Framework and Specifications for the Nutritional Composition of a Food Supplement for Pregnant and Lactating Women (PLW) in Undernourished and Low-Income Settings

Report of an Expert Consultation held at the

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Preface: Rationale for the Expert Consultation and Consensus Process

Maternal undernutrition (low body mass index, short stature and micronutrient deficiency), which remains a problem of public health significance in many low and middle income countries (LMIC), particularly Sub-Saharan Africa and South Asia, has negative consequences for the health of both the mother and child. Nutritional inadequacy during pregnancy results in poor fetal development and increases the risk of adverse birth outcomes and mortality. While significant progress has been made, it is estimated that approximately 32 million babies are born too small (small for gestational age [SGA]). About 6 million SGA births are associated with maternal short stature in pregnancy.

Reaching nutritional requirements during pregnancy and lactation is often unattainable for many women in low income settings. Adequate energy, micronutrients, essential amino acids (protein) and fatty acids are required to promote adequate maternal weight gain and healthy maternal and infant outcomes. The new WHO antenatal care guideline has a context-specific recommendation of balanced energy-protein supplementation in undernourished populations to reduce the risk of stillbirths and SGA. Programmatic experience around food supplementation during pregnancy suggests some benefit in terms of birth weight, but net increase in nutrient intake is limited due to problems of accessibility, sharing and substitution. Ideally, a pregnancy supplement would fill the energy/nutrient gap and yet there are few products that have been designed and made available for such use. There is an urgent need for affordable, nutritious food supplements for pregnant women that are designed to be ready-to-use and meet specified levels of macro- and micronutrients. Targets for product design are required, including nutrient content, product type(s), packaging and promotion, and cost. Although recommendations are for pregnant women and requirements are different during lactation, such a food supplement could also be considered for use by postpartum women to support lactation.

The Bill and Melinda Gates Foundation sponsored and organized an expert consultation on September 19-20, 2016 for the purpose of developing nutrient content targets for affordable, nutritional supplements for use by pregnant and lactating women (PLW) in low income and food insecure contexts. The consultation, which brought together experts (Appendix I) from academia, public sector, private sector and the donor community, was not only a greatly needed discussion on a topic that warranted further attention, but an event that was timely as well, in view of the recent WHO antenatal care recommendations.

The objective of the consultation was to i) share lessons from the field from varying contexts on the development of a daily nutritious food supplement for PLW, ii) reach a consensus on nutrient content targets and possible types and forms for a daily nutritious food supplement for PLW in low income and food insecure settings, and iii) discuss the 'use-case' for such products.

This document is a report by the expert group capturing the considerations and consensus of the expert consultation on the framework and specifications for macro- and micronutrient composition, form and type, and use-case for nutritious, ready-to-use food supplements for PLWs who are inadequately nourished, and/or at-risk of suboptimal nutrient intake related to food insecurity (e.g. residing in food insecure household or in an area affected by (seasonal food insecurity) in low and middle income country settings.

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I. Background

It is well-established that poor maternal nutrition has major implications for fetal growth and development, and likely long term health consequences. Despite the existing and mounting evidence for the importance of maternal nutrition, and global efforts and initiatives that have been established to prevent growth faltering during the first thousand days of life (striving to meet World Health Assembly and Sustainable Development Goals targets), maternal nutrition continues to be a neglected area.

In low and middle income countries, approximately 32 million children are born small for gestational age (SGA), caused in part by the poor nutritional well-being of the mother before and around conception and throughout pregnancy. Maternal nutrition, in terms of energy/protein balance and other macro and micronutrient deficiency, has been shown to impact fetal growth. Targets have been created to drive impetus towards action. The WHO Global Targets for 2025 for Maternal Nutrition are: to 1) reduce by 50% (compared to 2010) anemia in women of reproductive age (WRA) and 2) reduce by 30% the incidence of low birth weight.

Maternal Nutrition

Nutritional requirements are increased during pregnancy (Appendix II) and frequently unmet, leading to the high burden of maternal undernutrition that contributes to fetal growth restriction in many settings. Adequate energy, micronutrients and essential amino acids and fatty acids are required to promote adequate maternal weight gain and healthy maternal and infant outcomes.

Data on weight gain in pregnancy are not commonly collected or available and inadequate energy intake during pregnancy may be a concern, especially in settings where the rates of low birth weight are high. Despite increasing overweight and obesity globally, and the recognition of a “dual burden of malnutrition,” maternal underweight continues to be a major issue in many LMIC contexts. For instance, while obesity affected 20 million women in India in 2014, the number of women considered underweight rose to 100 million (41.6% of women underweight globally) from 58.3 million in 1975 (NCD Risk Factor Collaboration, 2016). Micronutrient deficiencies (MND) during pregnancy are also common, resulting in poor birth and neonatal outcomes; iron-deficiency anemia prevalence in pregnancy is at almost 20% globally and iodine deficiency, using low median urinary iodine excretion in school-age children as a population indicator of iodine deficiency, is at approximately 28% (Black et al, 2013). There is a profound need to address the issue of filling the nutrient/energy gap for PLW, especially in food insecure and low income settings.

