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Rang-Din Nutrition Study: Assessment of Adherence to Lipid-Based Nutrient Supplements and Micronutrient Powders among Children 6–23 Months in Bangladesh

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Contents

Abbreviations and Acronyms

ANOVA	analysis of variance
BCC	behavior change communication
BMI	body mass index
CHDP	Community Health and Development Program
CHW	community health worker
cm	centimeter(s)
FANTA	Food and Nutrition Technical Assistance III Project
g	gram(s)
HVT	home visit team
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
IFA	iron and folic acid
IQR	interquartile range
kg	kilogram(s)
LAMB	Lutheran Aid to Medicine in Bangladesh
LNS	lipid-based nutrient supplement(s)
m^2	square meter(s)
MNP	micronutrient powder(s)
PE	process evaluation
PEPA-C	Process Evaluation Participant Adherence among Children
PEPA-PLW	Process Evaluation Participant Adherence among Pregnant and Lactating Women
PET	process evaluation team
RC	reported consumption
RDNS	Rang-Din Nutrition Study
SD	standard deviation
SE	standard error
SDU	safe delivery unit
SVT	safe delivery unit visit team
UCD	University of California, Davis
USAID	U.S. Agency for International Development
VHV	village health volunteer
y	year(s)

Executive Summary

Overview. The U.S. Agency for International Development (USAID)-funded Food and Nutrition Technical Assistance III Project (FANTA) and FANTA-2 (Food and Nutrition Technical Assistance II Project), in collaboration with the University of California, Davis (UCD), the International Centre for Diarrhoeal Disease Research, Bangladesh (ICCDR,B), and Lutheran Aid to Medicine in Bangladesh (LAMB), initiated the Rang-Din Nutrition Study (RDNS), which began in 2010. RDNS was a cluster-randomized, controlled effectiveness study to evaluate the use of lipid-based nutrient supplements (LNS) provided to pregnant and lactating women and their children for the prevention of chronic malnutrition in children and the improvement of nutritional status among pregnant and lactating women in Bangladesh.

The RDNS had four study arms:

1. LNS for the mother during pregnancy and the first 6 months postpartum, plus LNS for the child starting at 6 months of age and continuing to 24 months.
2. Iron and folic acid (IFA) for the mother during pregnancy and the first 3 months postpartum, and LNS for the child starting at 6 months of age and continuing to 24 months.
3. IFA for the mother during pregnancy and the first 3 months postpartum, and micronutrient powder (MNP) for the child starting at 6 months and continuing to 24 months.
4. IFA for the mother during pregnancy and the first 3 months postpartum, and no additional supplement for the child.

As part of the effectiveness trial, the research team also conducted a process evaluation (PE) of the supplement-distribution program of LAMB's Community Health and Development Program (CHDP). During the program, CHDP community health workers (CHWs) were instructed to visit women monthly to distribute supplements and give standard messages regarding the supplements. For children provided with LNS, caregivers were instructed to add one 10-g sachet of LNS to the child's food at two different meals each day (for a total of 20 g of LNS per day). For children provided with MNP, caregivers were instructed to mix one packet of MNP per day with the child's food.

This report summarizes the findings from the RDNS Process Evaluation Participant Adherence among Children (PEPA-C) assessment. The purpose of this assessment was to evaluate components of the LAMB CHDP child supplement distribution; to determine adherence to LNS and MNP among children participating in the RDNS; and to compare the adherence indicators from the PEPA-C assessment and the RDNS 18-month follow-up (a time point at which women were asked about the child's intake of the supplements provided).

Assessment Methods. The PEPA-C assessment was a cross-sectional survey of a random sample of RDNS participants, to assess adherence to child supplementation recommendations after the child had been receiving the supplements for a year (i.e., at 18 months of age). The target population for the PEPA-C assessment was women whose children were near 18 months of age and scheduled to complete their RDNS 18-month home and clinic follow-up visits between May 18 and July 31, 2014. The target sample size was 256: 128 from the MNP arm and 128 from the two LNS arms combined. Women were interviewed in their homes regarding the child's intake of the supplements and their experiences with receiving the supplements.

The PEPA-C questionnaire was similar to the one used to assess adherence to maternal supplement consumption in the Process Evaluation Participant Adherence among Pregnant and Lactating Women (PEPA-PLW) assessment, with some modifications (Harding et al. 2014b).

To assess supplement adherence, women were asked how many days in the previous week their child consumed the supplements and how many supplements were consumed per day in the previous week. From these two values, a maternal report of each child's supplement intake during the previous 7 days, also known as reported consumption (RC), was calculated. From RC, a variable for "percent adherence" was created by dividing RC by the recommended number of supplements per week (14 LNS sachets or 7 MNP packets). The percent adherence variable was then used to create three yes/no variables: "adherence as recommended" (yes = 100-percent adherence), "high-adherence" (yes = ≥ 70-percent adherence), and "no-adherence" (yes = 0-percent adherence).

Generalized linear models were used to evaluate differences in adherence between groups, using appropriate link functions for the type of adherence variable. All models accounted for the cluster design effect. Data on shared, lost, destroyed, and sold supplements since the last supplement distribution were collected based on women's reports. Women were also asked about running out of supplements (ever and in the past month), travel away from home in the past month, and other nutritional supplements for children that they acquired in the past 3 months. Binary variables were compared between supplement groups using chi-squared tests accounting for the cluster design effect. Data were also collected on how women received the child's first and most recent supply of supplements and reasons for consuming more or less than the recommended number of supplements in the past week based on RC.

Additionally, at the 18-month follow-up visit among all RDNS participants, women were asked how many supplements the child had consumed in the past week, which differed from the PEPA-C assessment question about supplement consumption. These data were similarly converted into a variable for "percent adherence" and variables for "adherence as recommended," "high-adherence," and "non-adherence." Among the PEPA-C subsample of participants, the data collected at the RDNS 18-month follow-up visit were then compared with the PEPA-C adherence data to determine any differences. (These two adherence measures were taken by different data collection teams but were assessed among the same children when they were approximately the same age.)

Results. A total of 250 women were interviewed for the PEPA-C assessment (126 LNS recipients and 124 MNP recipients) between May 28 and August 14, 2014. Women in the PEPA-C sample were similar to the rest of the RDNS sample (n=3761), and characteristics of LNS and MNP recipients within the PEPA-C sample were generally similar.

Based on maternal reports in the PEPA-C sample, percent adherence did not differ by supplement group. Median percent adherence was 85.7 [interquartile range (IQR) 64.3–100.0] versus 85.7 [IQR 50.0–100.0] for LNS and MNP recipients, respectively. Overall, 43 percent of children consumed the number of supplements recommended (14 LNS sachets per week or 7 MNP packets per week), which did not differ by supplement type (43 percent for LNS recipients versus 43 percent for MNP recipients (p=0.98). Two percent of LNS and 9 percent of MNP recipients did not consume any supplements in the previous week (p=0.04).

Most women (92.8 percent) reported that they picked up the initial supply of the child's supplements from the LAMB safe delivery unit (SDU). Almost all of the women (98 percent) reported that delivery from the CHDP staff was the primary mode of supplement acquisition since they started receiving supplements for the child. For all of the women, this was also the preferred mode of receiving supplements.

All women reported that they were told how to give the supplements to the child when the first supply of LNS or MNP was provided to them, and 90.8 percent of women reported that they were told how to give the supplements to the child at the most recent supplement delivery.

A greater percentage of LNS recipients than MNP recipients reported sharing supplements and reported loss or destruction of supplements since they received their last supply of supplements [sharing: 20.6 percent versus 10.5 percent (p=0.008); loss or destruction: 27.0 percent versus 15.3 percent (p=0.004)]. There were no reports of supplements from the most recent supply being sold or exchanged.

When women were asked about the acquisition and use of other supplements for their child, seven women reported that they had collected or received supplements other than the LAMB CHDP supplements for the child in the past 3 months. The children of two of these women were in the MNP arm, and the children of five of them were in the LNS arm. For these seven children, the women reported that there was little use of the other supplements in addition to the LAMB-distributed supplements.

If a woman reported that the child consumed more or less than the recommended number of supplements in the previous week, she was asked to give reasons for the child's supplement intake. Forgetfulness and illness were the two most common reasons reported for the child consuming less than the recommended amounts. Only three LNS recipients and no MNP recipients reported that the child consumed more than the recommended number of sachets in the previous week. All three of these LNS recipients reported giving the child more LNS than recommended because the child liked the supplement. Two women also said that the child wanted the supplements.

We compared adherence reported during the PEPA-C assessment with adherence reported at the RDNS 18-month follow-up visit among the PEPA-C survey participants. Women reported significantly higher mean percent adherence at the RDNS 18-month follow-up than at the PEPA-C survey. The mean percent adherence was 82.2 [standard deviation (SD) 32.1] versus 74.6 (SD 31.4), and the median percent adherence was 100 (IQR 71.4–100.0) versus 85.7 (IQR 57.1–100.0). This difference between assessments did not differ by supplement type.

