Anthrologica

Maternal and Infant Nutrition Trial (MINT)

Testing the impact of nutritional supplements for women in pregnancy in Nepal – Phase 2

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Abbreviations

BEP	Balanced energy-protein
BMGF	Bill and Melinda Gates Foundation
BMI	Body Mass Index
DHS	Demographic Health Survey
FCHV	Female Community Health Volunteers
GWU	George Washington University
IRB	Institutional Review Board
IUGR	Intrauterine growth restriction
JHU	John Hopkins University
MMEIG	Maternal Mortality Estimation Inter-Agency Group
MMR	Maternal Mortality Ratio
MINT	Maternal and Infant Nutrition Trial
NHRC	Nepal Health Research Council
NNIPS	Nepal Nutrition Intervention Project – Sarlahi
PAF	Product Acceptability Form
PRF	Product Ranking Form
RCT	Randomized controlled trial
SBA	Skilled birth attendants
SGA	Small-for-gestational-age
VDC	Village Development Committee
WHO	World Health Organization
WV	Ward Volunteer

Introduction

Background

According to the UN Maternal Mortality Estimation Interagency Group (MMEIG), the maternal mortality ratio (MMR) in Nepal declined from 901 per 100,000 live births in 1990 to an estimated 258 per 100,000 live births in 2015 (WHO 2015). In contrast, the Maternal Mortality and Morbidity Study 2008/09, which was not a nationally representative survey, put the MMR at 229 per 100,000 (Pradhan et al. 2010).

Maternal mortality is difficult to estimate with certainty because a large number of births do not occur in hospitals and the cause of a woman's death may be unknown or unreported, especially in rural areas (Engel et al. 2013). According to the 2016 DHS, 44.2% of rural women in Nepal delivered in healthcare facilities, while 46.8% of rural births are attended by skilled birth attendants (SBA) (Ministry of Health 2017). Despite marked improvements, Nepal remains a country with one of the highest MMRs in the world (Ernst & Young 2017). The reasons for this are manifold and complex. Access to and use of antenatal care (ANC) has improved over the past 20 years, but the number of mothers who receive at least four ANC visits in Nepal remains relatively low, particularly in rural areas and in those areas with a high percentage of individuals of low socioeconomic status (Price and Bohara 2013; Singh et al. 2017; Målqvist et al. 2017).

Poor nutrition, including energy and micronutrient deficiencies, and a large number of adolescent pregnancies contribute to poor maternal outcomes (Acharya and Alpass 2004; Acharya et al. 2010). Women who enter pregnancy with low Body Mass Index (BMI) or short stature are at increased risk of adverse health outcomes (Rahman et al. 2015) as well as small-for-gestational age (SGA) births (Kozuki et al. 2009). According to the 2016 DHS, 17% of Nepali women of reproductive age are thin or undernourished, with BMI less than 18.5. Women in the Terai zone are nearly twice as likely to be thin as women living in Mountain or Hill zones (23% versus 12% respectively), and rural women are more likely to be thin than urban women (19.9% versus 15.6%) (Ministry of Health 2017). Eleven percent of Nepali women are shorter than 145 cm, the height below which women are at increased likelihood of difficulty during delivery and at risk of bearing low birth weight babies (Ministry of Health 2017). A full 30% of Nepali women in the 15-19-year-old age group are thin (Ministry of Health 2017), and in this age group, 7.1% have already borne children (Government of Nepal and UNICEF 2015). Being underweight is a particular concern for young pregnant women. The young mothers are still growing themselves and thus both their bodies and those of their foetuses draw from available energy and nutrition, which may increase the incidence of low birth weight in young pregnant women (King 2003; Acharya and Alpass 2004).

Women's micronutrient needs increase during pregnancy to meet the needs of the growing foetus, and multiple rather than single micronutrient deficiencies affect women of reproductive age, particularly in low-income countries (Christian 2010). A 2005 study by Jiang et al. in the Sarlahi district of Nepal examined micronutrient status of women in early pregnancy and found deficiencies in Vitamins A, E, D, riboflavin, B-6, B-12, folate, zinc, iron, and copper. More than 80% of the women in the study were deficient in two or more micronutrients; the authors suggested that these deficiencies likely reflected dietary inadequacy prior to pregnancy (Jiang et al. 2005). Recent data from the Nepal DHS indicates that the prevalence of anaemia among pregnant women decreased slightly from 2011 to 2016, which may be attributable, in part, to the government's universal iron-folic acid (IFA) supplementation program for pregnant women (Ministry of Health 2017).

Current World Health Organization (WHO) antenatal care guidelines recommend provision of balanced energy-protein (BEP) supplements in populations where the prevalence of undernourished pregnant women (low BMI) is greater than 20% (WHO 2017). They also recommend provision of IFA supplements to all pregnant women (WHO 2016) but further note that some countries may decide to switch to the

provision of multi-micronutrient (MMN) instead of IFA supplements. This is particularly the case where multiple deficiencies are the rule rather than the exception, as MMN supplements have been shown to result in better birth outcomes than IFA alone (Haider and Bhutta 2017). However, since the WHO antenatal care guidelines mention this as an option, rather than a recommendation, use of MMN instead of IFA supplements is not yet widespread. The Bill and Melinda Gates Foundation (BMGF) convened a consultation in September 2016 to discuss the content and possible forms of BEP supplements; the outcome was the proposed macro- and micronutrient content for fortified BEP supplements.

Aims and objectives of research

BMGF commissioned the three-phase research study 'Maternal and Infant Nutrition Trial (MINT): Testing the impact of nutritional supplements for women in pregnancy in Nepal'. The overall study seeks to evaluate the preferred product type for the provision of fortified BEP supplements and its impact on pregnancy outcomes. In Phase 1, 11 products of different types and flavours were rapidly assessed in terms of short-term acceptability. During Phase 2, these two most acceptable BEP supplements identified in Phase 1 were tested for longer-term acceptability and home consumption for a period of eight weeks. The BEP supplement(s) selected from the formative research in Phase 2 will then be administered to pregnant women in Phase 3, a randomized controlled trial (RCT) designed to test the efficacy of the BEP supplement(s) during pregnancy and lactation on pregnancy and child health outcomes. The nutritional composition of the specific BEP supplements was established during the expert consultation convened by the BMGF in September 2016. The form of BEP supplements selected for Phase 3 may be modified if necessary, according to the preferences of the target population. The research partners, including BMGF, have liaised with private sector partners to request supplements in the selected forms with the recommended nutrient composition for the formative research in Phases 1 and 2.

Report structure and outputs

This draft report synthesises findings from Phase 2 of the formative research study. The data collected comprised a number of related components: a quantitative survey and qualitative data collection (in-depth interviews and focus group discussions) using open and inductive methods. Adopting a mixed methods approach allowed for triangulation of material and for increased validity of findings. The study was able to provide insight to inform the selection of products for Phase 3 of the project.

Following the introduction, the study's methods are outlined in detail. The subsequent three chapters present: (1) summary of findings; (2) direction for Phase 3 product choice; and (3) conclusions and recommendations. The analysis was conducted by Tsering Pema Lama, George Washington University (GWU) (quantitative analysis) and Anthrologica (qualitative analysis). The report was compiled by Leslie Jones and Katie Moore (Anthrologica). Prior to its finalisation, all colleagues had the opportunity to provide written and verbal feedback, which was incorporated into the final report as appropriate. The report is structured to be of operational use in Phase 3 of the MINT project.

Methodology

The research was conducted in line with prevailing ethical standards that seek to protect the rights and welfare of all participants (Graham et al. 2013). Ethical permission to undertake the study was granted by Nepal Health Research Council (NHRC) in Nepal, GWU Institutional Review Board (IRB), Johns Hopkins School of Public Health (JHU) IRB, and the Harvard T.H. Chan School of Public Health IRB. The research was a collaboration between GWU, JHU and the Harvard T.H. Chan School of Public Health, working with Anthrologica. Phase 2 of the formative research study ran from January 2019 to October 2019, including a period of intensive data collection in Nepal in May 20– August 1, 2019.