Two meta-analyses of studies of balanced energy-protein supplementation (BEP) during pregnancy demonstrated a positive effect of improved birth weight among 'malnourished' women (Imdad & Bhutta 2013; Ota et al, 2015).

The different types of formulations that were used in the existing BEP trials were examined showing a wide variation in both the forms used and the energy and protein content (Appendix III). Even so, these heterogeneous studies have been combined under a similar umbrella of interventions termed as BEP. Program experience in some settings where food supplementation has been done exists. Programs, in the absence of specific food products for PLW, have used fortified blended foods (corn and wheat soy blends; CSB, WSB) for supplementing PLW, however, sharing and substitution are a problem and the quality of protein may be an issue. Despite the evidence for a benefit of BEP supplementation, there have been no previous WHO guidelines for supplementation in pregnancy (there were none at the time when the convening was held in Sept, 2016), until most recently in November 2016 when new ANC guidelines from WHO were issued that include maternal nutritional care in pregnancy (WHO, 2016). Weighing the evidence from trials, the WHO now recommends BEP for pregnant women in undernourished settings (Appendix IV).

Thus, there exists an exciting opportunity to operationalize this new recommendation. The development of compositional guidance for a suite of products could drive a potential public-private partnership to deliver this intervention in undernourished populations. Below is the section describing the specifications for macro- and micronutrients, forms and use-case, for a ready-to-use affordable food supplement for pregnant women in low income settings.

II. Nutrient Specifications

Macronutrient Requirements

When considering macronutrients, a number of aspects for the supplement were discussed including: Amount of energy, and carbohydrates (% of energy); proteins (% of energy and type); fats (fatty acids, % of energy, type) to be provided, and whether or not sugar and salt should be included. The proposed macronutrient content that was developed was intended to be broad, to allow for different types of food (e.g. with higher or lower fat content) and compatibility with micronutrient content targets. The following was proposed in terms of macronutrient content and types:

- **Energy Balance from Macronutrients:** One portion/serving of the product should provide between 250 and 500 kcals. In a high risk population, where the prevalence of low birth weight is higher, or when large protein and energy gaps exist (such as in an emergency context, or when seasonal access is low), the portion size could be doubled. Alternately, in a low-to-moderate risk context, the supplement could provide the lower daily energy value.

- **Fat:** It was agreed the fat content allowed would encompass a broad range between 10% and 60% of energy, which in turn would allow development of products that were lipid-based pastes, or those using flours (e.g. that have corn, wheat or rice as a base) or low-moisture products, which may be important in certain contexts where product stability is a concern (e.g. in humanitarian emergencies where a 24-month shelf life is often required).

- **Protein:** With regard to protein, it is proposed that the supplement provides approximately 50% of the additional protein requirement in the third trimester, i.e. 0.5 * 31.2 = 16 g (range 14-18 g), and for that to have a DIAAS of ≥0.9, as there is a body of evidence that suggests that a proportion of pregnant women in low-income setting have difficulties meeting the recommended protein intake (which are substantially higher in the third trimester of pregnancy) and achieving the recommended quality (Lee et al; 2012). Given the range for the energy content of the supplement, the protein content target is expressed in grams, i.e. 16 g, rather than energy%. For example, providing 16 g protein in 250 kcal is equivalent to 25.6 energy%, in 350 kcal it is 18.3 energy% and in 500 kcal it is 12.8 energy%. Also, this amount of protein with DIAAS of ≥0.9 would be expected to cover the essential amino acid (AA) requirements for pregnant women who have a low AA intake from their regular diet. It was decided not to specify the source or type of protein (i.e. not specifically suggesting dairy or animal source) in order to allow the potential option of adding amino acids (albeit recognizing that this would increase the cost). The group recognized that the above-mentioned protein quality requirements called for animal source food ingredients at least partially.

- **Carbohydrate:** No recommendations were made for the amount of carbohydrates in the food product as this would depend on the chosen fat content. The WHO recommendation for limiting total added sugar in the diet to a maximum of 10% of total energy was discussed, and while savory product types were preferred, no 'must have' lower or upper limit for added sugar was proposed. It is important to note that the WHO recommendation should be applied to the daily diet as a whole and individual foods contribute to it.

- **Trans Fats:** It was recommended that trans fatty acid content should be ≤1%, as a standard requirement.

- **n-6: n-3 ratio**: Addition of n3-PUFAs, specifically DHA, was considered optional. There was a rich discussion on the n-6: n-3 essential fatty acid ratio. With the specified fat content for the food supplement, it was assumed that a minimum of 1.3 g of n-3 or 200 mg of DHA in some sort of additive form, e.g. from marine sources, would achieve a healthy n-6: n-3 ratio of 5-10:1. Because DHA is a very costly nutrient, yet potentially important, its inclusion should best be context specific. DHA could also be used in a supplement form where possible. Where fish is commonly consumed intakes may be adequate.