Conclusions. We conclude that reported adherence to both LNS and MNP for children, after 12 months of usage, was relatively high in the RDNS, with median adherence above 70 percent (our cutoff for high adherence). Forgetfulness, illness, child's perceived acceptance of the supplements, and travel were the most common reasons for low adherence. Finding ways to address these barriers will likely improve adherence to LNS and MNP. Sharing of supplements and loss or destruction of supplements were reported more often among LNS recipients than among MNP recipients. Greater sharing of LNS could be related to the palatability and novelty of LNS, while greater loss or destruction may be related to attempts by children to open the LNS sachets. Reported adherence at the regular RDNS home visit at 18 months was higher than in the PEPA-C assessment, probably because of greater social desirability bias in the former due to familiarity with the regular RDNS data collectors. This reinforces the need for collecting various types of information about adherence in programs that include distribution of food or supplements.

1. Introduction

1.1 The Rang-Din Nutrition Study

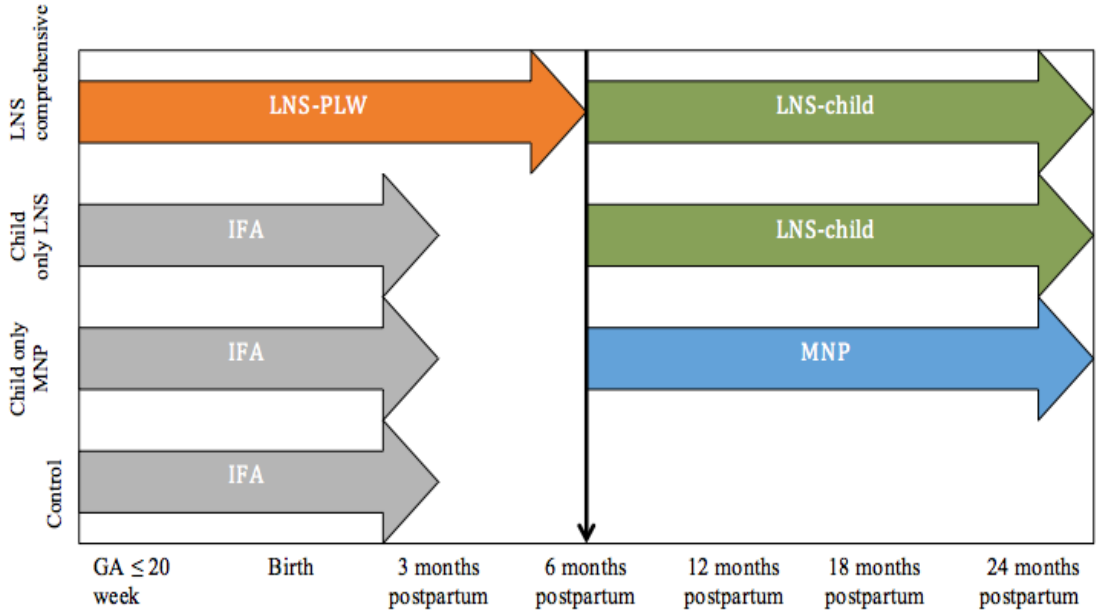
1.1.1 Background

The U.S. Agency for International Development (USAID)-funded Food and Nutrition Technical Assistance III Project (FANTA) and FANTA-2 (Food and Nutrition Technical Assistance II Project), in collaboration with the University of California, Davis (UCD), the International Centre for Diarrhoeal Disease Research, Bangladesh (ICCDR,B) and Lutheran Aid to Medicine in Bangladesh (LAMB), initiated the Rang-Din Nutrition Study (RDNS), which began in 2010. RDNS was 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 in Bangladesh.

The RDNS had four study arms (**Figure 1**):

1. LNS for the mother during pregnancy and the first 6 months postpartum, plus LNS for the child starting at 6 months of age and continuing to 24 months.
2. Iron and folic acid (IFA) for the mother during pregnancy and the first 3 months postpartum, and LNS for the child starting at 6 months of age and continuing to 24 months.
3. IFA for the mother during pregnancy and the first 3 months postpartum, and micronutrient powder (MNP) for the child starting at 6 months and continuing to 24 months.
4. IFA for the mother during pregnancy and the first 3 months postpartum, and no additional supplement for the child.

Figure 1. Timeline of Supplemental Intervention by Study Arm



LNS-PLW, lipid-based nutrient supplement designated for pregnant and lactating women; LNS-child, lipid-based nutrient supplement designed for children; IFA, iron and folic acid; MNP, micronutrient powder; GA, gestational age

The study evaluated the impact of these approaches 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, the research team also conducted a process evaluation (PE) to assess barriers and constraints to optimal delivery and uptake of the LNS and MNP interventions.

The product and information delivery platform for the RDNS was LAMB's Community Health and Development Program (CHDP). The CHDP provides a host of services to the community, including maternity services in villages, maternal services at safe delivery units (SDUs), and behavior change communication (BCC) sessions on a wide variety of health topics. CHDP staff includes community facilitators and field coordinators, skilled birth attendants cum paramedics, community health workers (CHWs), and village health volunteers (VHVs). Each CHW provides maternal and child health care in a geographic area with approximately 2500–6000 people.

1.1.2 Study Area

Bangladesh is divided into divisions, which consist of districts that are further subdivided into sub-districts. The rural areas of sub-districts are divided into approximately 7–10 unions, with each union consisting of multiple villages.

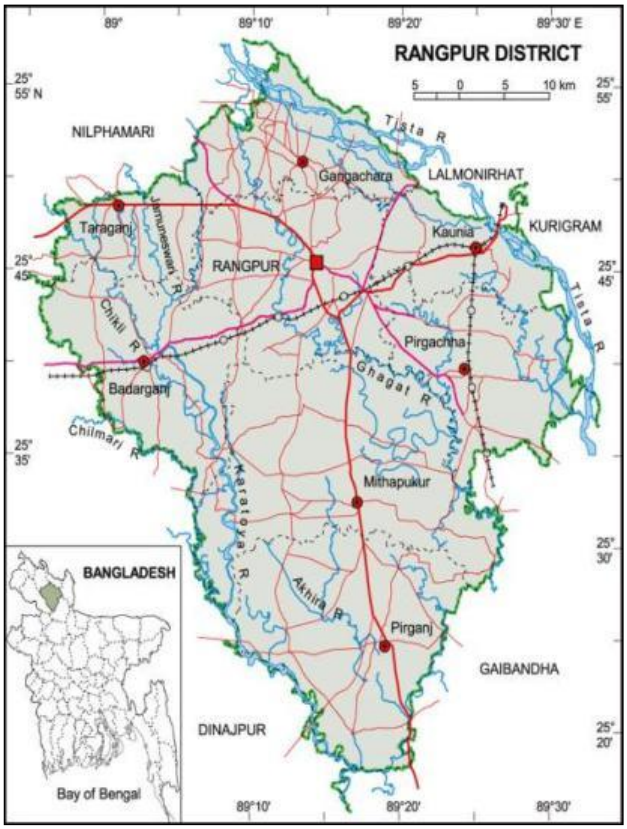
The RDNS project was implemented in six unions (Auliapukur, Tentulia, Nasratpur, Fateajangpur, Satnala, and Saintara) of the Chirirbandar sub-district (**Figure 2**) of Dinajpur district (**Figure 3**) and in five unions (Ramnathpur, Damodorpur, Madhupur, Bishnupur, and Lohanipara) of the Badarganj sub-district (**Figure 4**) of Rangpur district (**Figure 5**) in northwest Bangladesh.

Figure 2. Map of Chirirbandar Sub-District

Figure 3. Map of Dinajpur District

Figure 4. Map of Badarganj Sub-District

Figure 5. Map of Rangpur District



1.1.3 The Rang-Din Nutrition Study Design

The RDNS used a longitudinal, cluster-randomized design. In this design, "clusters" (i.e., the work areas of specific CHWs and the populations served within these work areas), rather than individual mothers, were randomly assigned to one of the treatment arms. In total, 64 clusters were randomized to the four study arms (**Figure 1**), with 16 clusters per arm. The women were enrolled during the first or second trimester of pregnancy (≤ 20 weeks gestation) and followed through pregnancy to 6 months postpartum. Their children were followed from birth to 2 years, with health and growth assessments conducted at several time points.

CHWs were the key field-level CHDP staff members who implemented the RDNS intervention. According to the LAMB CHDP protocol, women were to pick up the first supply of their supplements (upon enrollment in the study) and the first supply of their child's supplements (at approximately 6 months postpartum) at the LAMB SDU. Upon the women receiving the initial supply of supplements for the child, CHWs were to provide and read aloud to the women a card containing key messages about the supplements (**Appendix 1**). Separate cards with distinct messages were given at the initiation of the women's supplementation regime and at the initiation of the children's supplementation regime. Once the initial supply of supplements was received by the women, the CHWs were to deliver all forthcoming supplies of supplement to the women's homes on a monthly basis.

In the RDNS, primary data were collected by two teams: the home visit team (HVT) and the SDU visit team (SVT). Details on data collection are described elsewhere (Mridha et al. 2016). Briefly, the HVT interviewed each mother at her home every 6 months. The mother and child were scheduled for a follow-up visit at the SDU within one week of the home visit, where the SVT conducted interviews, measurements, and child development assessments.

