Improving maternal health outcomes by increasing access to preventative maternal nutrition products

RHSC GMM, MHS Caucus
October 17, 2023

Results for Development (R4D), Market Shaping Practice
Agenda

• Introductions (of R4D team) – 5min
• Importance of preventative maternal nutrition commodities in the care continuum (5min)
• ANC Supplementation – barriers to access (20 mins)
• Moderated discussion (15 mins)
Introducing Our Speakers

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R4D's Market Shaping Practice strengthens systems and markets to *increase access* to and *catalyze appropriate use of* essential health and nutrition products, which are key building blocks to ensure effective program coverage.

We do this by:

**Solving immediate challenges**
- Engage in product / product class areas *prioritized by change agents*
- Take a *holistic and analytical approach* to identify barriers to introduction and scale-up
- *Catalyze alignment of priorities and incentives* of key market actors, across regulatory, financing, supply and demand aspects, at global, regional and country levels.

**Stronger systems**
- Support systems to move towards *country-led introduction* of new products and *ongoing optimization* of lifesaving commodity markets
- Ensuring practical knowledge gained from individual markets are *appropriately adapted to strengthen other systems and markets* across the globe.

Product access is essential to effective program coverage:

- **Scale up access to products**
- **Effective coverage**
- **Scale up of service delivery implementation**
Expanding the MHS Caucus's focus to include a full continuum of care of products for maternal health can reduce preventable maternal deaths.

**Continuum of Care:**

During pregnancy

- Access to nutrition products and medicines

During labor

- Access to medicines and safe blood

\[=\]

Decreased maternal deaths

MHS Caucus historically has focused on medicines for prevention and treatment of pre/eclampsia and PPH. However, there are **opportunities to expand product focus** to include the full continuum of care for maternal health:

- **Maternal nutrition** for prevention of micronutrient deficiencies, which increases PPH risk
- **Safe blood** for treatment of most severe PPH cases

**Focus of this discussion**
Micronutrient deficiencies are linked to **adverse maternal health outcomes**, like anemia and postpartum hemorrhage (PPH).

Micronutrient supplementation is one of the **key interventions** for improving maternal nutritional status.

Yet, maternal nutrition has been **silotted and under-prioritized** in maternal health supplies dialogue.
Micronutrient deficiencies are a leading cause of maternal anemia, which in turn is linked to PPH, a leading cause of maternal mortality

1 in 5 pregnant women are iron deficient, the leading cause of anemia

- Iron deficiency underlies 60% of anemia cases
- More than 1 in 3 pregnant women worldwide are anemic

Anemia, and other micronutrient deficiencies, are associated with poor maternal health outcomes, including PPH

- Results from the WOMAN-2 trial suggest that:
  - Lower prebirth hemoglobin levels increase risk of PPH
  - Women with severe anemia are 7 times more likely to die or nearly die as a result of PPH
- Other micronutrient deficiencies including folate, zinc, iodine, calcium, and vitamins A, D, and B12 are also associated with adverse maternal health outcomes

![Link between Anemia and PPH](image)

- Odds of clinical PPH increase by 29% when prebirth hemoglobin decreases by 10 g/L
- Risk of PPH is almost double for women with severe anemia

(Figures are from WOMAN-2 Trial website “Resources” page: https://woman2.lshtm.ac.uk/resources/infographics)
Preventative ANC supplementation products that target micronutrient deficiencies can improve nutritional status and reduce adverse maternal health outcomes...

Examples of preventative maternal nutrition products that need more direct attention to increase access:

<table>
<thead>
<tr>
<th><strong>Iron Folic Acid (IFA)</strong>*</th>
<th><strong>Multiple Micronutrient Supplements (MMS)</strong>**</th>
<th><strong>Balanced Energy Protein (BEP)</strong>**</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Current standard of care for ANC supplementation to prevent and treat anemia and reduce risk of poor birth outcomes</td>
<td>• More efficacious and cost-effective alternative to IFA to prevent anemia and reduce risk of poor birth outcomes</td>
<td>• Ready-to-use food supplements for underweight pregnant and lactating women to promote gestational weight gain and reduce risk of poor birth outcomes</td>
</tr>
<tr>
<td>WHO recommends: IFA containing 30-60 mg elemental iron – 60 mg in contexts with ≥40% prevalence of anemia among pregnant women – and 400 mcg folic acid daily throughout pregnancy</td>
<td>• Recommended by the WHO for use in “contexts of rigorous research”</td>
<td>• WHO recommends BEP for underweight women during pregnancy</td>
</tr>
<tr>
<td><strong>UNIMMAP formulation</strong> (gold standard, backed by global actors) contains 30 mg iron, 400 mcg folic acid, and 13 additional micronutrients</td>
<td><strong>UNIMMAP formulation</strong> (gold standard, backed by global actors) contains 30 mg iron, 400 mcg folic acid, and 13 additional micronutrients</td>
<td>Includes multiple micronutrients, energy, and protein</td>
</tr>
</tbody>
</table>

*In the LEAP Report as a Priority Maternal Health Drug; included in MNCHN asset tracker; included as a part of the R4D MNCH project to identify market barriers and co-create solutions

**Included in MNCHN Asset Tracker & projects identifying market barriers to support intro and scale-up
The Challenge: a mix of product access and service barriers lead to significant unmet need in ANC supplementation, which is often limited to IFA currently in best-case scenarios.