***Further discussion**: For all macronutrient recommendations, every context will be operating under the auspices of a national food safety agency which should guide the food safety and labeling requirements.*

Summary of Macronutrient Targets

Total energy: 250-500 kcal per daily serving

Fat Content: 10-60% of energy

Protein Content: 16 g (range 14-18 g) with a Digestible Indispensable Amino Acid Score (DIAAS) of ≥0.9

Carbohydrate (CHO) Content: No specific recommendations, and depends on the fat content of product type

Trans Fats: No more than 1%, as a standard safety requirement

Fatty Acid *(optional)*: Min of 1.3 g of n-3 or 300 mg DHA+EPA (of which 200 mg DHA) to achieve a healthy n-6: n ratio of the supplement of 5:1

Micronutrient Requirements

There were several guiding principles used for the micronutrient specifications:

It was agreed that specifications for micronutrients would be provided as ranges (minimum and maximum). Both US Institute of Medicine's Dietary Reference Intakes (DRIs) and FAO/WHO's Recommended Nutrient Intakes (RNIs) were considered but the probability based IOM DRIs provide a common framework that allowed unifying the specifications for a single daily serving of the food supplement. It was recommended that the minimum desired intake from a food supplement for PLW would be the estimated average requirement (EAR), which when provided, would push the entire population above the EAR. It was recommended that the RDA recommendation by the IOM would be the maximum of the range. Hence, as a general guideline, the EAR was set to be the minimum desired target and the RDA the maximum allowed from a single serving of the food supplement. A target of an EAR in a single serving was deemed appropriate given the fact that there may be concurrent intake of iron-folic acid or multiple micronutrient supplements. Also, in some settings two servings per day may be recommended, so the total amount provided would be a minimum of 2EAR and a maximum of 2RDA. There is some evidence that providing 2RDA for certain nutrients may result in improved birth outcomes in vulnerable populations (Kaestel et al. 2005).

Other considerations were as follows:

- For some nutrients for which nutrient intake recommendations are based on an adequate intake (AI), the AI would be the RDA equivalent (i.e. maximum), and 80% of the recommendation was used to set the minimum.

- Differences exist in the nutrient requirements of pregnant and of lactating women. It was decided to use the higher of the two values recommended.

- *Macrominerals and other nutrients:* For several macrominerals (e.g. potassium, phosphorus, magnesium, calcium) and choline, it would be difficult to reach an EAR in the portion size of the food product. Additionally, there is a dearth of data linking the intakes of these nutrients to pregnancy specific effects with the exception of calcium for which WHO guidelines exist. Thus, the minimum for these was set at 50% of the EAR (whether the EAR was a hard number or derived from the Adequate Intake). It cannot be ruled out that macrominerals may play an important role in improving pregnancy health, but the quantity of these nutrients should be maximized only to the extent that they do not negatively affect the taste of the product, with cost considerations also taken into account.

Several individual nutrients prompted further consideration:

- **Vitamin A**: Because there is concern with high-dose pre-periconceptional vitamin A intake and to remain prudent, the pregnancy value (lower of the two options) was used. Commercial fortification must also be taken into account, which may lead to country-specific or regional adaptation of the desired vitamin A content of the food product. Beta-carotene in either a synthetic or natural form could be used to partially fulfil the vitamin A specification for the food.

- **Vitamin E**: Two considerations must be taken into account with vitamin E viz. the PUFA content in the diet and vegetable oil consumption. PUFA content affects vitamins E (also A and D) due to peroxidation, and while vegetable oil intake is rising in LMICs, there is limited information about how that oil is processed and how it is stored, transported and cooked, all of which impact the vitamin E levels in oil. Thus, there is little understanding of how much of a vitamin E gap exists in the diets of women and how much vitamin E is needed to support the high requirements during this life stage.

- **Vitamin K**: There may be a concern around cost, which may need to be taken into account.

- **Folic acid**: It was noted that iron-folic acid (IFA) supplementation and use as recommended by WHO may be prevalent, and that the WHO recommends folic acid levels at 400 µg daily. Thus, the minimum amount for folic acid in these food products may warrant a lower value than the current IOM EAR. The RDA of 600 µg is used for the maximum amount as per the IOM RDA.

- **Pantothenic Acid**: Because only an AI is provided, 80% of the recommended IOM value was used, but pantothenic acid was listed as an optional nutrient.

- **Calcium**: The current WHO guideline is to supplement women in low calcium intake areas with 1.5 to 2 g calcium daily for reducing preeclampsia. As of yet, very few countries are implementing calcium supplementation programs, but this may change. Furthermore, there are limits to the amount of calcium that can be included in foods, for taste reasons. Thus, the minimum amount for calcium for the food supplement is specified to be different from the IOM EAR. Instead of the food supplement fully providing the EAR it is assumed that about 300 mg of calcium would be derived from the diet, and that the addition of 500 mg would help achieve the daily EAR of 800 mg. There is also the need to take the calcium/phosphorus ratio into consideration, which should be between 1.0-1.5. Thus, the minimum target is set at 500 mg and the maximum at 1000 mg, which is the RDA for pregnancy/lactation.