1.2 The Rang-Din Nutrition Study Process Evaluation

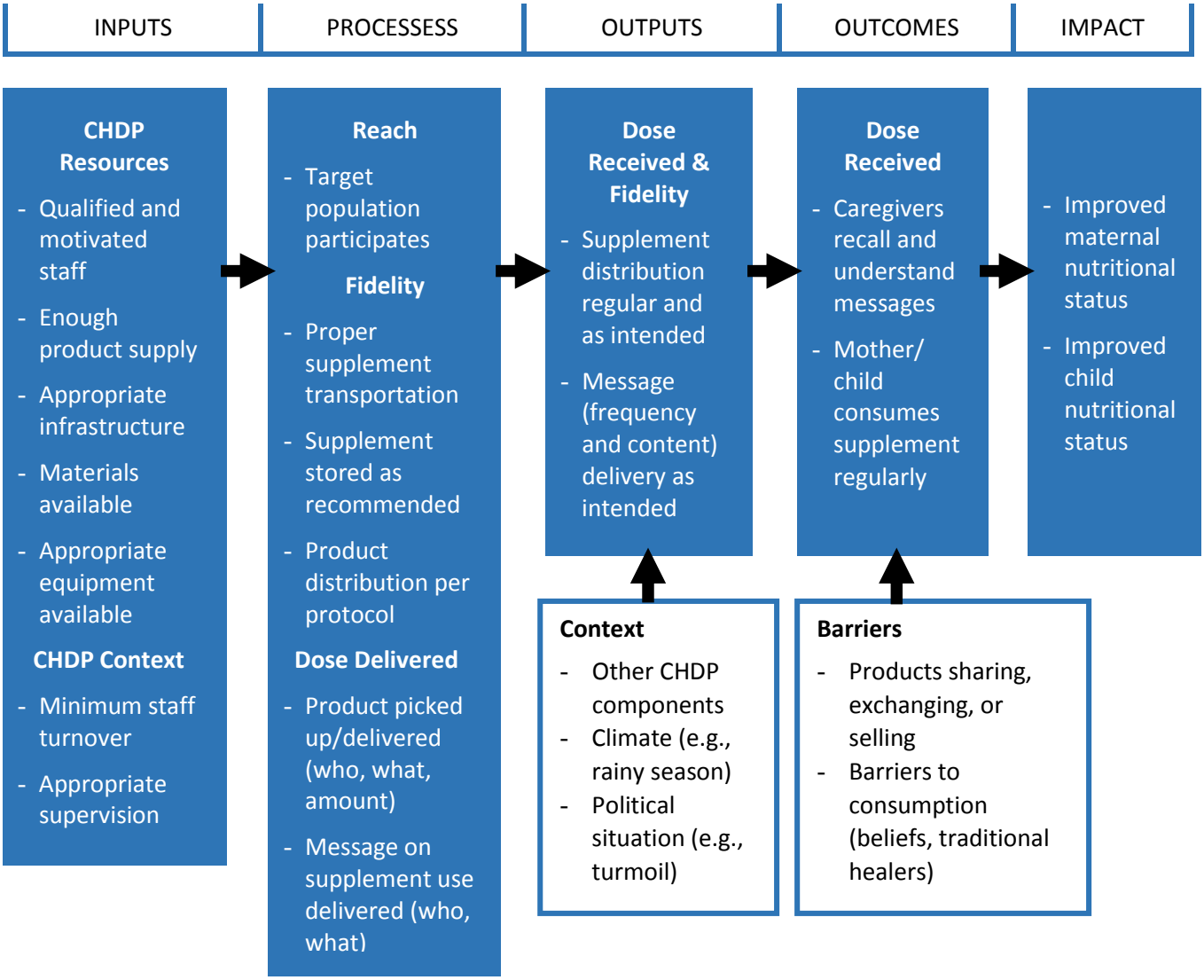
The two primary objectives of the RDNS PE were 1) to document and evaluate the resources (human, capital, financial, and informational) and processes needed to implement interventions that provide a nutrient supplement, such as LNS or MNP, in the context of the CHDP; and 2) to use the PE findings to explain and interpret program effectiveness and identify important facilitators and barriers to the success of the nutrition intervention, which can be used to improve the performance of LAMB CHDP and future programs to scale up LNS or MNP distribution.

A key component of the RDNS PE was the assessment of expected program outcomes based on the expected inputs, processes, and outputs (**Figure 6**). The PE assessed what would be needed to successfully initiate and implement supplement distribution. This assessment included documentation of conditions before, during, 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 1) consume the supplements as recommended and 2) recall and understand the related messages. Assessment of supplement delivery and supplement utilization should allow for a more informed explanation and interpretation of the overall study findings, as well as aid in identifying the barriers to and facilitators of participation of women and children in the program that could impact program success.

All PE activities were conducted by the PE team (PET), which included different personnel than those collecting the evaluation data for the RDNS (i.e., the HVT and SVT). Contact with RDNS participants

was more limited for the PET than for the HVT and SVT, as the PET rarely collected data directly from participating women and their activities also included data collection from CHDP staff and leadership.

Figure 6. RDNS PE Model



1.3 Process Evaluation Participant Adherence among Children Assessment

As part of the PE, the PET conducted the Process Evaluation Participant Adherence among Children (PEPA-C) assessment, which assessed adherence to child supplementation after the child supplement distribution had been operating for more than one year. The present report describes the main results of this assessment. Other components of the PE, such as adherence to maternal supplementation (Harding et al. 2014b) and the effects that adherence to child supplementation can have on nutrition and health outcomes, are beyond the scope of this report.

This difference may have made the PET a more suitable data collection team for cases in which there were high levels of social desirability, which can affect the data collected.

1.3.1 Objectives of the Process Evaluation Participant Adherence among Children Assessment

The PEPA-C assessment aimed to evaluate several aspects of the child nutrient supplementation provided by the LAMB CHDP. MNP packets were readily available in the Dinajpur and Rangpur markets prior to this study. In contrast, LNS for children was a novel product that was being distributed only by LAMB in the study unions. As LNS was an unfamiliar product, it was important to evaluate whether it was being used as intended by the target population. The LNS product, a 10-g sachet of fortified paste to be consumed twice daily (**Figure 7**), differs considerably from MNP, which is a daily 1-g packet (**Figure 8).** The composition of the LNS and MNP products used in this study can be found in **Appendix 2.**

Figure 7. Local LNS, "Sonamoni"

Figure 8. Local MNP, "Pushtikona"

The main objective of the PEPA-C assessment was to assess adherence to the intake recommendations for LNS and MNP among children participating in the LAMB CHDP and to assess whether adherence levels were similar for LNS and MNP. Furthermore, to identify shortfalls in outcomes outlined in Figure 6, we aimed to summarize the uses of the supplements beyond those intended, barriers to adherence, and women's recall of messages about supplement use. Additionally, we aimed to compare the adherence indicators from the PEPA-C assessment and those from the RDNS adherence assessment conducted at approximately 18 months postpartum, to evaluate the consistency of the results and determine if comparability between adherence estimates differs by supplement type.

2. Methodology

2.1 Process Evaluation Participant Adherence among Children Study Design and Sample

The PEPA-C assessment was a cross-sectional survey of a randomly selected sample of RDNS participants. Although the RDNS design consisted of four arms (**Figure 1**), with regard to child supplementation there was no difference in treatment between the "LNS comprehensive" and "child-only LNS" arms. Therefore, because adherence to child supplementation was the focus of the PEPA-C assessment, the "LNS comprehensive" and the "child-only LNS" arms were collapsed into one arm before sampling. The "control" arm (no supplement) was not considered in the sampling frame because children in the "control" arm did not receive any supplement.

Also, because one of the objectives of this report was to compare results from this survey with those from the RDNS 18-month follow-up visit, the sampling frame for the PEPA-C assessment consisted of women whose singleton was going to turn 18 months 2–3 months following the date we planned to start the assessment. Therefore, these women were due to complete their RDNS 18-month follow-up visits between May 18 and July 31, 2014 (n=733).[1] Choosing to conduct the PEPA-C assessment after the distribution of the child supplements had been implemented for more than a year allowed ample time for such distribution to be fully integrated into the program. It also helped avoid problems likely to be encountered in the first few months of child supplement distribution and bias due to possible "best behavior" during the early period of program implementation.

We aimed to be able to detect a 14-percentage point difference in mean percent adherence (between supplement types) during the past week, which corresponded to one day of consumption during a one-week time frame for recall. For sample size calculation, we assumed an alpha of 0.05 and a beta of 0.20, and we used a weighted average of standard deviations (SDs) obtained from RDNS data on child adherence available at that time; we also allowed for a 20-percent attrition or refusal rate in our calculations. Thus, the target sample size for the PEPA-C assessment was 256 (128 from the MNP arm and 128 from the combined LNS comprehensive and child-only LNS arms). We aimed to select four children per cluster from each of the two LNS arms, and eight children per cluster from the MNP arm; however, when there were not enough children of the appropriate age in a specific cluster, we sampled more children from larger clusters in that arm to achieve the total target sample for that supplement type.

2.2 Data Collection Methods

2.2.1 Questionnaire Development

The PEPA-C questionnaire was similar to the one used to assess adherence to maternal-supplement consumption in the process evaluation participant adherence among pregnant and lactating women (PEPA-PLW) assessment (Harding et al. 2014b). However, some questions were revised based on the child supplementation regimen. Also, we removed questions that had not yielded enough variability in the PEPA-PLW assessment.