Research team

The overall research for Phase 2 was managed by Sheila Isanaka (SI) and Saskia de Pee (SdP) from Harvard, and Juliet Bedford (JB), Leslie Jones (LJ) and Katie Moore (KM) from Anthrologica. The GWU team was led by James Tielsch, and the JHU team was led by Luke Mullany with in-country support from Subarna Kumar Khatry and Tsering Pema Lama (TPL).

With technical oversight from the core team, LJ and KM led the qualitative research. They developed the qualitative research tools, analysed the qualitative data, synthesised it with the quantitative analysis, and drafted the Phase 2 report. The quantitative tools were designed by SI with input from the core team. GWU and JHU collaborated with NNIPS, a long-running collaborative research effort headed by investigators in the Johns Hopkins Department of International Health, to conduct in-country data collection, transcription and translation.

The 20-person field research team was led on the ground by two field coordinators and included 3 supervisors, 7 members of the qualitative data collection team and 8 members of the quantitative team. KM provided project-specific training to the data collectors in Nepal in January 2019 and the team were then given ongoing supplementary training from TPL in the lead-up to the data collection period. The analysis of quantitative data was undertaken by TPL under the guidance of SI, GW and JHU.

Study sites

The NNIPS field office is based in Sarlahi district, and this is where data were collected. Sarlahi, in southern Nepal, is one of 75 districts in the country. The research sites were selected by GWU and JHU in collaboration with NNIPS, as both institutions had conducted previous research in the locale which was well accepted by the local community. The Village Development Committees (VDCs) of Mohanpur, Babarganj, Bela and Ishwarpur were selected for inclusion in Phase 2 on the basis that they were past NNIPS study area VDCs and representative of the study district in terms of ethnicity, caste and religion. Participants from the Mohanpur and Babargunj VDCs were assigned the Plumpy'Mum product and participants from Bela and Ishwarpur VDC were assigned the vanilla biscuit product. The participants were selected from certain wards (each VDC had 9 wards) and not all wards were included in this study given the small target sample size.

Participants and sampling

Prior to initiating the study, in the selected VDCs, each household in the study area was visited and a recruitment list of pregnant women who met study inclusion criteria was created. The inclusion criteria for women were: married; age (15-40 years); gestational age (13-28 weeks); and residing in the study area for at least two months. Women were excluded from participation if they refused to provide

informed consent or if they were allergic to milk, peanuts, or soy. During this process, the name and address of each woman and that of her husband were recorded along with age and gestational age information. This list was then used to select and enrol pregnant women into the study after obtaining informed consent. The women were purposively selected based on their geographical location in order to facilitate supply distribution and weekly visits.

Consent

Informed consent was obtained prior to data collection. Researchers provided a full explanation of the study and emphasised the voluntary, confidential and anonymous nature of participation. Participants were told that the research involved development of a food supplement to be used during pregnancy and lactation in order to improve birth outcomes and infant growth. It was made clear that their participation would not affect any medical service required or provided during their pregnancy and after the birth of their child, and that they were free to withdraw at any time without giving a reason. The study's consent form was explained in detail in order to ensure that all participants, including illiterate women, understood the form before giving consent. All participants were given the opportunity to ask questions and seek further explanation. Participants willing to take part completed the consent form with a signature or thumbprint. At the conclusion of the fieldwork, all completed consent forms were retained in hard copy by NNIPS and stored in a secured location.

Methodological limitations

It was possible that participants may have expressed answers they perceived to be appropriate or socially desirable. This is an inherent risk in rapid qualitative data collection. However, participants were encouraged to speak openly and honestly, and the frank and sincere dialogue elicited from participant discussions suggested that such socially desirable bias was minimised. Findings were triangulated across research tools and participant groups to test the consistency of answers.

To be responsive to the local environment, research activities at the community level were conducted in the local language (Maithili). Risks associated with mistranslation or miscommunication were minimised by conducting multiple pre-tests and pilots of the research tools, thoroughly briefing the research team, agreeing to use short phrases of speech, and repeating specific sections of narrative back to participants to ensure colloquialisms and meaning had been well captured.

When working with pregnant women it can be anticipated that participants may have higher levels of fatigue. Despite the efforts of the facilitators, levels of engagement diminished as the discussion continued. Completing long interviews and focus group discussions with women who were pregnant was challenging, as long periods sitting made many uncomfortable and tired. Observations from facilitators included references to women yawning during the sessions, and indications that there was a level of frustration and agitation amongst participants. The focus group discussion and in-depth interview tools were heavily edited over the course of the data collection to reduce the length of the sessions. This ensured that the facilitators could move more quickly through the key topics and try to overcome issues of tiredness and fatigue amongst participants.

The collection of quantitative data became complicated if women missed their scheduled weekly visits from the research team. Where possible data was collected over the phone, but where this was not feasible, it resulted in missing information in weekly consumption forms for that woman. Missed visits also mean that the research team was unable to deliver the supply of the product for the following week. In order to mitigate these issues and ensure women had enough product to continue daily consumption, a two-week supply of supplements was given ahead of time if the women informed staff of their movements in advance.

During this, Phase 2 of the MINT study data collection was limited to 8 weeks and it is difficult to predict use and compliance over a longer trial period. Women in the Phase 3 trial will be required to consume the product throughout pregnancy and lactation, and it should be acknowledged that the longer consumption period may impact these women's experiences.

A final limitation lies in the potential for response bias in women's reporting of product consumption. Although low levels of sharing and minimal impact of the BEP on usual food intake were reported by women, this feedback back is based on self-reporting from women themselves. Self-reported answers may be exaggerated; respondents may not reveal certain details and various biases including social desirability bias (discussed above) may have impacted their responses. There were limited measures to verify responses regarding whether full or partial portions were consumed, and also to validate sharing responses. Although researchers did try to confirm women's reported intake with sachet counting, the responses regarding whether they ate the full servings or partial and on sharing behaviour could not be verified.

Summary of findings

Product use during Phase 2

Compliance

Quantitative data indicate a high compliance for both products. Compliance rates were calculated in several ways, as set forth in Box 1. Unadjusted compliance (a), which was calculated based on the number of unopened packets returned to study staff, resulted in overstatement of compliance as some women ate more than one packet in a day and/or ate only a partial packet (which in this method was counted as a full packet).

Adjusted overall compliance (b) corrected individual compliance to a maximum of 100%. These two measures included only women who were met in person. Measures (c) and (d) included women's self-reported consumption (non-sachet count method) for those contacted by phone or met in person, with (c) being self-reported consumption of a full serving and (d) being self-reported consumption of any portion of a day's serving. Calculation (c) may serve as the better indicator to understand the full compliance, as option (b), calculated using unopened sachets count, does not clearly differentiate the partial from the full portion compliance.

Box 1: Measurement of overall compliance over 8 weeks

a. Unadjusted overall compliance (any portion) over 8 weeks among those who were met in person all 8-weeks:

$$\text{Compliance definition (sachet count)} = \frac{\Sigma \text{ sachets used}}{\Sigma \text{ follow up time}} = \frac{\Sigma \text{ sachets distributed over 8 weeks} - \Sigma \text{ sachets returned unused over 8 weeks}}{\text{last follow up date} - \text{first follow up date}}$$

b. Adjusted overall compliance (any portion) over 8 weeks among those who were met in person all 8 weeks:

Adjusted the>100% results of option (a) to 100%.

c. Overall compliance of FULL portion over 8 weeks among those who were met in person or met over the phone all the 8 weeks:

$$\text{Compliance FULL portion definition} = \frac{\Sigma \text{number of days reported eating full product}}{\Sigma \text{ follow up time}}$$

d. Overall compliance of ANY portion over 8 weeks among those who were met in person or met over the phone all the 8 weeks:

$$\text{Compliance ANY portion definition} = \frac{\Sigma \text{number of days reported eating product}}{\Sigma \text{ follow up time}}$$

Adjusted compliance rates based on packets returned unopened (calculation b) were 95.5% for Plumpy'Mum and 93.9% for the vanilla biscuit during the first 8 weeks (see Table 1). Data also suggest high consumption of both supplements in their totality (calculation c, full portion) by the participants, with self-reported compliance at 87.6% for Plumpy'Mum and 88.4% for the vanilla biscuit.