- **Phosphorous:** 50% of the EAR was used, and then rounded up to a whole number.

- **Iron:** IFA supplementation was taken into consideration, as well as intake from other sources and environmental aspects (iron in groundwater), which is context specific. The recommended IOM EAR and RDA were used, but it was thought important to maintain an iron/zinc molar ratio that was 1-2:1. Overconsumption of iron during pregnancy is of concern, thus a "middle of the road" value was used to minimize the concerns of making specifications too high, and due to organoleptic issues. These values can therefore be lowered in places where there is high IFA coverage, or where there are bioavailability and food matrix issues involved in the design of the product. While iron is essential to be included in the food supplement, it is equally important to minimize the possibility of approaching values that can lead to negative effects. Concurrent fortification of foods for the general population, e.g. of flour, must also be taken into account.

- **Zinc:** Given that the UNIMMAP supplement formulation uses 15-20 mg of zinc (UL being 40 mg), it was assumed that this amount would be a safe recommendation.

- **Iodine:** The IOM EAR and RDA were adopted, but there was a recognition that universal salt iodization may be present and the range may need to be adapted to the context.

- **Potassium**: The IOM recommendation is presented as an AI, thus 80% of the recommendation, and subsequently 50% of that, was used as the nutrient recommendation for the supplement. It was recognized that potassium's impact on taste would also play a role in determining the specific amount and the chemical form and level will need to be carefully adjusted for product taste acceptability, especially in products for which added sugar content is limited.

Some of the recommended nutrients are not in UNIMMAP, however the following nutrients were deemed mandatory to be added to food supplements in addition to those also included in UNIMMAP: iodine, vitamin K, calcium, and phosphorus (largely to achieve a balanced Ca:P ratio). The following nutrients were deemed optional largely because they are untested and not part of the tested UNIMMAP supplement: pantothenic acid, biotin, choline, manganese, potassium, magnesium.

Desired nutrient content can be adjusted based on knowledge of the prevailing diet in the target group. However, it is important to note that downward adjustments of nutrient content are only recommended when the population subset with the lowest nutrient intakes will also still have an adequate intake when the contribution from the supplement is reduced.

Table I: Micronutrient Targets per Daily Single Serving of 250-500 KCAL

Micronutrient	Unit	Minimum/Target (EAR)*	Maximum (RDA)*	Comments
Required				
Fat Soluble Vitamins				
Vitamin A	µg RE	550	770	IOM EAR and RDA values used. Because there is concern that high periconceptual vitamin A intake is harmful, the lower pregnancy values were used
Vitamin D	µg	10	15	IOM EAR and RDA values used. Values for pregnancy and lactation are equal
Vitamin E	mg	16	19	IOM EAR and RDA values were used. The lactation values were used as they are higher
Vitamin K	µg	72	90	Because only an AI is provided, 80% of the recommended value is presented as the minimum amount. The maximum value is the AI. AI values are the same for pregnancy and lactation
Water Soluble Vitamins				
Thiamin, B_1	mg	1.2	1.4	IOM EAR and RDA values are used. The lactation and pregnancy values are the same
Riboflavin, B_2	mg	1.3	1.6	IOM EAR and RDA values are used. The lactation values were used as they are higher
Niacin, B_3	mg	14	18	IOM EAR and RDA values are used. The pregnancy values were used as they are higher
Vitamin, B_6	mg	1.7	2	IOM EAR and RDA values are used. The lactation values were used as they are higher
Folate#, B_9	µg	400	600	Iron Folic Acid supplementation may be widespread, and given the WHO/FAO recommendation of 400 µg, the minimum warrants a lower value than the IOM EAR. However, the IOM RDA was used for the maximum (600 µg), based on pregnancy value, which is higher
Vitamin B_{12}	µg	2.4	2.8	IOM EAR and RDA values were used. The lactation values were used as they are higher
Vitamin C	mg	100	120	IOM EAR and RDA values were used. The lactation values were used as they are higher
Minerals				
Iron	mg	22	27	IOM EAR and RDA values were used. The pregnancy values were used as they are higher
Zinc	mg	15	20	The UNIMAP recommendation and other studies have used 15-20 mg of zinc per day (UL being 40 mg), it was assumed that 15-20 mg would be a safe recommendation as a minimum and maximum value
Iodine	µg	209	290	IOM EAR and RDA values were used. The lactation values were used as they are higher
Calcium	mg	500	1000	The minimum value assumes that 300 mg of calcium would be derived from the diet, and that an additional 500 mg in the food supplement would provide an EAR of 800 mg. The maximum value is 1000 mg based on the RDA for pregnancy and lactation
Phosphorus	mg	300	700	Phosphorous could be optional, but is included given that calcium is included and the ratio of Ca:P needs to be between 1.0-1.5. Because it is a macromineral, the value is 50% of the EAR and rounded to 300 and the IOM AI is the RDA. The pregnancy and lactation values are equal
Copper	mg	1.0	1.3	IOM EAR and RDA values were used. The lactation values were used as they are higher
Selenium	µg	60	70	IOM EAR and RDA values were used. The lactation values were used as they are higher
Optional				
Pantothenic Acid, B_5	mg	5.6	7.0	Because only an AI is provided, 80% of the recommended value is presented as the minimum amount. The maximum value is the AI. AI values for lactation were used
Manganese	mg	2.1	2.6	Because only an AI was provided, 80% of the recommended value was used to determine the EAR. The Maximum value is the AI. AI values for lactation were used
Potassium	g	2.0	5.1	Because only an AI is provided, 80% of the recommended value was used. The minimum value was 50% of this amount, whereas the maximum value is the AI. AI values for pregnancy were used
Magnesium	mg	145	350	Because only an AI is provided, 80% of the recommended value was used. The minimum value was 50% of this amount, whereas the maximum value is the AI. AI values for pregnancy were used
Biotin	µg	28	35	Because only an AI is provided, 80% of the recommended value is presented as the minimum amount. The maximum value is the AI. AI values for lactation were used
Choline	mg	220	550	Because only an AI is provided, 80% of the recommended was used. The minimum value was 50% of this amount, whereas the maximum value is the AI. AI values for lactation were used