[1] The enrollment period for RDNS was approximately 11 months; therefore, this sample frame does not represent a random selection of all RDNS participants.

We piloted the PEPA-C questionnaire during March 2014. Four PET members interviewed 21 women within the area where the RDNS was being implemented. There were no changes needed to the questionnaire after the pilot was completed.

2.2.2 Training Personnel

Training for the PEPA-C assessment was carried out from May 6 to May 12, 2014. Topics of the training included principles of data collection, the PEPA-C questionnaire, a mock group interview, and field testing of the PEPA-C questionnaire. The PET leader provided the training to two PE field supervisors and three field assistants. On the first day of data collection for the PEPA-C assessment, the field supervisors completed a first interview while the field assistants observed. The following three interviews on that first day were completed by the field assistants while the field supervisors and PET leader observed the interview process.

2.3 Ethical Approval

The PE activities were approved by the UCD institutional review board; the ICDDR,B ethics committee; and the LAMB ethics committee, as part of the RDNS activities approved by these organizations.

Each participant was read the 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. Women were provided with a copy of the consent form to keep.

2.4 Data Management

All completed questionnaires were submitted to the PET leader at the end of each day. The PET leader and field supervisors reviewed most of the questionnaires and consent forms within 24 hours (or 72 hours, after weekends) of data collection. The original forms were stored in a locked file cabinet in the PET archive before and after data entry.

Several questions were asked as open-ended questions with pre-coded response options. If a response did not fit within a pre-coded response option, the enumerator wrote the participant's response on the form. The responses were later translated into English at the data center and coded during the data cleaning and analysis process.

Double entry of data was conducted in an Oracle database, which was designed to flag unreasonable and incorrect values and which checked that correct skip patterns were followed on the PEPA-C questionnaire. The data collectors were asked to respond to queries raised by the PET leader or field supervisors. Primary data cleaning was done in SPSS, after which further cleaning and analysis was done in SAS 9.3.

2.5 Statistical Analysis

2.5.1 Sample Description

Baseline characteristics were compared between the PEPA-C sample and the rest of the RDNS sample and between the LNS and MNP groups within the PEPA-C sample using chi-squared and analysis of variance (ANOVA) that accounted for the random cluster effect.

2.5.2 Process Evaluation Participant Adherence among Children Adherence Analysis

The recommended supplement dosage for LNS was two sachets per day (or a total of 14 per week) and for MNP was one supplement per day (or a total of 7 per week). Women were asked how many days in the previous week their child had consumed the supplements and how many supplements were consumed per day in the previous week. From these two values, reported consumption (RC) (i.e., the maternal report of a child's supplement intake during the previous 7 days) was calculated. However, RC does not account for the exact quantity consumed, as a child could consume part of a sachet or supplement packet and the mother could report this as a supplement consumed.

From the variable of RC, variables for "percent adherence," "adherence as recommended," "high adherence," and "non-adherence" were created (**Table 1**). "Percent adherence" was defined as reported consumption in the previous week divided by the recommended number of supplements (14 LNS sachets or 7 MNP packets). "Adherence as recommended" was defined as a woman reporting that her child consumed the recommended number of supplements in the previous week. "High adherence" was defined as reporting the consumption of ≥ 70 percent of the recommended number of supplements (versus < 70 percent), and "non-adherence" was defined as reporting no supplements consumed by the child in the previous week (versus any supplement consumption). Thus, an LNS recipient was considered a "high adherer" if she or he consumed 10 or more supplements in the previous week, and an MNP recipient was considered a "high adherer" if she or he consumed five or more packets in the previous week.

Generalized linear models were used to evaluate differences in adherence between groups, using appropriate link functions for the type of adherence variable, comparing the distributions of percent adherence by group. For example, percent adherence was analyzed as a discrete variable with a multinomial distribution (cumulative logit link function in PROC GLIMMIX). Adherence as recommended, high adherence, and low adherence were binary variables and analyzed as such (logit link function in PROC MIXED). All models accounted for the cluster design effect.

Table 1. Adherence Variables Defined

Adherence Variable	Definition
Percent adherence	(RC/recommended intake) *100
LNS	*(RC/14) *100*
MNP	*(RC/ 7) *100*
Adherence as recommended	Percent adherence = 100
High adherence	Percent adherence ≥ 70
Non-adherence	RC = 0

LNS, lipid-based nutrient supplement; MNP, micronutrient powder; RC, reported consumption (maternal report of child's intake during the previous 7 days)

2.5.3 Adherence Indicator Comparison Analysis

To determine whether the adherence data collected during the PEPA-C assessment differed from the adherence data collected during the RDNS follow-up visit at 18 months postpartum, we compared the adherence variables among the same individuals using a linear mixed model for the percent adherence variable. Within the model, we accounted for the number of days between the two measurements, and set subject and cluster as random effects. Because the distribution of the percent adherence variable was close

to normal, we proceeded with this model. However, we also conducted a Wilcoxon signed rank sum test, which yielded similar results, thus giving us confidence in our linear model choice. Additionally, we created variables for high adherence, non-adherence, and adherence as recommended, as described above, from the percent adherence data collected during the RDNS 18-month postpartum follow-up. These variables were compared with those collected during the PEPA-C assessment using mixed logistic regression models.

3. Results

3.1 Sample Characteristics

A total of 250 women were interviewed for the PEPA-C assessment (126 LNS recipients and 124 MNP recipients) between May 28 and August 14, 2014. At the time of the interview, the children were on average 18.2 months old, which did not differ by supplement group (p=0.50).

Characteristics of the PEPA-C sample were compared with the characteristics of the rest of the RDNS population (**Table 2**). Women in the PEPA-C sample were similar to the rest of the RDNS sample (n=3761), with a few exceptions as seen in **Table 2**.

Within the PEPA-C sample, the LNS and MNP groups were similar with the exception of gestational age at enrollment and percentage of Muslims (**Table 3**).

Table 2. PEPA-C Sample and RDNS Characteristics at Baseline[a]

Maternal Characteristic at Study Enrollment	PEPA-C n=250	RDNS n=3761	p-value[b]
Gestational age (weeks)	13.5 (3.5)	13.0 (3.4)	0.03
Age (y)	22.0 (4.9)	22.0 (5.0)	0.98
Nulliparous[c] (%)	33	40	0.04
BMI <18.5 kg/m^2 (%)	26	29	0.27
Height <145 cm (%)	13	16	0.19
MUAC[c] (cm)	24.9 (2.7)	24.9 (2.6)	0.95
Highest grade in school completed (y)	6.1 (3.0)	6.2 (3.3)	0.47
Muslim (%)	81	80	0.89
Household food insecurity			<0.001
Food secure (%)	58	47	
Mildly food insecure (%)	6	14	
Moderately food insecure (%)	20	30	
Severely food insecure (%)	5	9	

PEPA-C, Process Evaluation of Participant Adherence among Children; RDNS, Rang-Din Nutrition Study; %, percent of women who fall within the given category; BMI, body mass index; kg, kilogram; m^2, square meters; MUAC, mid-upper arm circumference

[a] Continuous variables presented as mean (SD)

[b] p-values for categorical variables derived by chi-squared; p-values for continuous variables derived by ANOVA

[c] Missing 10 observations from the PEPA-C sample and 162 observations from the RDNS cohort

Table 3. PEPA-C Sample Characteristics by Supplement Group, at Baseline[a]

Maternal Characteristic at Study Enrollment	LNS n=126	MNP n=124	p-value[b]
Gestational age (weeks)	14.0 (3.4)	12.9 (3.5)	0.02
Age (y)	21.9 (5.0)	22.1 (4.8)	0.73
Nulliparous[c] (%)	37	29	0.18
BMI <18.5 kg/m^2 (%)	22	29	0.20
Height <145 cm (%)	12	14	0.65
MUAC[c] (cm)	24.8 (2.6)	25.0 (2.9)	0.59
Highest grade in school completed (y)	6.4 (2.9)	5.8 (3.2)	0.22
Muslim (%)	75	86	0.05
Household food insecurity			0.36
Food secure (%)	57	60	
Mildly food insecure (%)	14	19	
Moderately food insecure (%)	21	19	
Severely food insecure (%)	7	2	

PEPA-C, Process Evaluation of Participant Adherence among Children; LNS, lipid-based nutrient supplement; MNP, micronutrient powder; %, percent of women who fall within the given category; BMI, body mass index; kg, kilogram; m^2, square meters; MUAC, mid-upper arm circumference

[a] Continuous variables presented as mean (SD)

[b] p-values derived for categorical variables derived by chi-squared; p-values for continuous variables derived by ANOVA.

[c] Missing five observations from the LNS group and five observations from the MNP group.

3.2 Distribution of Supplements and Related Messages

3.2.1 Supplement Distribution Channel

As shown in **Table 4**, most women (92.8 percent) reported that they picked up the initial supply of the child's supplements from the LAMB SDU. The rest of the women stated that the initial supply of supplements was dropped off at their homes by either a CHW (6.8 percent) or both a CHW and VHV (0.4 percent). Almost all of the women (98.0 percent) reported that delivery from CHPD was the primary mode of supplement acquisition since they started receiving supplements for the child. Approximately 2 percent reported that they typically picked supplements up from BCC or satellite sessions held by CHWs at their villages. This occurred when CHWs were unable to reach the women at their homes. All of the women reported that they preferred the supplements to be dropped off at their homes by CHDP staff.