Table 1. Overall compliance over 8 weeks by supplement group

	Plumpy'Mum	Vanilla biscuit
Overall compliance over 8 weeks using various definitions:	median (Q1-Q3), *mean*	median (Q1-Q3), *mean*
Sachet-count method	N=26	N=34
a. Unadjusted overall compliance (%) over 8 weeks among those met in person	101.8 (94.8-105.3) *99.0*	100 (96.4-101.8) *95.3*

b. Adjusted overall compliance (%) over 8 weeks among those met in person	100 (94.8-100) *95.5*	100 (96.4-100) *93.9*
Non-sachet count method	N=30	N=37
c. Overall compliance of full portion only over 8 weeks among those met in person or over the phone	91.1 (85.7-98.2) *87.6*	96.4 (87.5-98.2) *88.4*
d. Overall compliance of any portion only over 8 weeks among those met in person or over the phone	98.2 (87.5-100) *92.9*	100 (94.6-100) *93.0*

Qualitative findings confirm that most women ate each product every day. Women reported consuming at least part of the supplement daily and in only a small number of cases were days of intake missed completely. Although the majority of women and family members reported that at least part of the product was eaten every day, on further probing it became clear that this was not always the case. A small handful of women said that they were unable to eat Plumpy'Mum because they didn't like it or couldn't tolerate it. Three women initially indicated that they consumed the product every day; however, further comments may be more illustrative of their actual practices. One woman, for example, said "*Yes, I ate it every day. I have only left it for two days when I had problem in the stomach*." Similarly, another participant stated:

Participant:	*In the beginning I ate all of it…*
Interviewer:	*At the beginning, they came and provided it to you, in the first week how many packets did you eat?*
Participant:	*I ate only one packet.*
Interviewer:	*What about second week?*
Participant:	*I ate all.*

A small number of women in both groups recalled being unable to finish the full portion of the products every day because they didn't like it and or they found it to be too much. This was supported by findings from the quantitative data regarding reasons for not consuming the product every day: 'did not like it', 'not well' and 'other' were reported as 22.5%, 25%, 47.5% in these categories for Plumpy'Mum and 17.5%, 12.5%, 27.5% for the vanilla biscuit.[1]

<u>General factors relating to use of the supplement</u>

The supplements were most often consumed in the morning. Nearly half (48.3%) of the Plumpy'Mum supplements were consumed in the morning (before 12pm) and 45.6% of the vanilla biscuits were also consumed at this time. Women generally reported eating the supplement with breakfast, as a snack after breakfast or between other meals. The supplements were most often consumed in the place of a snack, in line with the women's usual daily food intake. As such, the supplements appear to appear to constitute part of the women's daily snack intake rather than replacing specific meals. A large majority (82.5%) of women in the Plumpy'Mum group and 65.1% in the vanilla biscuit group agreed that during the 8-week tasting period they ate meals and snacks as they 'normally would'.

1 There was no option in the quantitative survey for 'too full' and it can be assumed that in these cases, this has been captured under 'other'.

Table 2. Acceptability of supplement products at 8 weeks

	Plumpy'Mum N=38[2,]	Vanilla biscuit N=40[3]
Appreciation of Product (1=Dislike very much to 7=Like very much), median (Q1-Q3)		
Colour	7 (6-7)	6 (6-7)
Taste	7(6-7)	6 (6-7)
Texture	6 (6-7)	6 (6-7)
Smell	6 (6-7)	6 (5-7)
Overall appreciation	6 (6-7)	6 (6-7)
Perceived child likeability	6 (6-7)	6 (6-7)
Perceived adult likeability	6 (5-7)	6 (4.5-7)
Perception of product use (1=Very difficult to 7=Very easy), median (Q1-Q3)		
Product is convenient to eat	6 (6-7)	6 (6-7)
Product is convenient to eat between meals	6 (6-7)	6 (6-7)
Product is medicine or food or both, n (%)		
Medicine	7 (18.4)	14 (35)
Food	28 (73.7)	20 (50)
Both a medicine and food	3 (7.9)	6 (15)
Feel full after full portion, n (%)		
Very full	16 (42.1)	17 (42.5)
Moderately full	18 (47.4)	18 (45)
Slightly full	4 (10.5)	5 (12.5)
Would use daily if provided, n (%)		
Definitely would eat every day	25 (65.8)	25 (62.5)
Probably would eat every day	9 (23.7)	9 (22.5)
Definitely or probably would eat every day	34 (89.5)	34 (85)
Not sure if I would eat every day	3 (7.9)	3 (7.5)
Probably would not eat every day	0 (0)	2 (5)
Definitely would not eat every day	1 (2.6)	1 (2.5)
Definitely or probably would not eat every ay	1 (2.6)	3 (7.5)

The qualitative data indicate that the supplements were consumed both in a single sitting and in multiple sittings throughout the day, depending on personal preference, hunger, and ability to tolerate the product at a specific time. Quantitative data indicate that the vanilla biscuits were more frequently consumed over multiple sittings than the Plumpy'Mum (20.2% versus 7.9%). This could be attributed to the composition of a full portion of vanilla biscuits (in which 6 individual biscuits needed to be eaten) rather than the Plumpy'Mum (where one dose equalled the full packet). A small number of women from both groups reported that the products needed to be consumed in one sitting because open packets left throughout the day allowed air into the product, attracted ants and changed the overall taste.

<u>Preferred characteristics and improvements</u>

A series of questions was asked regarding participants' opinions of various aspects of the products, including questions related to hedonic characteristics and overall appreciation. Possible responses were on a Likert scale of 1 to 7, with 1=dislike very much/disagree strongly and 7= like very much/agree strongly. A summary of responses to those questions is presented in Table 2. The results present very little variation in the median responses for Plumpy'Mum versus the vanilla biscuits on any metric, including on overall appreciation with a median (Q1-Q3) score of 6 (6-7) for both products.

Of the women in the vanilla biscuit group, the most preferred aspect of the product was its taste. A number of women noted a very strong aversion to the smell of the biscuits, many describing it as a 'stink'. The following feedback was consistent amongst these women: '*Its taste is good, but it stinks. It smells like medicine… and it smells like pesticides which are used in green leafy vegetables.'* Taste was

2 Two participants could not be met (in person or over the phone) at the end of the 8 weeks for the Hedonic Testing Form Interview as they had gone to India

3 Two participants were interviewed over the phone at the end of 8 weeks as they had travelled outside the district

also the preferred characteristic of the Plumpy'Mum amongst women interviewed. Many compared the taste to familiar ingredients such as nuts (cashews and almonds), chickpeas and *Kismis* (raisins). Although women responded positively to the taste overall, a number commented that it was *'very sweet'* or *'too sweet'*. There were minimal reflections, positive or negative, on other characteristics (colour, texture) of the supplements. Neither the quantitative data nor the individual interviews about the product used for 8 weeks revealed strong preferences between the two products. However, as noted below, in focus group discussions most women in both groups preferred the biscuit over the Plumpy'Mum.

Few women suggested improvements that could be made to either product; most women indicated that 'everything was okay' with the products. Where improvements were suggested, they were primarily related to the making the taste 'better'. Women in both groups proposed adding additional ingredients, such as salt or spice, or reducing the sugar content to improve taste. One woman reported, *'cashew, raisins, ground nuts, grams, ghee if all these would be there then it would be even better'.* Only one woman in the Plumpy'Mum group suggested that additional ingredients should be added to increase the health benefits of the supplement; another said that *'to make it better, nut, chickpea and Saatanna should be mixed. If these things were mixed it would be better for the health. Sometimes mixing it with maize, sometimes mixing it with almond.'*

Changes in opinion over time

The majority of women in the interviews and focus group discussions reported changes in their perceptions of the products. A minority of women began by liking the product but became more bored by it over time; more admitted to not liking the product in the beginning but to getting used to it over the course of the 8-week trial period. The following report from one woman in the Plumpy'Mum group was illustrative: *'Initially I didn't like it because it was hard to digest. Nowadays I am used to it and I like it.'* Another woman in the vanilla biscuit group confirmed, *'I did not like this product in the initial days, eating it continuously, I like it, it's good.'* Quantitative data on weekly compliance in the Plumpy'Mum group (presented in Annex 1), confirmed lower levels of compliance amongst women in the first two weeks of the 8-week trial. Interviews with family members aligned with feedback from the pregnant women, and most agreed that the pregnant woman in their household who was consuming the supplement (wife/daughter/daughter-in-law) had grown more accustomed to the product over time. Family members also noted perceived changes to women's physical health, some commenting that her face 'is bright' or that she 'looks healthier' since taking the supplement.