** Generally the IOM EAR was used for the minimum value, and the RDA was used as the maximum value. Exceptions are explained in the comments column.*
 # Expressed as dietary folate equivalents (DTE).

III. Form and Type

Considerations for the form and type of the food supplement involved a variety of products and advantages and disadvantages of each type based on existing experience and knowledge. Solid, semi-solid and liquid products were considered and aspects such as convenience, risk of meal replacement, ease of packaging, safety and transport, among others, were evaluated. Some guiding principles were agreed upon when developing and recommending types of products and forms. These included a) not considering staple foods, b) not considering condiments, c) products that could be packaged in individual servings, d) foods (and drinks) that can be consumed between meals, e) products amenable to modification in the variety of flavor to reduce monotony, and f) having an adequate shelf life.

The following ready-to-use foods were prioritized for discussion:

- High energy biscuits, e.g. as currently used in humanitarian supply chains or two biscuit layers with cream in-between
- Brittle (cooked sugar with some type of protein or legume)
- Lipid-based spreads
- Extruded snacks (savory, puffy crispy product, with an option to have a paste inside)
- Bar
- Encapsulated foods (e.g. a sweet or savory outer covering with a legume-base inside)
- Liquid drink/drink powder

The considerations for each form included:

- **Risk of overconsumption:** There is a potential risk of overconsumption for most solid products, although risk for a drink was considered low as it is constrained by the volume. If solids are packaged in a daily serving size and with clear instructions on the package, this might mitigate the risk of overconsumption.

- **Sharing risk:** If the product is considered to be a treat, sharing may occur to a greater extent. Savory products may be less likely to be shared and more palatable for adults vs. sweet ones especially with children in the household

- **Stability once opened:** Drinks seemed to have the highest risk of bacterial growth due their high water activity, especially when left out over the course of several hours. Humidity may be an issue for solids, but would still have lower microbiological safety risk than drinks.

- **Packaging and distribution cost**: This was particularly important for extruded snacks; when thinking about storage and a product that needs an air-tight package, the more-dense options may be better and more cost-effective. Packages should be harder for children to open.

- **Taste:** The product would need to be tasty, but should not promote sharing. Consideration of women's preferences for consumption on a daily basis, and variety were deemed important.

- **Nutrition specifications:** For example, calcium in the recommended amounts would be more feasible to include in spreads than in brittle and extruded snacks.

- **Salt**: This was not discussed in depth, but it was recognized that a maximum amount may be more important to specify than a minimum.

- **Sugar:** Use sugar sparingly and not to increase energy density as done in lipid-based supplements for young children.

- **Energy density criteria**: The volume of the food is important to consider during pregnancy; as higher volume may be harder to consume. Thus, these "snack type foods" should be designed to provide the required energy content using a small serving size, although concomitantly being consumable in smaller parts over a few hours.

- **Hot versus cold**: A hot snack may likely impact the desired "ready-to-use" nature of the food product, and also may cause meal replacement in addition to packaging challenges. Heating would likely destroy some nutrients. Ready-to-use soup products may be an option, yet the need for fuel and cooking time may be constraints. Yogurt requiring a cold chain was ruled out. Also, its energy density is quite low, and it would be challenging to increase it such that it will be able to fill the gap as required for PLW.

There was then an informal vote on each participant's top 3 preferred forms to get a general ranking from the group. The results of this ranking are captured below in Table II.