Table 4. Channel of Supplement Distribution [%(n)]

Channel	Supplement Provisions		
	Initial n=250	Primary Mode n=249	Preferred n=250
Pick up from safe delivery unit	92.8 (232)	0 (0)	0 (0)
Drop off at home by CHDP staff	7.2 (18)	98.0 (244)	100.0 (250)
CHW[a]	(17)	(209)	(219)
VHV[a]	(0)	(1)	(0)
CHW and VHV[a]	(1)	(34)	(31)
Pick up from CHW during BCC or satellite session	0 (0)	2.0 (5)	0 (0)

CHDP, Community Health and Development Program; CHW, community health worker; VHV, village health volunteer; BCC, behavior change communication
[a] (n) out of drop off at home from CHDP staff

3.2.2 Days Passed Since Supplement Distribution

As per the LAMB CHDP supplement distribution protocol, supplements were to be provided to women monthly. The number of days that had passed since a woman last received supplements was calculated based on the woman's report of the date she had received her most recent supply of supplements and the date of the interview. Calendars including local holidays and events were used to help women recall the date they last received supplements. Twenty-two women (12 LNS and 10 MNP recipients) could not recall the date they had received their most recent supplement supply, and one woman reported that she had received the supplements on a day that occurred after her interview (i.e., an invalid response). Of the women who could recall the most recent date they had received supplements (n = 227), supplements were received a mean of 13.8 days prior to the interview, with no significant difference by supplement type (p=0.69).

There were two reports of supplements being received more than 30 days prior, with one of these women reporting 32 days and the other woman reporting 36 days since she had received supplements. Although we do not have field notes from all 22 women who could not recall the date they had received supplements, some field notes from the enumerators explained that due to travel or illness, the last supplement distribution had been a while ago, so one woman could not recall the date. Other field notes explained that due to travel, another woman was not present for the supplement delivery and thus did not know the date the supplements were delivered.

3.2.3 Supplement Messages at Most Recent Visit

Women were asked if they were told how to give the supplements to their child, both at the time of their first supplement collection and at the time of their most recent supplement collection. If women were given instructions at their most recent collection, they were asked to report what they had been told and their open-ended answers were coded into a number of response categories (**Table 5**). All women reported that they were told how to give the supplements to their child when the first supply of LNS or MNP was provided to them, and 90.8 percent of the women (88.9 percent in the LNS group versus 92.7 percent in the MNP group; p=0.34) reported that they were told how to give the supplements to their child at the most recent supplement delivery. Most commonly, women were reminded to feed their child two sachets of LNS or one packet of MNP per day, depending on the supplement group they were in (95.5

percent and 94.8 percent of LNS and MNP recipients, respectively). All of the messages that women reported being told at the most recent supplement delivery are summarized in **Tables 5 and 6** for LNS and MNP recipients, respectively.

Table 5. Supplement Consumption Messages Received at Most Recent Supplement Distribution Reported by Mothers of Children Receiving LNS (n=112)

Messages	Beneficiaries Received (%)[a]
LAMB CHDP standard messages	
Use two sachets of LNS per day	95.5
Mix the supplement with food	75.9
Do not take the supplement with hot foods	7.1
Do not heat foods mixed with supplements	5.4
Do not feed more than two sachets per day	3.6
Messages that are not part of the standard LAMB CHDP messages	
Take the supplement as you wish	35.7
Clean the child or your own hands before or after feeding	3.6
Take the supplement without any other food or liquids	1.8
Do not mix with specific liquids	1.8
Do not feed to any other children	0.9

LNS, lipid-based nutrient supplement; LAMB, Lutheran Aid to Medicine in Bangladesh; CHDP, Community Health and Development Program

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

Table 6. Supplement Consumption Messages Received at Most Recent Supplement Distribution Reported by Mothers of Children Receiving MNP (n=115)

Messages	Beneficiaries Received (%)[a]
LAMB CHDP standard messages	
Use one packet of MNP per day	94.8
Mix the supplement with food	93.9
Do not take the supplement with hot foods	17.4
Do not feed more than one packet per day	5.2
Do not heat foods mixed with supplements	5.2
Do not feed other vitamins if you give Pushtikona[b]	0.9

Messages	Beneficiaries Received (%)[a]
Messages that are not part of the standard LAMB CHDP messages	
Take the supplement as you wish	23.5
Take the supplement without any other food or liquids	10.4
Take it with liquid foods	7.8
Take the supplement with juice or fruit juice	2.6
Do not mix with specific liquids	2.6
Clean the child or your own hands before or after feeding	1.7
Use two packets of MNP per day	0.9

MNP, micronutrient powder; LAMB, Lutheran Aid to Medicine in Bangladesh; CHDP, Community Health and Development Program

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

[b] The local name for the MNP provided by LAMB

3.3 Adherence to Supplement Intake Recommendations

Based on the mother's report of the number of supplements her child consumed in the past week, 43 percent of children consumed the recommended number of supplements (14 LNS sachets per week or 7 MNP packets per week) and 6 percent of children did not consume any supplements in the previous week. LNS recipients reportedly consumed a median of 12 [interquartile range (IQR) 9–14] supplements in the previous week and MNP recipients reportedly consumed 6 (IQR 3.5–7) supplements. After converting these values into a percentage of the recommended consumption, the median percent adherence to the recommendation among all children was 86 percent (IQR 57–100 percent). Overall, 68 percent of children consumed ≥ 70 percent of the recommended number of supplements and 1 percent (n = 3) consumed more than the recommended number of supplements in the previous week.

Percent adherence based on mother's report of child consumption did not differ by supplement group (p=0.23; **Table 7**). Similarly, the prevalence of adherence as recommended and of high adherence did not differ significantly by supplement group. Non-adherence was significantly higher among MNP recipients than among LNS recipients (8.9 percent versus 2.4 percent; p=0.04). No MNP recipients and three LNS recipients reported adherence > 100 percent. Because the LNS group represented a mix of women who 1) received LNS for themselves (prenatally and postpartum) and their child and 2) women who received only LNS for their child, we explored percent adherence among LNS recipients by RDNS study arm, with limited power for this test. We found no difference in adherence (p=0.298).

Table 7. Adherence Comparisons among Supplementation Groups

	LNS n=126	MNP n=124	p-value[e]
Mean (SD) percent adherence based on RC[a]	78.2 (28.8)	71.1 (33.5)	0.23[f]
Median (IQR) percent adherence based on RC	85.7(64.3–100.0)	85.7 (50.0–100.0)	
Prevalence of adherence as recommended[b] (%)	42.9	42.7	0.98
Prevalence of high adherers[c] (%)	71.4	64.5	0.25
Prevalence of non-adherers[d] (%)	2.4	8.9	0.04

LNS, lipid-based nutrient supplement; MNP, micronutrient powder; RC, reported consumption (reported number of times supplement was consumed in the past week)
[a] Unadjusted mean
[b] Unadjusted prevalence of women who reported that their child consumed 14 supplements per week among LNS recipients and 7 supplements per week among MNP recipients
[c] Unadjusted prevalence of women who reported their child consumed ≥ 70% of recommended supplements based on RC of previous week
[d] Unadjusted prevalence of women who reported that their child consumed no supplements in the previous week
[e] p-value derived from mixed models controlling for cluster design effect
[f] p-value derived from a generalized linear mixed model predicting percent adherence, with a multinomial link function, comparing the distributions of percent adherence by group, rather than the mean or median percent adherence by group

3.4 Supplement Sharing

Mothers were asked whether any of the child supplements from their most recent supply had been shared (recall period based on number of days since most recent supplement supply received), how many supplements had been shared, with whom they had been shared, and the primary reason the supplements had been shared. A greater percentage of LNS recipients than MNP recipients reported sharing supplements (20.6 percent versus. 10.5 percent; p=0.008). LNS recipients also reported sharing a greater number of supplements, although this was likely a reflection of the greater number of supplements distributed to LNS recipients than to MNP recipients, due to the difference in number of sachets distributed (**Table 8**).

Table 8. Supplement Sharing by Supplement Type Since the Last Distribution Date

	Reported Sharing[a]	p-value[b, c]	Reported Number of Supplements Shared Since Last Distribution Date[d]
LNS (n=126)	20.6 (26)	0.008	7 (2–20)
MNP (n=124)	10.5 (13)		3 (2–4)

LNS, lipid-based nutrient supplement; MNP, micronutrient powder
[a] Percent (n)
[b] p-value derived from Rao-Scott chi-squared for prevalence of sharing by supplement type
[c] The model could not be adjusted for number of days since the women received the children's supplements because inclusion of that variable in the model prevented convergence. However, as reported in section 3.2.2, supplements were received a mean of 13.8 (SD 8.4) days prior to the interview, and this did not differ significantly by supplement type
[d] Median (IQR) among those who reported sharing

Among LNS recipients who reported that supplements from the most recent supply had been shared (n=26), 16 reported sharing with one of their older children, 5 reported sharing with another child in their household, 8 reported sharing with a child outside of their household, and 3 reported sharing with other relatives. Women were asked to provide the reasons the supplements were shared and were allowed to provide more than one reason. The reasons reported for sharing LNS with others were that another child wanted it or cried for it (n=18), someone else liked it (n=6), and another child took it on her own (n=2).