Changes in opinions of family members to the supplements were not frequent. Instead women highlighted strong support for the product at the household level. Asked if the perceptions of her family towards the product had changed, one woman affirmed, *'No, no change, they say just eat* [the product]*. If you eat continuously you can digest it better. If I feel weak, they bring glucose for me. This product keeps my stomach warm to make it cold they bring glucose. They suggest me not to discontinue* [with the supplement]*.'*

Pregnancy, customary diet and traditions

Women's role and changes during pregnancy

In order to understand the changing role of women in the household during pregnancy and to assess potential factors that may or may not impact product usage, women and family members were asked in in-depth interviews about the pregnant woman's role in the household. Most women and their relatives agreed that there was little difference in the chores they performed whether pregnant or not. What was acknowledged, however, was a change in their ability to perform these tasks comfortably. Many women highlighted that difficulties breathing, increased levels of fatigue, and back and abdominal pain made completing tasks more problematic. A small handful of women and family members noted that heavy lifting should be avoided during pregnancy.

Diet during pregnancy

Women, their family members and health workers all recognised the importance of a healthy and balanced diet to protect the wellbeing of pregnant women and their unborn children. Women indicated that they should eat well in order to ensure that they have sufficient energy. Foods such as dal, leafy greens, fruits and vegetables were highlighted as being particularly important for a nutrient-rich diet during pregnancy. Women consistently emphasised that frequency of eating fruits and vegetables was dependent on seasonality and availability. Health workers showed a more technical understanding of the elements of a healthy diet during pregnancy and also underlined the limitations on availability in the community:

> *Nutritious food means containing the proper amount of carbohydrate, protein, fat, minerals, vitamins containing all this nutritious food. Like fruits, green leaves, whatever is available in the local level must be bought and eaten, it is so expensive, this society is poor …. those who do not buy, they eat from their own gardens: green leaves, fruits whatever is available, we need to tell them to eat grains, pulses.*

Health workers and some family members emphasised the importance of including meats, fish, eggs, milk and other protein-rich foods, as well as foods containing iron, calcium and potassium, in a pregnant woman's diet.

The foods actually consumed by pregnant women and their families varied. In interviews, pregnant women and family members said that they frequently consumed fruits and vegetables, specifically leafy greens, rice, lentils and roti. Less frequently they reported eating protein-rich products such as fish, eggs and meat. Several family members mentioned green vegetables as being a part of the customary diet.

Certain foods were identified as to be avoided during pregnancy, including hot and spicy foods, oily foods, sour foods such as *aachar* (pickles) and dishes containing mustard seeds/oil. It was suggested that pregnant women should not eat these foods as they create a 'hotness' in the body and contributed to issues with stomach pain, digestion and diarrhoea. One woman suggested,

> *when I am pregnant I usually have indigestion…the thing that makes indigestion is like hot, spicy food so we don't eat that. From the start till the end I have the problem of indigestion, so I don't eat those foods which harm, I eat only simple food. I also don't eat mango a lot, or milk, if we eat all these then we have problem in the digestion. I eat only one or two mangoes if I eat more then I have problem in the stomach.*

A family member offered that the result of too much consumption of hot or sour foods can also be that *'then you have warm (increase in temperature), blood becomes thinner like water that's why must not eat'*. Although most pregnant women were aware of foods to be avoided and why, one woman suggested that it was the older community members who dictated the customs around diet during pregnancy.

Health workers specifically mentioned the dangers of spoiled foods, with one referring to *'bright foods'* as among those that should be avoided: *'[bright foods are] for example leftover foods from early days (which are not kept properly). They need to eat fresh food. They should not eat foods from the market….Market foods are not hygienic, they do not keep safely, and they might have bacteria and virus'*. Family members had a longer list of specific foods that some believe should be avoided; these included *brinjal* (eggplant/aubergine), pumpkin, banana, dry foods, biscuits and *pani puri* (a local spicy snack). It seems, however, that few of these recommendations are followed with any regularity.

Dietary customs and practices

The hot and cold characteristics of foods were widely said to dictate what should and should not be eaten at certain times of the year. For example, one woman suggested, *'this is hot season because of that cold food are good'* and another agreed, '*If someone gets pregnant during winter time and at that time, if she eats cold food then her baby will get cold and if someone gets pregnant during summer time and she eats cold food it helps her.'* Although consumption of foods to warm or cool the body were understood to be seasonal, there was wide disparity in women's explanations of what foods were considered to be have a warming or cooling effect on the body, and definitions of 'hot' and 'cold' foods were not offered. Some family members also indicated that, although conventions about hot and cold food existed, they were not widely followed by pregnant women.

Aside from observations on hot and cold foods, few participants reported following other dietary taboos during pregnancy and there were no traditions that would appear to influence at-home supplement use. It was reported by some women that eating foods that could not be easily digested would cause the child to have gas. Others suggested the foods such as mangoes, guava and cold drinks may 'harm' the pregnancy or the developing foetus.

Meal patterns, snacking and decision making

Qualitative data confirmed that most families had sufficient food to ensure satiety. Most participants indicated that families eat two meals per day which were supplemented by periods of snacking. There were some reports that family members might eat a third meal if they were hungry.

Amongst pregnant women, snacking practices appeared *ad hoc* and inconsistent. Some women reported eating one or two snacks per day, some in the morning, others in the evening, and others suggested that they never needed to eat between meals. For the most part, it was agreed that if a woman was hungry, she would snack as per her needs. Family members also uniformly said that pregnant women do snack.

Pregnant women most frequently reported consuming roti, beaten rice, samosas and biscuits as snacks. A small number of women who claimed not to snack suggested that instead they eat fruits and seemed to indicate that fruits, as such, did not constitute what was widely understood as a snack. The following was consistent amongst these participants: *'I do not eat* [snacks] *nowadays, if there are fruits available then I eat some, otherwise, I eat rice* [meals] *in the morning and then later.'* Family members included fruits and vegetables, *satua* (roasted flour), *halwa* (semolina pudding), milk and lentils, within the snack foods that pregnant women consume.

Guardians, mothers-in-law and fathers-in-law were reported to make most of the family-level decisions about food purchase and preparation. There was no consensus about order of serving within the family; in some families the men ate first, in some the pregnant woman might eat first if she were hungry, in others there was no fixed order. Two family members stated specifically that their household did not believe that the women/daughter-in-law should eat last, although they recognized that this was the case in some families. Pregnant women and their family members frequently highlighted that the decision about how much food an individual consumed on a day-to-day basis was their own.

Intentional food restriction

A majority of women indicated that they eat less food during pregnancy than before. Participants were asked whether the reduced intake was intentional (the phenomenon that has been recognized as 'eating down' (Christian et al. 2006)); however, reasons cited for the reduction appeared to be linked primarily to other factors including reduced appetites, feelings of fullness and increased episodes of nausea. As one woman affirmed, *'how can I eat a big amount, even after a small amount I feel discomfort'.* Only a small number of women indicated that they had heard about intentional restriction

of diet in pregnancy and in cases where women were familiar, information about restriction had come from elders in the wider community. One participant explained, '*elderly people…they say, "have you heard that you must eat less, not too much", there are lots of people in the village saying this'.* No reasons were cited for why food intake during pregnancy would be restricted.

Most family members and health professionals likewise said that any reduction in food intake during pregnancy was due to factors relating to digestion and appetite rather than concerns about the baby's size and difficult delivery. Several participants said that pregnant women do not eat large meals but rather smaller, more frequent meals to avoid indigestion.

Reasons cited for women maintaining the same or greater food intake were linked to the perceived benefits to the 'health' and 'strength' of both the pregnant woman and her child.