Table II: Form and Type

Ready to Use Foods	Rankings
Spreads*	17
Biscuits*	12
Bar*	8
Extruded Snack*	7
Instant Drink Powder*	7
Coated Bites	5
Liquid drink	3
Brittle	0

** Denotes Top Choices by expert consultation*

IV. Target Populations and Use-Case

The following three scenarios were discussed to develop a "Use-Case" for a nutritious food product for PLW:

1. Emergency situations (environmental disasters, civil unrest, refugee contexts, etc).
2. Chronic and high household food insecurity settings
3. Low food insecurity settings

Context specific considerations are likely to drive the use-case for the PLW food supplement and each country/setting would need to modify the use-case based on existing public sector programs (e.g. antenatal care, health-services and social protection) and market access (physical and purchasing power) and experiences. The following were main issues that were considered and discussed:

- The group did not focus on food distribution in a humanitarian emergency situation, largely because the mechanisms for distribution are relatively well-defined and so are the in-kind rations/food offerings that are feasible in such circumstances. The exception is in protracted emergencies where women and children may experience food and nutritional deprivation for extended periods of time, in which case such products for PLW could be well suited for distribution purposes. The use-case in such situations would be free distribution supported by humanitarian or government agencies.

- Given the new WHO ANC guidelines, discussions with governments will be needed both for adopting a policy that includes fortified balanced energy and protein supplements as a pregnancy intervention in areas with a high burden of undernutrition and for strengthening the ANC platforms. The proposed nutritious food supplement will fill the gap vis-á-vis a product for implementing the new guideline through ANC or extended community platforms, including market-based distribution.

- The proportion of the population that is affected by food insecurity varies by setting and by circumstances and this determines the different distribution strategies that can be used. In most contexts, PLWs of food insecure households are likely to need public sector support to access a food supplement.
    - In a context where PLW face high food insecurity or undernutrition, e.g. related to poverty and household food insecurity, the supplements could be distributed free during ANC visits or through community outreach.
    - In moderate food insecurity situations, other strategies such as offering voucher systems or other means of subsidized purchase could be used.
    - In settings where self-purchasing by PLW that want to add a balanced, nutrient-dense product to their diet may be possible as a hybrid (or 'blended') distribution model can be considered. Thus, the designed product(s) could be promoted using a blended or "layered" approach that combines a market-based strategy with public distribution. Similar concepts are being developed and tested for complementary foods and home-fortification products such as micronutrient powder for children aged 6-23 months.

- The "market" problem: It is important to note that there is no viable commercial model for a preventive nutrition intervention that can work entirely on its own. The reason is that the communication needs about why this is a good product to consume during pregnancy are quite complicated, especially when compared to promotion of 'general' food products. Furthermore, the cost of ingredients, manufacturing and packaging of the product are relatively high compared to the price target for a product of low-income consumers, which leaves little budget for investments and marketing.

- To help women, their families and the wider public understand what is needed in order to reach nutritional adequacy during pregnancy and why that is important, demand generation and communication are vital, and would require support from the public sector, such as the health system or other platforms (e.g. women's self-help groups, others).

- The specific challenge/need is to create a market and desire for good nutrition, e.g. for PLW and children aged 6-23 months, and then offer specific products as solutions. In other words, it would not be realistic to just advertise a food supplement for PLW alone, without raising the awareness about a need for such products, and expect a high demand for the product.

- Beginning with a public approach of promoting better nutrition and offering specific solutions may work in some settings, before marketing strategies are also adopted. This approach does not preclude an opportunity for a private public partnership, with the government playing a stronger role in creating it. Furthermore, having both public sector and commercial demand may make it viable for a company to develop and produce these types of products. Agencies that provide humanitarian assistance may also add to the demand, albeit less predictable and less consistent.

- Peer-to-peer marketing can be especially effective, as it can combine education and follow up in a way that many retail outlets cannot. Also, it may be possible to propose a subscription model for the use of such a product. Those who don't have purchasing power could procure it through a voucher system, while those who do have purchasing power could purchase it.

- It was suggested that key enabling activities would need to be initiated through demonstration of the benefit of the product. In other words, a key first step would be to show, for instance somewhere in Asia and in Africa, the acceptability and efficacy of such a nutritious, well designed food supplement product. This would secure the support of experts, civil society and the government. Subsequently, specific marketing and communication of the food supplement would be needed. This would need to be led by the manufacturers with support from government and donors.

- Importantly, under any scenario of distribution or combination thereof, there is a need for behavior change communication and demand generation to ensure adequate uptake/consumption of the supplement by consumers as well as the wider population. In addition, there is a need to better understand why many women in lower-income populations don't gain adequate weight during pregnancy, even when food insecurity is not an issue. Helping women to overcome appetite constraints (e.g. nausea; infections; food aversions) is also important. In other words, simply providing the food does not ensure that it will be consumed in the desired amounts.

Summary

There are multiple elements of the use-case; the concept of a fortified balanced energy protein supplement may be simple, yet getting it to the women who need it and having them consume it regularly and in the required quantities is a challenge that needs to be addressed through a combination of efforts from the public and private (commercial) sector, which would benefit from a shared ecosystem.