**Product access barriers**

- Insufficient funding to meet full need, leading to out-of-pocket burden on patients (if they can afford it)
- ANC supplementation guidelines are unclear, leading to procurement fragmentation and confusion in patients
- ANC supplementation is not quantified robustly, contributing to challenges in procurement and financing decisions
- Low and varying supply base of ANC supplementation leads to mixed quality and supply fluctuations
- Inefficient supply chain from centralized medical stores to points of care

**Service barriers**

- Women delay or do not access ANC services continually
- Health Care Workers provide inadequate nutrition counseling around importance of continual ANC supplementation and use
- Anemia screening not conducted
- Side effects are not appropriately managed or contextualized

If A, an incumbent product, faces market barriers leading to low availability (<40% in 5 sub-Saharan African countries) and unmet need.

ANC supplementation is not available at the right quantity, cost, and quality

Poor maternal nutrition and birth outcomes

Illustrative Current state in LMICs

1. Data comes from available national surveys between 2016-2018 (E.g. SARA’s and additional reports)

Pregnant women are not adhering to a full course of ANC supplementation
For example, funding for IFA is insufficient, which limits access to this life saving maternal nutrition commodity.

There was an estimated 62% annual funding gap across five geographies between 2016 – 2018...

Estimated Funding Needed for IFA$^1$ vs. Actual Government and Donor Spent for IFA Per Year (USD in millions, 2016-2018)$^2$

<table>
<thead>
<tr>
<th></th>
<th>Quantified</th>
<th>Procured (2016-2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gov't funded</td>
<td>$3.6</td>
<td>$1.9</td>
</tr>
<tr>
<td>Donor funded</td>
<td>$14.3</td>
<td>$5.5</td>
</tr>
</tbody>
</table>

Funding gap of ~$8.8M

... and donors funded more than half of IFA procurements in the public sector suggesting sustainability concerns

Government vs. Donor Average Funding of IFA Per Year (USD in millions, 2016-2018)$^2$

- Gov't funded & allocated: $1.9 (35%)
- Donor funded - gov't allocated: $2.8 (52%)
- Donor funded & allocated: $0.7 (13%)

Note: geographies of analysis included Ethiopia, Tanzania, Uganda, Kenya, and Kano State, Nigeria

1. The forecasted addressable market for the public sector was calculated using a demographic- and morbidity-based methodology, focused on the uses of the priority medicines for MNCH conditions in country STGs and triangulating publicly available data, guidance, and expert opinion for 2016-2018. Pricing data collected between 2016-2018 was applied to both forecast and procurement volumes to then calculate a funding gap as a total and disaggregated by countries.

2. Values were calculated using the procurement data sourced from country government procurement agencies (EPSS, FMOH, MSD, NMS, KEMSA, DMCSA), other procurement agencies (JMS, SOML), and donors

Opportunity: Holistic resource mobilization support at federal and state level to expand financing for ANC supplementation should be prioritized
Specificity in country guidelines and alignment across guidelines, quantification, and procurement is key to minimizing fragmentation and optimizing resource allocation to increase access to IFA

1. The WHO recommends 60 mg elemental iron in populations where anemia in pregnant women is a severe public health problem (prevalence ≥40%), like Ethiopia and Nigeria.
2. The equivalent of 60 mg elemental iron varies by the type of iron compound. The IFA product with 200mg of ferrous sulfate specified in Ethiopia specifies that it contains 60mg of elemental iron and thus aligns with the WHO and country guidelines.
4. Procurement data was sourced from country government procurement agencies – EPSS between 2019-2022 and DMCSA between 2016-2018. (We are still waiting on data from 2019-2022 for Kano.)
5. Kano’s broad recommendation for hematinics is from 2018. It has since been updated to be more specific, but the 2018 guideline is being used here for the purpose of comparing to the 2016-2018 procurement data.