Vitamin and supplement awareness and use in community

Vitamin supplements

Both health workers and family members were familiar with vitamin supplements for pregnant women. Family members were aware of iron and calcium supplements and said that their pregnant family members were currently taking one or both. Health workers were more specifically aware of iron-folic acid (IFA) supplements and also discussed use of vitamin A for postpartum women. Some health workers also were familiar with multivitamins or B complex supplements, and one mentioned a supplement called *'RB-TON'* [sic] prescribed for anaemia. (This is presumably a reference to 'R.B. TONE' syrup, a product containing folic acid, vitamin B12, iron and calcium and advertised as a 'Tonic for Red Blood Corpuscles'.)

Iron/IFA supplements were said to be available for free from government health facilities. Some of the health workers interviewed stated that calcium was also available from the government, but others said that it was available only for a cost from pharmacies. Interestingly, two health workers noted that some pregnant women preferred to obtain their supplements from private sources (pharmacies), either because of a perceived difference in taste or quality:

> *…some pregnant women say that the medicines provided by the government health facilities are not good quality. They like to pay money and buy from us. In that case, we try to convince them medicines are the same. Their works are similar, wherever you get it from. Some people listen and understand it….*

There was consensus that women begin taking iron/IFA and calcium at approximately 3-4 months, which may correspond with their first ANC visit. One health worker said these supplements are started 'immediately'. Another health worker said that iron and calcium can only be provided '*after the development of babies' hands and feet…*' Health workers stated that pregnant women are given a one-month/30-day supply of government-supplied supplements; this was said by most to be in order to encourage women to return regularly to the health post but also potentially to avoid misuse of the product. One family member stated that their pregnant relative had been taking supplements monthly but stopped taking them when she started receiving Plumpy'Mum from NNIPS during Phase 2 of this MINT study. Research staff should be alert to this going forward and ensure that women understand the role of iron and/or calcium supplements in the context of the trial.

Food supplements

Questions regarding familiarity with and use of food supplements did not always appear to be well understood, particularly by family members. This may be in part because the question was often phrased

as referring to 'supplementary foods', at least in the English translations, which one interviewer clarified to mean 'foods containing protein'. In response to questions about food supplements, some participants mentioned additional healthy foods to be added to the diet, such as dal, fish, milk and meat. One family member said that her daughter-in-law uses *'Frooti'* (a mango-based fruit drink) and Red Bull as well as protein powder and Glucose-D powder. Several family members said they were unfamiliar with food supplements.

Regarding supplements available locally, most of the health workers named various protein powders designed to be mixed with milk, which are marketed in the community under the brands '*Proteinex', 'Alprovit', 'Proton', 'M powder', and 'Protein Granular'.* Health workers and family members also cited *'Horlick's'* nutritional malt powder in response to questions about locally available food supplements and one family member referred to ayurvedic supplements intended to boost immunity.

Protein powder supplements are available from medical shops/pharmacies; they must be purchased. Horlick's may be purchased at both pharmacies and retail grocery stores. When recommended, use of protein supplements begins at 2-4 months, though one health worker said that it may be commenced earlier. Other than this, prior experience with food or nutrition/energy supplements was limited to a government programme supplying chickpeas to pregnant women and food supplements for children.

Acceptability of vitamin/supplement usage

Health workers were in accord about the importance of 'supplementary foods' in pregnancy, drawing the link between diet and healthy pregnancies. One health worker said that supplementary foods are '100%' necessary for pregnant women: *'Supplementary food needed for the growth and development of a child (refer to the unborn child), to make a pregnant woman safe, to increase the iron level to pregnant women's body and to gain the weight of a child. It gives immunity power to both mother and baby'*. Others noted that supplementary food was necessary to prevent complications (e.g., IUGR, pre-eclampsia, anaemia, premature delivery) and ensure a healthy child.

Several health workers had previously recommended use of protein supplements to pregnant women. Others, however, do not generally recommend food supplements. One said that it is not *'within their jurisdiction'* while another said *'We cannot recommend ready-made protein. We need to go for natural health*'. Those who recommend protein powder to pregnant women give them information on how to take the product and why it is necessary. They stated that women do appear to understand the information provided, based on follow up information obtained. One health worker noted that some women think that supplementary foods lead to fat babies and therefore difficult deliveries, but she says that they understand after counselling that this is not the case.

Factors impacting use and compliance

Cited barriers to pregnant women's use of food supplements included household economics, family (husband/mother-in-law) opposition and lack of knowledge/education. As one health worker stated:

> *It depends on the education, if families are not educated, they do not understand. For example, in the Muslim community they do not even accept iron and calcium. They do not want to eat iron and calcium because they think that if they eat it, their child will be overweight, and it will be difficult to deliver the baby…. We tell them this is not reality; you must eat it.*

Again, it appeared that some participants may have understood the question to refer to additional (supplementary) foods for the pregnant women rather than food supplements such as the products in the present study.

Considerations for Phase 3

The research team identified a number of specific focus areas for analysis to inform Phase 3 of the study. These areas included willingness to eat the product, health worker support, distribution and information preferences, barriers, sharing, desired information and future product preferences. The following sections discuss the findings related to these focus areas.

Willingness to eat the product daily

As reflected in Table 2, the quantitative data demonstrate that a strong majority of women definitely or probably would eat both products daily in the future if they were provided, with very little distinction between the two products.

Of the 38 women who completed a hedonic testing form after using Plumpy'Mum for eight weeks, 34 (89.5%) definitely or probably would eat it daily; 34 (85%) of 40 women would eat the vanilla biscuits daily. Three women (7.5%) would probably or definitely not eat the vanilla biscuit daily, and one woman (2.6%) would definitely not eat the Plumpy'Mum daily (none said they would probably not eat the Plumpy'Mum).

These data were confirmed in the focus groups, where all but two of those who responded[4] said that they would eat Plumpy'Mum every day for the remainder of their pregnancy and until 6 months postpartum if it were free. Of the two who would not do so, one said she might not eat it every day; the other said that she would not be able to eat it at all because she does not like it. Similarly, all except three participants in the vanilla biscuit group said they would eat the product every day; of those three, all would continue to eat it if different flavours and/or a different product were made available on alternate days/weeks. For example, one participant said: *'If the same biscuits were provided in different tastes, I would eat. I would eat until six months after delivery; if provided in the same flavour, then I would not be able to eat'*.

Health worker support

Several health workers had a generally favourable attitude towards the product and would recommend its use. One described the product as *'a very good* thing' and said he would recommend it because it is good for pregnant women and their babies. Another said that the product is good but would be better if it were given to all pregnant women. He, too, expressed a willingness to recommend its use.

Others, however, had reservations. One health worker expressed serious concerns about the product:

> *It's just like junk food and this type of supply is not in our government supply system. So far, we are encouraging women to eat protein-rich food which is available in their villages. We are not giving then any sort of outside product like this. If this is certified through WHO, we can distribute it. There are so many better products than this*.

He said he didn't know enough about the product and needed to know more about how it works and its potential side effects. He further said that he would not recommend it until 'the reporting office' told him to do so, but that he would upon receiving instruction.

4 Not all women in the focus groups responded to all questions.

Another health worker was concerned that the product wasn't coming from the government and stated that the government should run the project in the future so that it is free and 'reliable'. Appearing to refer to the packaging, he noted that some people might not trust the current logo but would trust a Government of Nepal label. One said *'This product is a good one'* and that he would encourage use -- if he had more information about its composition. Other health workers had unspecified concerns about the product. For example: *'Concern when it is new, when not known then there will be anyways while understanding content in this (Product anyways there is things that are need for them (Pregnant women)), right, it is good like it'*.

Health workers' comments appear to reflect an overall receptiveness to, and potential support for, the concept of food supplements for pregnant women in this community. However, they also clearly indicate concerns and the need to provide more detailed information and sensitisation for health workers. This should therefore be a focus during Phase 3 and any ultimate broader roll-out of the product. The sachets also need to be appropriately labelled so that health workers and others can be assured that it is safe and sanctioned for use by pregnant women.