V. Next Steps

- Disseminate the proposed nutritional composition and the nutrient content targets for a nutritious food supplement for PLW in low-income and under-resourced settings
- Design and develop prototypes of food products
- Identify two to three suitable prototypes that can span across different geographies, cultures and contexts
- Test acceptability and utilization of a few types of products and, under programmatic circumstances, test the impact on birth outcomes
- Create a task force to work on "use-case" using a blended market and public distribution model (e.g. as done with contraceptives)

References

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Appendix I: Expert Group

Name	Organization
Saskia de Pee	World Food Programme (WFP), Rome
Ashish Deo	Children's Investment Fund Foundation (CIFF), London
Kay Dewey	University of California Davis, Davis
Edward Fischer	Vanderbilt University, Nashville
Alison Fleet	UNICEF, New York
Nicolle Götz	DSM Nutritional Products, Basel
Sheila Isanaka	Epicenter, Harvard School of Public Health, Boston
Sarah Jensen	Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, Eschborn
Ralph Jerome	Mars, Davis
Klaus Kraemer	Sight and Life Foundation, Basel
Katharine Kreis	PATH, Seattle
Mark Manary	Washington University School of Medicine, St. Louis
Shahid Minhas	WFP, Pakistan
Saskia Osendarp	Consultant, MI
William Petri	University of Virginia, Virginia
Keith West Jr.	Johns Hopkins School of Public Health, Baltimore
Tahmeed Ahmed *(absent)*	icddr,b, Dhaka
Parul Christian	Bill and Melinda Gates Foundation, Seattle

Appendix II

IOM DRIs/RDAs/AIs and FAO/WHO RNIs for Pregnant and Lactating Women for Macro- and Micronutrients

Pregnancy

IOM Energy DRIs for 19-30 y of age			FAO/WHO Energy DRIs for 19-30 y of age		
(additional kcal/day)					
1st TM	2nd TM	3rd TM	1st TM	2nd TM	3rd TM
None	340	452	85	285	475

Lactation

IOM Energy DRIs for 19-30 y of age		FAO/WHO Energy DRIs for 19-30 y of age	
(additional kcal/day)			
Lactating (≤6 mo)	Lactating (> 6 mo)	Lactating (≤6 mo)	Lactating (> 6 mo)
330	400	505	675

(Continued on the following page)

		IOM[1] DRIs for 19-30 y		FAO/WHO[2] RNIs for 19-30 y		
		Pregnant	Lactating	Pregnant	Lactating	
CHO (g)	RDA	175	210			
Protein (g)[3]	RDA	71	71	Additional 1, 9 and 31 g in 1st, 2nd and 3rd trimester	Range of additional 14.3 to 16.2 g in 1st 6mo	
Lipids total (g)	-	ND	ND			
Linoleic acid (g)	AI	13	13			
Linolenic Acid (g)	AI	1.4	1.3			
Fiber (g)	AI	28	29			
Vitamin A (µg RE)	RDA	770	1300	370 800	450 850	RNI Safe intake
Vitamin D (µg)	RDA	5	5	15	15	
Vitamin E (mg)	RDA	15	19	*NR	*NR	
Vitamin K (µg)	AI	90	90	55	55	
Thiamin (mg)	RDA	1.4	1.4	1.4	1.5	RNI
Riboflavin (mg)	RDA	1.4	1.6	1.4	1.6	
Niacin (mg)	RDA	18	17	18	17	
Vitamin B_6 (mg)	RDA	1.9	2.0	1.9	2.0	
Folate (µg)	RDA	600	500	520 (600)	450 (500)	EAR (RNI)
Vitamin B_{12} (µg)	RDA	2.6	2.8	2.2 (2.6)	2.4 (2.8)	EAR (RNI)
Vitamin C (mg)	RDA	85	120	55	70	
Calcium (mg)	RDA	1000	1000	1200 (last trimester)	1000	
Iron (mg)	RDA	27	9	-	10-30	Based on % dietary iron bioavailability
Zinc (mg)	RDA	11	12	5.5, 7, 10 (1st, 2nd 3rd trimester)	9.5, 8.8, 7.2 (0-3, 3-6, 6-12 mo)	Based on moderate bioavailability
Iodine (µg)	RDA	220	290	200	200	
Biotin (µg)	AI	30	35	30	35	
Pantothenic acid (mg)	AI	6	7	6.0	7.0	
Choline (mg)	AI	450	550			
Phosphorus (mg)	RDA	700	700			
Magnesium (mg)	RDA	350	310	220 for females> 19, NR**	220 for females> 19, NR**	RNI
Manganese (mg)	AI	2.6	2.6			
Copper (µg)	RDA	1000	1300			
Selenium (µg)	RDA	60	70	28 (2nd trimester) 30 (3rd trimester)	35 (0-6mo pp) 42 (7-12 mo pp)	
Potassium (g)	AI	4.7	5.1			

[1] Source:https://fnic.nal.usda.gov/sites/fnic.nal.usda.gov/files/uploads/recommended_intakes_individuals.pdf
[2] FAO/WHO 2001, 2004, 2010
[3] Based on per kg of body weight for reference body weight at 0.80 g/kg/d or 46 g for a 57kg reference woman; additional 25 g the RDA for adult woman
* "No specific recommendations concerning the vitamin E requirements in pregnancy and lactation have been made by other advisory bodies (42, 43) mainly because there is no evidence of vitamin E requirements different from those of other adults and presumably also as the increased energy intake would compensate for the increased needs for infant growth and milk synthesis."
** "It is assumed that during pregnancy the foetus accumulates 8 mg and foetal adnexa accumulate 5 mg magnesium. If it is assumed that this dietary magnesium is absorbed with 50 percent efficiency, the 26 mg required over a pregnancy of 40 weeks (0.09 mg/day) can probably be accommodated by adaptation. A lactation allowance of 50–55 mg/day for dietary magnesium is made for the secretion of milk containing 25–28 mg magnesium (21 ,64)."