Among MNP recipients who reported that supplements from the most recent supply had been shared (n=13), eight reported sharing with one of their older children, five reported sharing with another child in their household, and one reported sharing with a child outside their household. The reasons reported for sharing MNP with others were that someone else liked it (n=7), another child took it on her own (n=5), and another child wanted it or cried for it (n=1).

3.5 Loss or Destruction of Supplements

Women were asked if any of the supplements from the most recent supplement supply had been lost or destroyed, how many were lost or destroyed, and the main reason for the loss or destruction of supplements. The percentage of women who reported supplements lost or destroyed was significantly greater among LNS recipients than among MNP recipients (27.0 percent versus 15.3 percent; p=0.004) (**Table 9**). Although the number of supplements distributed to LNS recipients was approximately twice that distributed to MNP recipients due to the difference in intake recommendations, the number of supplements lost or destroyed by participant appeared to be similar between the two groups. Reasons women reported for the loss and destruction of supplements are summarized in **Table 10**.

Table 9. Supplement Loss and Destruction by Supplement Type Since the Last Distribution Date

	Reported Loss/Destruction[a]	p-value[b]	Number of Supplements Lost or Destroyed Since Last Distribution Date [c]
LNS (n=126)	27.0 (34)	0.004	2 (1–5)
MNP (n=124)	15.3 (19)		3 (2–4)

LNS, lipid-based nutrient supplement; MNP, micronutrient powder
[a] Percent (n)
[b] p-value derived from Rao-Scott chi-squared for prevalence of loss or destruction by supplement type
[c] Median (IQR) among those who reported loss or destruction

Table 10. Reasons for Loss and Destruction of Supplements Stratified by Supplement Type [%(n)]

Reason	LNS n=34	MNP n=19
Supplement was opened but not consumed	44.1 (15)	68.4 (13)
Ruined or spoiled by a child	29.4 (10)	7.7 (1)
Left somewhere else	8.8 (3)	7.7 (1)
Ants ruined the supplements	2.9 (1)	0.0 (0)
A bird took the supplements	2.9 (1)	0.0 (0)
Did not know or could not remember	5.9 (2)	0.0 (0)
Mistakenly thrown away	0.0 (0)	7.7 (1)
Lost somewhere in the house	0.0 (0)	7.7 (1)
No reason given	5.9 (2)	10.5 (2)

LNS, lipid-based nutrient supplement; MNP, micronutrient powder

3.6 Exchanging Supplements for Other Commodities and Capital

When asked if any of the supplements from the most recent supply had been given to others in exchange for money or goods, all respondents reported that no supplements had been exchanged or sold.

3.7 Running Out of Supplements

Women were asked if they had ever run of out the child's supplements and if they had run out of them in the past month. The LAMB CHDP supplement distribution protocol indicates that CHDP staff members should have provided women with more than enough supplements for the child each month so that their supplement supplies would not run out, assuming the supplements were used as recommended. Thus, running out of supplements was an indicator that the supplements were not being distributed as recommended, supplements were not being used as recommended, or a combination of both. The prevalence of reportedly running out of supplements was 9.2 percent for ever running out and 3.6 percent for running out within the past month. There were no significant differences between the supplement types (**Table 11**).

Table 11. Reports of Running Out of Supplements

	Reported Ever Running Out of Supplements[a]	p-value[b]	Reported Running Out of Supplements in the Past Month[a]	p-value[c]
LNS (n=126)	8.7 (11)	0.77	4.0 (5)	0.73
MNP (n=124)	9.7 (12)		32.3	

LNS, lipid-based nutrient supplement; MNP, micronutrient powder
[a] Percent (n)
[b] p-value derived from Rao-Scott chi-squared for prevalence of ever running out of supplements by supplement type
[c] p-value derived from Rao-Scott chi-squared for prevalence of running out of supplements in the past month by supplement type

Of the nine participants who reportedly ran out of supplements in the past month, six reported that they had traveled away from home in the past 3 months. Field notes from three of these interviews further explained that the supplement supplies had been interrupted due to the women's travel. One MNP recipient reported that she had collected the supplements since running out. In that particular case, the woman had moved to another region 2 months earlier and had just returned to her father's house 2 days before the interview took place, which was the same day that more supplements were provided to her from the SDU.

3.8 Travel in Relation to Supplement Use

Travel of women and their children can impact adherence to supplementation programs by interrupting the supply of supplements and disrupting the practice or habit of feeding the supplements regularly. In this particular program, participants typically received their supplements at their homes from CHDP staff. However, if women were not at home, it could be challenging for CHDP staff to deliver the supplements. Additionally, if women did not bring supplements with them when they traveled, the child's intake of the supplements would be interrupted. Thus, we asked about women's travel in the past 3 months, the number of times they left home for more than 1 day, and whether they brought the child's supplements with them when they traveled. Approximately 70 percent (n=174) of respondents reported that they had traveled away from their homes for more than 1 day in the past 3 months, and left home a median of 2 (IQR 1–3) times (**Table 12**).

Table 12. Travel Lasting More Than 1 Day in the Past 3 Months

	Percent Who Reported Any Travel[a]	p-value[b]	Number of Times Woman Left the Home[c]
LNS (n=126)	70.6 (89)	0.70	2 (1–3)
MNP (n=124)	68.6 (85)		1 (1–2)

LNS, lipid-based nutrient supplement; MNP, micronutrient powder
[a] Percent (n)
[b] p-value derived by Rao-Scott chi-squared for prevalence of travel by supplement type
[c] Median (IQR) among those who reported any travel

Of the 174 women who reported that they traveled for more than 1 day in the past 3 months, 49.4 percent reported that they took a supply of the child's supplements with them all the time and 12.1 percent reported that they took a supply with them most of the time. The remaining 38.5 percent reported that they never or almost never brought supplements with them when they traveled. The reasons these women gave for not taking supplements with them are summarized in **Table 13**.

Table 13. Reasons Women Reported Not Bringing Supplements with Them While Traveling (n=67)[a]

Reason	% (n)
Forgot	77.6 (52)
Unwilling to take supplements with them	9.0 (6)
Unplanned travel or they did not bring enough supplements for the duration of their trip	6.0 (4)
Child was sick	3.0 (2)
Preventing other children from eating the supplements	1.5 (1)
Too busy with wedding activities	1.5 (1)
One night trip did not require bringing supplements	1.5 (1)

[a] Among those who reported never or almost never bringing supplements with them when they traveled

3.9 Use of Other Supplements

Although the LAMB CHDP distributed LNS and MNP free of cost, other nutritional supplements for children were available in the local markets and were being sold by other community health programs in the area. This created an environment in which there was the possibility for children to receive more than the recommended amount of some nutrients if they were consuming nutritional supplements in addition to those provided by LAMB. Thus, it was deemed important to assess the use of other nutritional supplements and determine whether children were at risk for nutrient toxicity.

Women were asked about the acquisition and use of other supplements for their child, including how many other nutrient supplements their child consumed in the past week and past month.

Seven women reported that they had collected or received supplements other than the LAMB CHDP supplements for their child in the past 3 months. Two of these women were in the MNP arm and five were in the LNS arm. The supplements that women reportedly received were Monimix (locally available MNP), Sprinkles (locally available MNP), Pushtikona (locally available MNP that was provided by LAMB as part of the study), and Sonamoni (LNS provided by LAMB as part of the study). Three children were reported to have consumed at least some of the supplements received from a source other than LAMB in the past week. In one case, the woman explained that her child was consuming Monimix instead of Pushtikona, and in two cases, Sonamoni recipients reported acquiring additional Sonamoni. However, neither of these two women reported that her child consumed more than the recommended 14 sachets in the previous week.

3.10 Reasons Reported for Children Consuming More or Less than the Recommended Number of Supplements in the Previous Week

If a woman reported that her child consumed more or less than the recommended number of supplements, she was asked to provide the reasons why (and could provide multiple reasons) (**Table 14)**. Forgetfulness and illness were the two most common reasons reported for a child consuming less than the recommended amount. Other reasons commonly reported included the child not liking or wanting the supplement, being away from home, and the child's loss of appetite.

No MNP recipients reported that the child consumed more than 7 packets in the previous week, but 3 LNS recipients reported that the child consumed more than 14 supplements in the previous week. All

three of these women reported giving the child more LNS than recommended because the child liked the supplement, and two of the women also said that the child wanted the supplements. The women explained that the child would cry for the supplement, indicating that s/he wanted it. Additionally, one of the women said that her child took the supplement himself when she was busy.