Distribution Preferences

In focus groups, many of the women stated that they would like to continue to receive the product from NNIPS and/or desired continued home delivery. The hospital, local government/village and local health post were also mentioned as preferred distribution outlets, with WVs (these are NNIPS staff, women in the community, who are responsible for the weekly distribution of the product during the pilot trial phases) as preferred providers. Health workers also said that they would like to have the products distributed at health posts, by Female Community Health Volunteers (FCHV), ANMs/staff nurses or the health post 'in-charge'; one expressed a desire for NNIPS staff to distribute the product.

The pregnant women who expressed a preference said they would like the product to be made available weekly. Several health workers agreed, although a few suggested either bi-weekly or monthly distribution (to coordinate with monthly iron/calcium distribution).

Barriers to obtaining and using the product

Questions regarding barriers and facilitators to obtaining and using the products were not well understood in some of the focus group discussions; women sometimes gave the same responses to questions regarding using the products as they had to obtaining them, and many of the responses centred on physical factors such as illness or dislike of the product. Identified barriers to obtaining the product included vomiting, fever, dislike of the product, cost and inability to get to the market or hospital to pick up the product. Facilitators to obtaining the product were listed as home delivery, if *'WV of NNIPS will give this in free of cost'* or it is available in local shops, if it is available in hospitals or from NNIPS, and '*if you like it'*. Barriers and facilitators to use were largely the same as barriers and facilitators to obtaining the product. Additional barriers included forgetting to eat the product while working and forgetting to eat it when outside of the home; identified facilitators included liking the product and '*making it our habit.*'

Information Preferences

There was broad consensus that health workers, family members, community members and pregnant women should all receive information regarding the products. Focus group participants said that they would like additional information both for themselves and in order to provide it to other pregnant women; they specifically mentioned sharing with other pregnant women information regarding the products' benefits and how to use them. One participant suggested telling others, for example: *'If you*

eat this the baby will be healthy, your own body will be healthy. It is good.' Pregnant women also noted that they were well-placed to provide such information to others in the community*:*

> *Beside Sister* [WV of NNIPS]*, we know it better because we have eaten this product. So, we will share our experience of eating this product (vanilla biscuit) with their family members and other persons so that they can know about this product. Then, they can tell others that these people had eaten it. They can also tell others about that it will make them healthy after eating it. Then, they will say, let's go to ask her because she had eaten this product before, won't they say? Who knows about this product, everybody asks her, don't they?*

Health workers agreed that pregnant women should be informed about the benefits of the supplements, how they affect women's bodies, how to use them and the importance of not sharing with others. One health worker recommended that pregnant women be told of both normal side effects and any dangerous side effects that might be associated with the products.

One focus group participant highlighted the importance of providing information to family members, particularly the guardian of the family: *'First of all, the guardian must know and only they will let you eat, and they will say 'it is beneficial, do eat'; if the guardian is not informed then how will they let you eat?*' One of the health workers interviewed also referred to the importance of informing family members that the product is for pregnant women only. Members of the community at large were also mentioned by both focus group participants and health professionals as needing information about the product, particularly its health benefits and the fact that it is intended for use only by pregnant women. Health workers also focused on providing information to community leaders, so that they can spread the word about the products, create demand and encourage compliance. One health professional stated that the community needed to have information about why the government has allowed this project and highlighted that information should come from health institutions because they are trusted by the community. Pregnant women similarly mentioned in focus group discussions that hospitals were a trusted source of information regarding the products. NNIPS and WVs were also identified by participants in all focus groups as preferred providers of information.

Health professionals wanted detailed information about the product, including dosage, composition, where/how/by whom it is made, and the results of the study. One health professional suggested providing information or training to the 'whole health post team', and two of the health workers interviewed pointed out the importance of providing information to FCHVs so that they can in turn communicate information to the community.

Several health professionals suggested communication methods for informing pregnant women and others about the products. One advocated for a drama or demonstration for the public, while another suggested an organized orientation by the health facility and the ward office, including all health post staff and door-to-door visits in the community. Another health worker suggested a similar orientation programme with ongoing training in the community, media mobilisation, and provision of information through the school health programme. It was suggested that face-to-face provision of information or an informative poster was best, and that case studies or examples should be given to pregnant women.

All health workers reported that they currently provide advice to pregnant women regarding their diet and nutrition. They inform them about recommended foods, the importance of eating sufficient protein, and they also advise family members about the importance of a healthy diet during pregnancy. Given their interest in providing information to pregnant women and their willingness to support product use (once they have sufficient information and confidence themselves in the products), these professionals are a potential rich source of support for pregnant women's product use. They provide information through various methods and in various contexts, including in private sessions during clinic visits, in groups and in mothers' group meetings. Information is provided orally, for the most part, but some provide posters, pamphlets, flipcharts and other visual aids to women who are able to understand them.

Women are receptive to their advice, according to the health workers interviewed, as are many family members, though mothers-in-law were singled out as being potentially non-supportive, saying that *'they didn't do this in my time'*.

Sharing

Sharing practices

Quantitative data show a slight difference in the mean number of days that the products were shared over the 8-week period, 0.4 for the Plumpy'Mum versus 1.0 for the vanilla biscuits. The percentage of participants who shared the products were 27.5% and 37.5% respectively, and in both groups, women were most likely to share with children than with other members of the family.

In in-depth interviews and focus group discussions, women highlighted limited sharing of the product; any sharing that was reported was primarily with women's children and was reported to have occurred rarely over the 8-week testing period. At the onset of the study, participants had been advised that the supplement was to be taken by pregnant women only, and as such women appeared to adhere to the directions given. The understanding that the supplement was beneficial to the health of pregnant women, and the perception of the supplement as a medicine helped women justify their sole consumption of the product. As one woman highlighted:

> *No, I didn't share, sister. If children asked with me, I would say this is medicine. So, they don't eat assuming that it is medicine. I don't share.* [Children] *they eat lentil and rice so they won't need this much, but if a pregnant women eat only rice and lentil alone it won't be beneficial to her. This product is beneficial to the pregnant women. The pregnant women eat more those things which will be beneficial to them, because of that I eat this product.*

Acceptability and expectation of sharing

Women in both groups also noted strong household-level support and understanding for the instruction not to share. One woman in the vanilla biscuit group recounted,

> *[T]his product was recommended only for pregnant women and they told us not to share it with anyone. Used packets were retrieved, they come and take the empty packet and they even told family members not to eat this product. They said that this is only for pregnant women… I have never* [shared]. *Even my sister-in-law said this is for pregnant women so only pregnant women need to eat.*

Another woman in the Plumpy'Mum group agreed,

> *I gave him* [my son] *some of one packet, after he started to cry because he wanted that and once he tried to steal and eat it. But my husband scolded me and told me not to share with children, he asked me to eat the product* [alone] *and I have not shared after that day.*

In contrast to the responses of pregnant women in the hedonic testing and in-depth interviews, family members stated unequivocally that their pregnant relatives did not share the supplements. One family member said that a child in the family was offered the product to taste on one occasion but '*threw it'* [presumably did not care for it] while another stated that sharing might be expected in families with young children. Family members confirmed reports from pregnant women that there were high levels of acceptance for the product at the household level.

Future sharing practices

Qualitative data indicated that most participants did not intend to share the product in the future, even with their children. Many expressed an understanding that if the product was shared, they would not benefit from its full nutritional value. As one woman explained, *'I won't share; the product is only for me, so why share it? We cannot share Plumpy'Mum, because it is for mothers' health.'* Others anticipated that sharing would diminish the overall health benefits of taking the supplement during pregnancy. The following except was consistent with this view:

> *No I won't share, I eat it myself. If I have a* [health] *problem, if I eat the product then I will be okay. If I give it to others, then the problem with me [will continue] as usual…so I eat it all myself. How can I eat it all if I am sharing…I give other things to them* [the children] *to eat. I have been given* [this supplement] *therefore I eat it myself.*

Women also suggested that the decision to share would be theirs alone and said that family members would 'scold' them or 'damn' them if they were found to be sharing with others. This was in line with women's feedback on sharing practices in general [see above] in which high levels of support and acceptance for the products were displayed.