Appendix III

Types of Balanced Energy Protein Supplements Used in Studies

Study	Description of Food Supplement	Calories (kcal)	Protein (g)
Atton et al 1990	Flavored milk product packaged in a 200-ml Tetrabrick carton (with choice of flavors)	407	14.6
Blackwell et al 1973	Protein-calorie liquid supplement (milk-based) taken daily plus vitamins and minerals	800	40
Campbell et al 1983	Three different supplement options were offered based on subjects' preference: • 0.5 pint of flavored milk drink • 1 pint of fresh milk • 75 g cheddar cheese	300	14.6
Ceesay et al 1997	High energy groundnut biscuits (2) containing roasted groundnuts, rice flour, sugar and groundnut oil	1017	22
Elwood et al 1981	Free tokens to purchase milk for their families		
Girija et al 1984	50 g of sesame cake, 40 g jaggery and 10 g oil	417	30
Huybregts et al 2009	72 g of a prenatal MMN-fortified spread consisting of 33% peanut butter, 32% soy flour, 15% vegetable oil, 20% sugar and an MMN at 1x RDA	372.6	14.7
Mardones-Santander et al 1988	There were two intervention groups, PUR and V-N • PUR group received powdered milk (an isocaloric supplement) • V-N group received a fortified formula milk (a balanced protein-energy supplement); In addition, through the same program all women received 2 kg of rice monthly	PUR: 498 V-N: 470	PUR: 27.9 V-N: 14.5
Metcoff et al 1985	Monthly WIC vouchers for supplements of milk, egg and cheese	900 – 1000*	40 - 50*
Mora et al 1978	Supplement provided 60 g of dry skim milk, 150 g of enriched bread and 20 g of vegetable cooking oil; plus, a vitamin mineral supplement	856	38
Rush et al 1980	• Supplement: A 16-oz beverage (high protein-energy) • Complement: A 16-oz drink (balanced energy and protein)	Supp: 470 Comp: 322	Supp: 40 Comp: 6
Viegas et al 1982	Flavored carbonated dietary protein energy supplement (PrEnVit): containing 1/3 liquid glucose drink, chocolate flavored skim milk powder (26 g provided daily) along with vitamins	273	30

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Appendix IV

WHO ANC Guidelines on Energy and Protein Dietary Supplementation

WHO Recommendation A.1.3: Energy and Protein Dietary Supplements

In undernourished populations, balanced energy and protein dietary supplementation is recommended for pregnant women to reduce the risk of stillbirths and small-for-gestational-age neonates.
(*Context-specific recommendation*)

Selected Remarks:

• The GDG stressed that this recommendation is for populations or settings with a high prevalence of undernourished pregnant women, and not for individual pregnant women identified as being undernourished.

• Undernourishment is usually defined by a low BMI (i.e. being underweight). For adults, a 20–39% prevalence of underweight women is considered a high prevalence of underweight and 40% or higher is considered a very high prevalence (46). MUAC may also be useful to identify protein–energy malnutrition in individual pregnant women and to determine its prevalence in this population. However, the optimal cut-off points may need to be determined for individual countries based on context-specific cost-benefit analyses.

• A continual, adequate supply of supplements is required for program success. This requires a clear understanding and investment in procurement and supply chain management.

• Programs should be designed and continually improved based on locally generated data and experiences. Examples relevant to this guideline include:

– Improving delivery, acceptability and utilization of this intervention by pregnant women (i.e. overcoming supply and utilization barriers).

– Distribution of balanced energy and protein supplements may not be feasible only through the local schedule of ANC visits; additional visits may need to be scheduled. The costs related to these additional visits should be considered. In the absence of antenatal visits, too few visits, or when the first visit comes too late, consideration should be given to alternative platforms for delivery (e.g. community health workers, task shifting in specific settings).

– Values and preferences related to the types and amounts of balanced energy and protein supplements may vary.

• Each country will need to understand the context-specific etiology of undernutrition at the national and sub-national levels. For instance, where seasonality is a predictor of food availability, the program should consider this and adapt to the conditions as needed (e.g. provision of more or less food of different types in different seasons). In addition, a better understanding is needed of whether alternatives to energy and protein supplements – such as cash or vouchers, or improved local and national food production and distribution – can lead to better or equivalent results.

• Anthropometric characteristics of the general population are changing, and this needs to be taken into account to ensure that only those women who are likely to benefit (i.e. only undernourished women) are included.

GDG: Guideline Development Group

http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/