Table 14. Reasons Children Consumed Less Than the Recommended Number of Supplements in the Past Week [%(n)][a]

Reason	LNS n=69	MNP n=71
Forgot	43.5 (30)	38.0 (27)
Child or mother was sick	31.9 (22)	38.0 (27)
Child didn't like it or did not want to take it	23.2 (16)	11.3 (8)
Away from home	13.0 (9)	19.7 (14)
Child's loss or lack of appetite	17.4 (12)	11.3 (8)
Ran out of supplements	2.9 (2)	5.6 (4)
Laziness	1.4 (1)	1.4 (1)
Supplement made child sick or defecate	1.4 (1)	1.4 (1)
Mother was busy	1.4 (1)	1.4 (1)
Fed different supplement instead	0.0 (0)	1.4 (1)

LNS, lipid-based nutrient supplement; MNP, micronutrient powder

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

3.11 Comparison of Adherence Indicators

The PEPA-C survey and the RDNS 18-month postpartum follow-up were conducted on average 8.3 (SD 6.0) days apart (median 7; IQR 6–9). To determine whether reported adherence collected during the PEPA-C evaluation was different than reported adherence collected at the RDNS 18-month follow-up, we compared percent adherence as reported by PEPA-C survey participants at these different data collection occasions. We found that women reported significantly higher mean percent adherence during the RDNS 18-month follow-up than during the PEPA-C survey (mean difference in percent adherence ± standard error (SE): 7.66 ± 2.15; $p<0.001$; **Table 15**).

In a bivariate analysis, the time lag between the two assessments was associated with the difference in adherence and was included in the model as a covariate. When we explored whether the supplement type influenced the relationship between the percent adherence data collected for the PEPA-C assessment and the percent adherence data collected as part of the RDNS 18-month follow-up, we found no effect modification by supplement type (interaction term between supplement type and data collection occasion $p=0.23$). We further explored the relationship between PEPA-C and the RDNS 18-month follow-up adherence measures and found that although mean percent adherence reported at the RDNS 18-month follow-up was significantly higher than that reported during PEPA-C, the two reported adherence measures were, nevertheless, significantly correlated ($r=0.43$; $p<0.001$).

The prevalences of high adherence and adherence as recommended were also greater at the RDNS 18-month follow-up than during the PEPA-C survey, although the prevalence of reported non-adherence did not differ across the two data collection occasions ($p=0.278$; **Table 15**).

Table 15. Adherence Comparisons between Two Assessments (n=249)

Adherence	PEPA-C	RDNS 18-month follow-up	p-value[d]
Percent adherence based on RC			
Unadjusted mean (SD)	74.6 (31.4)	82.2 (32.1)	<0.00[e]
Adjusted mean (SE)	74.7 (2.1)	82.3 (2.1)	
Median (IQR)	85.7 (57.1–100.0)	100.0 (71.4–100.0)	
Prevalence of adherence as recommended[a] (%)	42.6	61.5	<0.001
Prevalence of high adherers[b] (%)	67.9	80.3	<0.001[f]
Prevalence of non-adherers[c] (%)	5.6	7.6	0.278

LNS, lipid-based nutrient supplement; MNP, micronutrient powder; PEPA-C, Process Evaluation of Participant Adherence among Children; RC, reported consumption (reported number of times supplement was consumed in the past week)

[a] Unadjusted prevalence of women who reported that the child consumed 14 supplements per week among LNS recipients and 7 supplements per week among MNP recipients

[b] Unadjusted prevalence of women who reported that the child consumed ≥ 70% of recommended supplements based on RC of previous week

[c] Unadjusted prevalence of women who reported that the child consumed no supplements in the previous week

[d] p-value from mixed models

[e] Controlling for time lag between data collection events

[f] The random effect cluster was removed from the model to achieve convergence

4. Discussion

After 12 months of the child supplementation portion of the intervention, the median percent adherence based on reported consumption among all children was 86 percent and did not differ by supplement group. There were also no significant differences between supplement group with regard to the prevalence of adherence as recommended and the prevalence of high adherence. However, the prevalence of non-adherence was significantly lower among LNS recipients than among MNP recipients (2.4 percent and 8.9 percent, respectively). We found that women typically reported higher adherence at the RDNS 18-month follow-up assessment than during the PEPA-C assessment (mean percent adherence 82.2 percent and 74.6 percent, respectively) and that this did not differ by supplement type.

Previous reports of adherence to child LNS supplementation in efficacy and acceptability trials vary. In a 9-month efficacy trial in Burkina Faso, reported adherence to supplement consumption and adherence based on supplement disappearance data collected on a weekly basis was on average 97 percent (SD 6) and 98 percent (SD 4), respectively. However, when adherence was evaluated using 12-hour in-home observations, observed consumption during those 12 hours ranged from 54 percent to 63 percent among the participants in the LNS arm (Abbeddou et al. 2014). This range is closer to the mean percent adherence observed in a 14-day home-use acceptability trial with Guatemalan children (74.6; SD 20.0) in which empty sachets were counted to estimate adherence (Matias et al. 2011). In an acceptability trial in Ghana, children consumed a median of 96.5 percent of the daily dose recommended (20 g/day) during the 14-day home-use period for the supplements (Adu-Afarwuah et al. 2011). Similar LNS acceptability trials have been conducted in Malawi and Burkina Faso. During the second week of the 14-day home-use period in Malawi, 94 percent of children consumed LNS every day. At the end of the 14-day home-use period in Burkina Faso, where LNS was provided in single cups rather than in individually packaged sachets and adherence was assessed based on the observed amount of supplement remaining, 7 percent of participants had about 25 percent of the LNS left and 3 percent had about 50 percent left (Hess et al. 2011, Phuka et al. 2011).

Prior to the implementation of the RDNS, we conducted an LNS and MNP acceptability trial among children 6–24 months of age in Dinajpur district using two flavors of LNS and one type of MNP. Mean percent adherence to LNS-regular and MNP during the 14-day home-use period was estimated as 93.4 (SD 11.6) and 95.7 (SD 6.8), respectively, and adherence did not differ between the two LNS flavors (Mridha et al. 2012). Mean percent adherence to LNS in the current assessment was 78 (SD 29) and was lower than that reported in the efficacy trials in Burkina Faso and Malawi and in the acceptability trials in Ghana and Bangladesh. However, some of those acceptability trials used different methods to assess adherence (i.e., counted remaining supplement sachets). In addition, all of the acceptability trials assessed adherence within the context of a short-term supplementation period of 14 days. It should also be noted that the RDNS was an effectiveness study, as opposed to an efficacy trial in which supplement adherence is usually monitored more frequently. As a result, there was a lower frequency of participant interaction with health workers and study staff in the current study than in the efficacy trial in Burkina Faso, which likely negatively influenced adherence in the current study.

Reported adherence to MNP-consumption recommendations is highly variable, with one recent Cochrane review reporting that the prevalence of high adherence to MNP-supplementation recommendations (≥ 57 percent of the recommendation) ranged from 32 percent to 90 percent (De-Regil et al. 2013). In the current study, the mean percent adherence to the MNP-consumption recommendations was 71 (SD 34) and the prevalence of high adherence (i.e., adherence ≥ 70 percent) was 64.5 percent. Compared with the acceptability trial we conducted in Bangladesh, we found lower reported adherence to MNP

supplementation in the current study, though the same limitations to this comparison of MNP adherence in the acceptability trial versus the RDNS evaluation exist as described in the previous paragraph.

This rural Bangladeshi population may be more familiar with MNP than with LNS supplementation, as the MNP product we used is commercially available. Thus, a noteworthy result from this study is that the level of adherence to supplement recommendations did not differ by supplement type, except for a higher prevalence of non-consumers in the MNP group. All of these results indicate that LNS was an acceptable children's nutrient supplement, even in the context of programmatic distribution.

Sharing was more common among LNS recipients than among MNP recipients; most reports of sharing were with another child in the household. Although the reasons for sharing were similar between the two supplement groups, the higher prevalence of sharing of LNS may have been due to the novelty of the supplements, as MNP has been available in this region for some time and can be purchased. Additionally, LNS may be more desirable to young children because it is a food and has a taste to it, while MNP does not add flavor to the food or liquid with which it is mixed.

In the previously cited LNS trial in Burkina Faso, self-reported sharing of LNS was highly prevalent (49.7 percent in the past week) and sharing was observed in 8 percent of the12-hour in-home observations (Abbeddou et al. 2014). Although sharing of LNS since the last supply was received in our population was substantially lower in comparison (21 percent), it is still an aspect of LNS supplementation programs that should be considered. However, if LNS distribution were to be scaled up so that all young children would receive it, then sharing with other young children might be expected to occur less frequently.

Travel was a common explanation for running out of supplements in the PEPA-C assessment. Approximately 70 percent of women reported that they had been away from home for more than 1 day in the past 3 months, and 39 percent of these women did not take the child's supplements with them, primarily due to forgetfulness. Forgetfulness was also the most commonly reported reason for a child consuming less than the recommended number of supplements in the previous week. This is not a novel challenge to MNP or LNS adherence. An MNP supplementation trial in Peru showed that 27 percent of caregivers found it difficult to remember to give MNP as recommended (Harding et al. 2014a). Forgetfulness was also mentioned as a reason for not feeding LNS as recommended to children in Burkina Faso (Abbeddou et al. 2014). This is consistent with our previously reported results on adherence to maternal LNS in our study context, for which forgetfulness was a barrier to high adherence (Harding et al. 2014b). Thus, addressing forgetfulness through reminder techniques such as text messages, or through other approaches such as involving other family members, could contribute to improving adherence to both maternal and child supplementation.