Future Product Choices

At the end of the eight-week trial, the pregnant women were given an opportunity to taste additional flavours of their assigned product as well as the product they had not been assigned.[5] They were asked their preferences for future use as well as whether they would like to alternate flavours or products on some regular basis (e.g., weekly or monthly).

Alternate flavours

All study participants who were met in person at the last visit were asked to quantify their appreciation of each new flavour's colour, taste, and smell as well as their overall appreciation for each flavour, using a 7-point Likert scale that ranged from 1 (dislike very much) to 7 (like very much). They were also asked to assess the likelihood that they would eat the flavour daily if it were provided, choosing from the options definitely would not/probably would not/not sure/probably would/probably would not. The results are provided in Table 3.

5 Participants were intended to taste the original flavour of the alternate product; however, in FGD 1A the moderator inadvertently brought the orange flavour biscuit for tasting rather than the original vanilla flavour.

Table 3. Acceptability of the three new flavours of supplement products (acceptability of original flavour also shown for comparison, from Table 2)[6]

	Plumpy'Mum N=36[7]			Plumpy'Mum N=38	Biscuit N=38[8]			Vanilla Biscuit N=40
	Cocoa	Vanilla	Strawberry	Original	Strawberry	Orange	Almond	Original (vanilla)
	Appreciation of Product (1=Dislike very much to 7=Like very much), median (Q1-Q3)							
Colour	6 (4-7)	7 (6-7)	7 (6-7)	7 (6-7)	6 (6-7)	6 (6-7)	6 (6-7)	6 (6-7)
Taste	6 (2.5-7)	6 (5.5-7)	6 (5-7)	7(6-7)	6 (5-7)	6 (6-7)	6 (3-7)	6 (6-7)
Smell	6 (4-7)	6.5 (6-7)	6 (5.5-7)	6 (6-7)	6 (5-7)	6 (6-7)	6 (5-7)	6 (5-7)
Overall appreciation	6 (2-7)	7 (6-7)	6 (5.5-7)	6 (6-7)	6 (6-7)	6 (6-7)	6 (5-7)	6 (6-7)
	Would use daily if provided, n (%)							
Definitely would eat every day	18 (50)	21 (58.3)	19 (52.8)	25 (65.8)	15 (39.5)	24 (63.1)	18 (47.4)	25 (62.5)
Probably would eat every day	8 (22.2)	10 (27.7)	9 (25)	9 (23.7)	15 (39.5)	10 (26.3)	11 (28.9)	9 (22.5)
Definitely or probably would eat every day	26 (72.2)	31 (86)	28 (77.8)	34 (89.5)	30 (79)	34 (89.4)	29 (76.3)	34 (85)
Not sure if I would eat every day	1 (2.8)	1 (2.8)	2 (5.6)	3 (7.9)	3 (7.9)	2 (5.3)	2 (5.3)	3 (7.5)
Probably would not eat every day	4 (11.1)	2 (5.6)	1 (2.7)	0 (0)	1 (2.6)	2 (5.3)	2 (5.3)	2 (5)
Definitely would not eat every day	5 (13.9)	2 (5.6)	5 (13.9)	1 (2.6)	4 (10.5)	0	5 (13.1)	1 (2.5)
Definitely or probably would not eat every day	9 (25)	4 (11.2)	6 (16.6)	1 (2.6)	5 (13.1)	2 (5.3)	7 (18.4)	3 (7.5)

[6] Numbers of participants who quantified their appreciation of the original flavours is greater than those who did so for the variants, because variant tasting required in-person participation (see notes 7 and 8).

[7] Four participants from the Plumpy'Mum group did not participate in the new flavour variant tasting and ranking exercise as they were out of the study district at the end of 8-week trial.

[8] Two participants from the Biscuit group did not participate in the new flavour variant tasting and ranking exercise as they were out of the study district at the end of 8-week trial.

Although the median Likert scores for product appreciation indicate that all of the new flavours were liked, the quartile scores show much more variation for the cocoa Plumpy'Mum and the almond biscuit. The likelihood of eating the various flavours daily also indicate that a high percentage of women probably or definitely would not eat the cocoa Plumpy'Mum (25%, n=9). The orange biscuit had the highest results for likelihood to eat daily; nearly 90% (89.4%, n= 34) probably or definitely would eat it daily, and only 5.3% (n=2) probably or definitely would not. In comparison, 85% (n= 34) women had said they probably or definitely would eat the original vanilla biscuit daily, and 10% (n=4) probably or definitely would not. Of the new flavours of Plumpy'Mum, the vanilla Plumpy'Mum variation also had high scores for probable or definite likelihood to eat daily (86%, n=31), but 11.2% (n=4) of women said they probably or definitely would not eat the product every day. In comparison, 89.5% (n=34) had said they definitely or probably would eat the original Plumpy'Mum and only 2.6% (n=1) said she definitely would not.

Women were also asked to rank the four flavours of their respective products (the three new variations plus the original flavour); each product was then given a score based on the sum of ranks method. The raw and weighted ranks for the Plumpy'Mum are set forth in Table 4 and for the biscuit in Table 5.

Table 4. Ranking results of the four flavours of Plumpy'Mum, N=36

Rank Distribution	**Original Plumpy'Mum**	**Cocoa Plumpy'Mum**	**Vanilla Plumpy'Mum**	**Strawberry Plumpy'Mum**
First (Most preferred)	3	9	13	11
Second	9	12	6	9
Third	12	4	13	7
Fourth (least preferred)	12	11	4	9
Ranking weighted score	**Original Plumpy'Mum**	**Cocoa Plumpy'Mum**	**Vanilla Plumpy'Mum**	**Strawberry Plumpy'Mum**
First	12	36	52	44
Second	27	36	18	27
Third	24	8	26	14
Fourth	12	11	4	9
Total score	**75**	**91**	**100**	**94**
Rank	**4**	**3**	**1**	**2**

Table 5. Ranking results of the four flavours of biscuit, N=38

Rank distribution	**Original Biscuit (Vanilla)**	**Strawberry Biscuit**	**Orange Biscuit**	**Almond Biscuit**
First (Most preferred)	6	4	26	2
Second	10	16	4	8
Third	11	11	3	13
Fourth (least preferred)	11	7	5	15
Ranking weighted score	**Original Biscuit (Vanilla)**	**Strawberry Biscuit**	**Orange Biscuit**	**Almond Biscuit**
First	24	16	104	8
Second	30	48	12	24
Third	22	22	6	26
Fourth	11	7	5	15
Total score	**87**	**93**	**127**	**73**
Rank	**3**	**2**	**1**	**4**

According to the Plumpy'Mum weighted rankings, all three of the new flavours are preferred over the original, with vanilla as the most preferred. It is interesting to note that more women ranked the strawberry first or second (n=24) than ranked the vanilla first or second (n=19) but that more ranked it last (n=9 for the strawberry vs. n=4 for the vanilla).

The rankings more clearly identify a preferred flavour for the biscuits. The orange was ranked first by 26 women; the next most-preferred flavour was the original vanilla, which 6 people ranked first. The weighted rankings place the orange flavour well out front with 127 points, followed by strawberry with 93 points – just ahead of the original flavour with 87 points. The almond was in last place with 73 points.

During focus groups the women were also asked to discuss their flavour preferences, though no product ranking activity was conducted. Among Plumpy'Mum users, one group strongly preferred the strawberry version (with five women picking it as their favourite, vs. one for the cocoa and one who liked both the cocoa and the strawberry). None in this group preferred the vanilla flavour. Participants liked the taste, texture, colour and smell of the strawberry flavour, likening it to ghee and to milk. The cocoa flavour was likened to 'Chocofun', a locally available chocolate-covered wafer candy [similar to Kit Kat bars]. The only suggested changes were to add ghee to the strawberry version and to add chocolate to one of the flavours (though which one was not clear).

Five members of the other Plumpy'Mum group preferred the vanilla flavour, one liked both the cocoa and strawberry, and one first said she liked the cocoa but later said she preferred the original, commenting that all of the new flavours tasted like medicine. Here, too, the cocoa flavour was compared to *'Chocofun'*, as well as to foreign chocolates and almonds/peanuts. In discussing her preference for the vanilla flavour, one FGD participant said: *'I liked it* [the vanilla]. *That one, that food product that we had for eight weeks, feels strange on the tongue. The Plumpy'Mum would stick in the throat and it was difficult to swallow without water'*. No changes to the product were suggested in this focus group.