Guidelines are specific and procurement largely aligned; leading to a more optimized market

Guidelines are not specific, contributing to more fragmented quantification and procurement for the IFA market

<table>
<thead>
<tr>
<th>WHO ANC guidelines</th>
<th>Country-level guidelines</th>
<th>Quantification</th>
<th>Country Procurement</th>
<th>Takeaway</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>60 mg elemental iron + 0.4 mg folic acid</td>
<td>Ferrous sulfate + folic acid (200mg + 0.4mg) enteric coated tablet</td>
<td>Ferrous sulfate + folic acid (200mg + 0.4mg) enteric coated tablet</td>
<td>X</td>
</tr>
<tr>
<td>Kano state Nigeria</td>
<td>Broad recommendation for hematinics</td>
<td>Ferrous fumarate + folic acid + vitamin B12 (200mg + 1mg + 10mcg) capsule</td>
<td>Ferrous fumarate + folic acid + vitamin B12 (200mg + 1mg + 10mcg) capsule</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ferrous fumarate + folic acid + vitamin B12 (300mg + 5mg) capsule</td>
<td>Ferrous fumarate + folic acid + vitamin B12 (162mg + 0.75mg + 7.5mcg) capsule</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Folic acid + iron polymaltose + vitamin C capsule</td>
<td>Folic acid + iron polymaltose capsule</td>
<td></td>
</tr>
</tbody>
</table>

Legend

- Aligned with WHO guidelines
- Not aligned
- Aligned
- Aligned, but not specific

Example: product access barrier
ANC supplementation can be broadened to include Multiple Micronutrient Supplements (MMS), which are a more cost-effective alternative to IFA and could prevent adverse maternal health outcomes. However, **access to MMS will face similar challenges present in the IFA market**

### Why MMS?

- Multiple Micronutrient Supplements (MMS) are an antenatal supplement that **addresses anemia and other micronutrient deficiencies**

- Compared to iron folic acid (IFA), UNIMMAP MMS – the gold standard MMS formulation containing iron, folic acid, and 13 additional micronutrients – is much **more cost effective** – with a **cost-benefit ratio of over 1,000x in some contexts** – at averting DALYs

- While MMS has a lower iron content (30 mg) than the WHO-recommended IFA (60 mg), it has been shown to be just as effective at preventing anemia

  - Additional micronutrients present in **MMS improve the absorption of iron** and may also improve other deficiencies known to cause anemia

  - It’s possible that MMS may have a **better taste and fewer adverse side effects** than IFA, due to its lower iron content, which could lead to **improved adherence**.

- There is significant interest from donors and partners in supporting countries in transitioning from IFA to MMS for prevention of anemia during pregnancy

### Emerging challenges in the MMS market

#### Demand

**Low demand** caused by low awareness, lack of clear WHO recommendation for use, and higher price compared to IFA

#### Supply

Lack of registered **UNIMMAP MMS suppliers** in countries

#### Regulatory

Risk of **regulatory fragmentation**

(Misalignment between country guidelines and EMLs, quantification, and procurement leads to sub-optimal resource allocation)

#### Financing

**Funding gap** and problems with domestic resource mobilization

**IFA market challenges that can impact the MMS market**

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Balanced Energy Protein (BEP), a food supplement for underweight pregnant women, can also improve maternal health, but the BEP market needs attention

Why BEP?

- BEP is a food supplement for pregnant and lactating women which includes multiple micronutrients, energy, and protein.

- BEP given to underweight pregnant women prevents adverse birth outcomes and promotes gestational weight gain.

- Recent analysis has shown that a targeted approach of providing BEP to underweight women and MMS to women with an adequate BMI is more cost-effective than supplying MMS alone.¹

Challenges with the BEP market²

**Demand**

- Low awareness among key country-level stakeholders about BEP and how to integrate it amongst other interventions to prevent malnutrition.

**Supply**

- Limited supply base for BEP; Suppliers aren’t entering the market due to low demand and prioritization of other products (i.e., RUTF).

**Regulatory**

- No clear standardized global guidance on quality standards and formulations.

**Financing**

- Insufficient funding from global donors and procurers.

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2. Source: R4D analysis for Maternal and Child Wasting project. Insights were collected from stakeholder interviews conducted between January – October 2023.
Conclusion

- Addressing micronutrient deficiencies in pregnant women can reduce risk of anemia and adverse health outcomes, including PPH.

- The MHS Caucus could help prioritize access to preventative ANC supplementation products, like IFA, MMS, and BEP.
1. Any reactions or questions? When we talk about adverse maternal outcome prevention, how do you see nutrition factoring in?

2. Has this come up/ how does this feature in your respective activities, priorities, or strategies on maternal health outcomes?

3. Any objections to including efforts on maternal nutrition into the MHC Caucus? How can we make ANC Supplementation a priority within MHS caucus? What are the next steps?
   - A sub-group?
   - Share updates on work done on nutrition from existing members?
   - Recruitment of additional orgs working primarily on nutrition?

4. What is the evidence base we need to explore?
   - What evidence is needed to enhance prioritization of interventions among governments, partners, and donors?

5. What other questions do we need to prioritize?
   - What efforts are currently underway to increase coverage of preventative nutrition products?
   - What learnings can be drawn from experiences to-date in scaling up access to these products?