Program planners considering supplementation with LNS or IFA in similar settings can use these findings to guide formative research and program design to maximize supplement adherence and enhance program impact.

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Appendix 1. Health Education Messages for Women regarding Jononi and Alic

The following messages are found in Bangla on the back of each Rang-Din Nutrition Study participant's registration card and recalled by the woman or read to the community health worker at each supplement distribution date. Women receiving Jononi (lipid-based nutrient supplement) were instructed as below for Jononi. Similarly, women receiving Alic (iron and folic acid tablet) were instructed as below for Alic.

Jononi health messages

1. Jononi is all for you, because women need special foods when they are pregnant and breastfeeding to be healthy and have strong babies.
2. Eat meat, fish, eggs, dairy, fruits and vegetables whenever you can. You still need these foods even if you eat Jononi.
3. Take 1 sachet of Jononi each day until your child is 6 months of age.
4. Do not take more than one sachet each day because it is not good for you to have too much. If you forget to take Jononi one day, do not take extra the next day—it is always one sachet per day.
5. It is best if you mix the Jononi with just a little bit of rice or other foods [4-5 large spoonfuls (or appropriate household measure)]. You can take Jononi at any meal of the day.
6. Store the Jononi in the container we are providing, where it will stay dry and out of the reach of children. Store it in the coolest and driest place that you can find in your house.
7. Please come with rest Jononi sachets with container and registration card to receive a resupply.
8. We do not expect any side effect after taking Jononi, but if so (like vomiting, pain in stomach, boil/etching in body, loose motion), please call respective VHVs or CHWs.
9. When you are taking Jononi, you don't need any other vitamins/minerals.
10. If you delivered or aborted, please call your assigned VHVs or CHWs immediately.
11. If you suffer from any Serious Adverse Event's (SAE) or admit in a hospital for any reason, please call your assigned VHVs or CHWs.

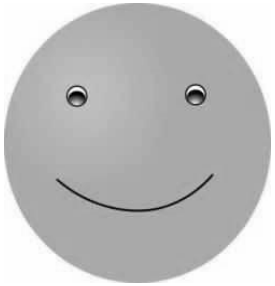
Alic health messages

1. Alic is all for you, because women need special foods when they are pregnant and breastfeeding to be healthy and have strong babies.
2. Eat meat, fish, eggs, dairy, fruits and vegetables whenever you can. You still need these foods even if you take Alic.
3. Take 1 tablet of Alic each day while you are pregnant and take 1 tablet every alternate day after you give birth until your child is 3 months of age.
4. Do not take more than one tablets each day because it is not good for you to have too much. If you forget to take Alic one day, do not take extra the next day—it is always one

tablets per day when you are pregnant, and one tablet every alternate day for three months after you have had your baby.

5. Take Alic with water, between meals. You should take the one tablet at the same time. You can take Alic at any time after meal.
6. Store the Alic in the container we are providing, where it will stay dry and out of the reach of children. Store it in the coolest and driest place that you can find in your house
7. Please come with the rest of your Alic tablets with the bag and registration card to receive your resupply.
8. We do not expect any side effect after taking Alic but if so (like vomiting, pain in stomach, boil/etching in body, loose motion), please call respective VHVs or CHWs.
9. When you are taking Alic, you don't need any other iron and folic acid tablets.
10. If you delivered or aborted, please call your assigned VHVs or CHWs immediately.
11. If you suffer from any Serious Adverse Event's (SAE) or admit in a hospital for any reason, please call your assigned VHVs or CHWs.

Appendix 2. RDNS PEPA-PLW Participant Questionnaire Facial Expression Scale

				
Dislike it a lot	**Dislike it a little**	**Neither like nor dislike it**	**Like it a little**	**Like it a lot**
1	**2**	**3**	**4**	**5**