Illness was the second most frequently reported reason for children consuming less than the recommended number of supplements in the previous week. From the responses provided, it is not clear if the children became sick and did not eat the supplements or if the supplements were associated with illness so were not fed to the children. In the acceptability trial in Bangladesh described earlier, of the 40 primary caregivers interviewed about health problems related to the child's consumption of LNS, 53 percent reported that the child experienced a cough, 20 percent reported nausea or vomiting, 18 percent reported breathing problems, 15 percent reported diarrhea, and 13 percent reported fever (Mridha et al. 2012). However, caregivers in that study also described perceived health benefits to taking the supplements, such as the child receiving the nutrition s/he needed, improved appetite, better sleep, more intelligence, and reduced disease.

The purpose of the comparison of adherence values collected during the PEPA-C assessment and the RDNS 18-month visit was to evaluate consistency between the two indicators, and to determine if

comparability between assessments differs by supplement type. Adherence between these two assessments did not differ by supplement type (MNP versus LNS); however, overall, participants reported higher adherence at the RDNS 18-month follow-up than at the PEPA-C assessment. There are several possible reasons for this difference, described below.

First, the PEPA-C survey took place an average of 8.3 (SD 6.0) days after the RDNS 18-month follow-up visit, and the amount of time that elapsed between these two assessments was associated with the difference in reported adherence in the bivariate model. We included a variable to represent this time lag in the multivariate model; however, time lag between the two data collection occasions was not significantly associated with the difference observed in adherence in the multivariate model. Second, it is possible that asking a woman similar questions regarding her child's supplement intake a second time may have introduced some bias. Third, the two assessments were conducted in different contexts, although both at the participants' homes. The RDNS 18-month postpartum follow-up was a much longer visit (~1.5 hours) and included a variety of questions including questions about feeding practices, socioeconomic information, health, and food security. The PEPA-C survey was usually completed in less than an hour and included detailed questions about the supplement use and a few on the CHDP. In the latter context, women may have provided more thoughtful answers about supplement use, as that was the focus of the interview. Last, the teams collecting the data may have influenced the women's responses. The 18-month postpartum follow-up was conducted by RDNS staff members who lived within or close to the union in which they were working, and they had likely visited the women previously (i.e., for the earlier RDNS follow-up visits). The community members may have associated that interviewer with the supplement program, even though the data collectors did not distribute supplements. By contrast, the PEPA-C survey was conducted by the RDNS PET, whose members did not visit participants' homes regularly and had likely not met the women previously. Therefore, there may have been more social desirability bias in the RDNS follow-up because of the relationship the women may have had with the interviewers and the connection the women may have made between the interviewers and the supplement program.

The limitations of this assessment should be considered in the interpretation of its findings. The use of a reported measure of supplement intake typically results in an overestimation of adherence when compared with the use of disappearance data, medication event monitoring systems, or in-home observations (Abbeddou et al. 2014, Jasti et al. 2005). Thus, the adherence values reported herein may be an overestimation of true adherence.

There are several strengths to this evaluation that should be noted as well. Because our findings on supplementation adherence were obtained within a context of programmatic distribution, they may better reflect supplement use in large-scale supplement distribution programs than adherence measured within efficacy or acceptability trials. In addition, the study design allowed for the comparison of two adherence indicators in the same sample, which will assist our understanding of adherence data collected among the larger RDNS population.

In conclusion, we found that reported adherence for children in the context of a long-term supplementation intervention was relatively high in the RDNS, with median percent adherence above 70 (our cutoff for high adherence) for both LNS and MNP. This is an encouraging finding for programs aimed at scaling up the use of such supplements. As expected, reported adherence at the regular RDNS home visit at 18 months was significantly higher than in the PEPA-C assessment, probably because of greater social desirability bias in the former. This reinforces the need for collecting various types of information about adherence in programs that include distribution of food or supplements.

Forgetfulness, illness, children's perceived acceptance of the supplements, and travel were the most common reasons for less than recommended adherence. Strategies to address these barriers, such as incorporating reminder techniques or systems to make traveling with supplements convenient, will likely improve adherence to LNS and MNP and should be considered by program implementers. Sharing of supplements and loss or destruction of sachets were reported more often among LNS recipients than among MNP recipients. Greater sharing of LNS could be related to the palatability and novelty of LNS, and greater loss or destruction may be related to attempts by children to open the LNS sachets.

Implementation of the RDNS supplement-distribution program appeared to be going as planned, although some potential deviations were observed (such as information reportedly received that conflicted with the intended messages regarding consumption of supplements). Providing frequent refresher trainings for staff involved with supplement distribution and education could help prevent or correct such deviations. This could also allow for more dialogue between staff and supervisors regarding barriers to adherence, which could then be addressed.

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Appendix 1. Health Education Messages Regarding Sonamoni and Pustikona

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 (CHW) at each supplement distribution date. Women receiving Sonamoni (lipid-based nutrient supplement) were instructed as below for Sonamoni. Similarly, women receiving Pustikona (micronutrient supplement) were instructed as below for Pustikona.

Sonamoni Health Messages

1. Sonamoni is for children only. Sonamoni is a special food for children 6-24 months of age. There are vegetable fat, dry skimmed milk, peanuts, sugar, mineral and vitamin complex, maltodextrin, and emulsifier-lecithin in the Sonamoni.
2. Feed two sachets of Sonamoni per day, one in the morning and one at night.
3. Feed two sachets of Sonamoni per day from 6 months to 24 months of age. It should not replace breast milk. Infants should receive only breast milk for the first 6 months of life. Breastfeeding should be continued along with other infant foods afterward. Give your baby meat, fish, eggs, dairy, fruits, and vegetables whenever you can. Babies need these foods and breast milk even if they receive Sonamoni.
4. Do not give more than two sachets of Sonamoni each day because it is not good for the baby to have too much. If you forget to give Sonamoni one day, do not take extra the next day—it is always two sachets per day.
5. Each time you feed your child Sonamoni, mix the entire sachet of Sonamoni with 2–3 spoonfuls of already-prepared food that you normally feed your child. Never cook the supplement with the food. Feed your child the whole mixture of food and Sonamoni at a time.
6. Store the Sonamoni 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 have the rest of your Sonamoni sachets with the container and registration card when you receive the resupply.
8. We do not expect any side effects from taking Sonamoni, but if your child experiences any side effects (like vomiting, pain in stomach, boil/etching in body, loose motion), please call respective village health volunteers (VHVs) or CHWs.
9. When you are feeding your baby Sonamoni, your baby does not need any other vitamins/minerals.
10. If your child suffers from any serious adverse events or is admitted to a hospital for any reason, please call your assigned VHVs or CHWs.

Pustikona Health Messages

1. Pustikona is for children only. Pustikona is a special food for children 6 to 60 months of age. There are mineral and vitamin complex, maltodextrin, and colloidal silicon dioxide in the Pustikona.
2. Feed one sachet of Pustikona per day. Pustikona does not change the taste or smell of food.
3. Feed one sachet of Pustikona per day from 6 months to 24 months of age. It should not replace breast milk. Infants should receive only breast milk for the first 6 months of life. Breastfeeding should be

continued along with other infant foods afterward. Give your baby meat, fish, eggs, dairy, fruits, and vegetables whenever you can. Babies need these foods and breast milk even if they receive Pustikona.

4. Do not give more than one sachet of Pustikona each day because it is not good for the baby to have too much. If you forget to give Pustikona one day, do not take extra the next day—it is always one sachet per day.
5. Each time you feed your child Pustikona, mix the entire sachet of Pustikona with 2–3 spoonfuls of already-prepared food that you normally feed your child. Never cook the supplement with the food. Feed your child the whole mixture of food and Pustikona at a time. Don't mix Pustikona with too-hot foods or liquid food.
6. Store the Pustikona in the zip lock bag 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 have the rest of your Pustikona sachets with the zip lock bag and registration card when you receive the resupply.
8. We do not expect any side effects from taking Pustikona, but if your child experiences any side effects (like vomiting, pain in stomach, boil/etching in body, loose motion), please call respective VHVs or CHWs.
9. When you are feeding your baby Pustikona, your baby does not need any other vitamins/minerals.
10. If your child suffers from any serious adverse events or is admitted to a hospital for any reason, please call your assigned VHVs or CHWs.

Appendix 2. Nutrient Composition of Sonamoni and Pushtikona

Nutrient	Unit	Sonamoni	Pushtikona
Dose	g	20	1
Energy	kcal	118	0
Protein	g	2.6	0
Fat	g	9.6	0
Linoleic acid	g	4.46	0
α-Linolenic acid	g	0.58	0
Calcium	mg	280	0
Copper	mg	0.34	0.56
Folate	µg	150	150
Iodine	µg	90	90
Iron	mg	9	10
Magnesium	mg	40	0
Manganese	mg	1.2	0
Niacin	mg	6	6
Pantothenic acid (B5)	mg	2.0	0
Phosphorous	mg	190	0
Potassium	mg	200	0
Riboflavin (B2)	mg	0.5	0.5
Selenium	µg	20	17
Thiamine (B1)	mg	0.5	0.5
Vitamin A	µg	400	400
Vitamin B12	µg	0.9	0.9
Vitamin B6	mg	0.5	0.5
Vitamin C	mg	30	30
Vitamin D	µg	5	5
Vitamin E	mg	6	5
Vitamin K	µg	30	0
Zinc	mg	8	4.1