The two focus groups conducted with biscuit users support the quantitative data showing a preference for the orange flavour. All of the women in the first focus group liked orange best (although two of the six said they liked both orange and strawberry). One participant commented that the orange and strawberry flavours tasted like biscuits you would buy in the shops. In the other focus group, three women preferred the orange and two preferred the strawberry. The almond was not widely appreciated; in the first focus group a majority of the women said it was like medicine and smelled like medicine. In the second group, almond was deemed merely *'okay'*.

Alternate products

As noted, women in both product groups were offered the opportunity to try the product they had not used for the previous eight weeks. Almost all participants in the Plumpy'Mum groups preferred the biscuit over the Plumpy'Mum: *'It is delicious'; 'The taste is good; the smell is also good and it is good to eat'.* In the biscuit groups, participants also preferred the biscuit over Plumpy'Mum, and six participants said they did not like the taste of the Plumpy'Mum: *'If Plumpy'Mum was given to us, we might not have eaten the product'*. One liked both products, though preferring the biscuits. In the other biscuit group, one preferred the Plumpy'Mum because it was new, she liked the taste and found it similar to *Halwa*. Another said she might like the Plumpy'Mum after eating it for a while, as had been the case with the biscuit: *'At first I had not even liked the biscuit but liked it after eating continuously, This* [Plumpy'Mum] *I have been just eating that's why did not liked it if I keep on eating then will like it'*. The four remaining participants did not like the Plumpy'Mum, commenting, for example, that it was more medicinal.

Availability of alternating products or flavours

Focus group participants were asked a series of questions about being allowed to change products or flavours periodically if they were to use the supplements in the future. Most women wanted to have

different flavours available, with the majority wanting to change weekly. Many also expressed interest in changing products, especially those in the Plumpy'Mum groups (who wanted to have the preferred biscuits available as well). Fewer women in the biscuit groups were interested in changing products, rather stating that they would like different flavours of the biscuit only. However, it should be noted the questions and responses were sometimes inconsistent and made it unclear whether women were asking to change products or just to change flavours. In one FGD, for example, two participants who said they would want to change products weekly had said earlier that they did not like Plumpy'Mum and wanted only to eat the biscuit.

Conclusions and Recommendations

Based on the analysis of qualitative and quantitative data, the two products tested as the preferred fortified BEP supplements for use in Phase 3 of the study (the sweet Plumpy'Mum and the Vanilla biscuits) were found to be acceptable. The research indicated similar levels of acceptance for both products with only small levels of variation across research tools. [9]

Overall levels of compliance to instruction appeared high for both products, with little variation between products. Women reported favourably in terms of their likelihood to continue to use the product in the future and provided positive feedback on the level of support from members of the household that could be expected. According to the data, choice is an important factor when considering future product use, and certain flavours emerged more favourably than others. Women and their families appeared to have understood and accepted instruction not to share but given that a number of women indicated some level of sharing with children, actual sharing practices should be monitored and findings acted upon. The introduction of the supplement into the diet of pregnant women in Phase 2 did not appear to impact normal meal and snacking habits nor did it affect the overall timing of consumption of meals.

In discussions about women's overall preferences for distribution of the product, a preference for monthly/weekly distribution visits was noted. Most women indicated that the supplements would be best received from the hospital or from members of the NNIPS team. It was also highlighted that efforts should be considered for how distribution mechanisms can be rolled into existing ANC structures. The involvement of the government in distribution (via the hospital) was also mentioned as an important factor to ensure the products were reliable and free.

Additionally, a need for more information about the products at the community level was revealed. Health workers are best placed to disseminate this information but should also focus on dispelling misunderstandings about the supplements and providing information to address concerns of pregnant women, their family members and others in the community.

Flavour recommendations for Phase 3

As a result of the above analysis, it is found that the orange biscuit is the most preferred product and should be considered for selection in Phase 3. Of the Plumpy'Mum flavours, the vanilla was the most preferred of the four flavours offered. Quantitative data revealed the highest predicted levels of future daily consumption with 63.1% of women indicating that they 'Definitely would eat' the Orange biscuit every day and 58.3% agreeing that they would definitely eat the Vanilla Plumpy'Mum every day. A number of women also indicated that being able to change products or flavours would make it easier to use the products every day.

The data gathered during Phase 2 should be considered to provide additional insights into factors affecting product use as well as any product modifications that may be needed before the commencement of Phase 3 of the MINT project.

[9] For example, there was some indication in the focus group discussion of a preference for the Vanilla biscuit, however given the limited sample size these findings cannot the generalised further.

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Annex 1

Table 6. Weekly compliance rates (%) using various definitions for Plumpy Mum group during the 8 weeks: median (Q1-Q3), mean

WEEK	1	2	3	4	5	6	7	8
Sachet-count method	N=39	N=38	N=38	N=35	N=34	N=36	N=36	N=35
a. Unadjusted weekly compliance (%) among those met in person	114.3 (100-114.3) *94.5*	100 (85.7-114.3) *90.8*	100 (100-114.3) *96.6*	100 (100-114.3) *104.6*	100 (85.7-114.3) *99.3*	100 (100-114.3) *104.4*	114.3 (100-114.3) *104.2*	114.3 (100-114.3) *103.3*
b. Adjusted weekly compliance (%) among those met in person	100 (100-100) *87.2*	100 (85.7-100) *85.0*	100 (100-100) *91.7*	100 (100-100) *96.7*	100 (85.7-100) *93.2*	100 (100-100) *95.9*	100 (100-100) *95.2*	100 (100-100) *95.0*
Non-sachet count method	N=39	N=40	N=39	N=37	N=36	N=37	N=36	N=37
c. Weekly compliance of full portion among those met in person or over the phone	100 (71.4-100) *78.0*	100 (57.1-100) 76.8	100 (85.7-100) *84.6*	100 (100-100) *91.9*	100 (85.7-100) *88.5*	100 (100-100) *91.9*	100 (100-100) *92.8*	100 (85.7-100) *87.6*
d. Weekly compliance of any portion among those met in person or over the phone	100 (100-100) *86..4*	100 (85.7-100) *82.9*	100 (100-100) *91.9*	100 (100-100) *98.1*	100 (100-100) *92.9*	100 (100-100) *94.2*	100 (100-100) *95.2*	100 (100-100) *89.6*

Table 7. Weekly compliance rates (%) using various definitions for Biscuit group during the 8 weeks: median (Q1-Q3), mean

WEEK	1	2	3	4	5	6	7	8
Sachet-count method	N=40	N=39	N=39	N=38	N=38	N=39	N=36	N=38
a. Unadjusted weekly compliance (%) among those met in person	114.3 (100-114.3) *105*	*100 (100-114.3) 102.6*	100 (100-100) *98.9*	100 (85.7-100) *94.4*	100 (100-100) *91.8*	100 (85.7-100) *93.3*	100 (100-100) *92.3*	100 (100-100) *88.7*
b. Adjusted weekly compliance (%) among those met in person	100 (100-100) *96.4*	100 (100-100) *98.2*	100 (100-100) *96.0*	100 (85.7-100) *92.1*	100 (100-100) 89.2	100 (85.7-100) *89.4*	100 (100-100) *89.1*	100 (100-100) *86.8*
Non-sachet count method	N=40	N=40	N=40	N=39	N=38	N=39	N=38	N=40

c. Weekly compliance of full portion among those met in person or over the phone	85.7 (78.6-100) *83.9*	100 (85.7-100) *92.5*	100 (100-100) *92.8*	100 (85.7-100) *90.8*	100 (85.7-100) 87.2	100 (85.7-100) 86.4	100 (100-100) *89.1*	100 (78.6-100) *81.4*
d. Weekly compliance of any portion among those met in person or over the phone	100 (100-100) *95.7*	100 (100-100) *98.6*	100 (100-100) *96.8*	100 (100-100) *93.8*	100 (100-100) *91.7*	100 (100-100) *90.8*	100 (100-100) *89.8*	100 (92.9-100) *84.2*