HF-TAG

Home Fortification Technical Advisory Group

Micronutrient powders added to the World Health Organization essential medicines list for children

What does this mean for country-level programming?

The recent inclusion of multiple micronutrient powders (MNP) to the Essential Medicines List for Children (EMLc) is intended to facilitate wider access to this critical product that delivers essential vitamins and minerals and is proven to prevent anaemia and other micronutrient deficiencies in children. Country-level decision makers should consider a number of factors when planning for MNP procurement and program implementation, including the public health context, World Health Organization (WHO) guidelines, regulatory options, funding mechanisms, and best practices of integration of MNP into existing infant and young child feeding programs.

IMPORTANCE FOR PUBLIC HEALTH

As of 2019, MNP have been added to WHO's Model EMLc to improve iron status and reduce anaemia among infants and children.[1] The Model EMLc is a core guidance document to recommend specific medicines and health products that countries should adopt into their country-specific Essential Medicines List. This list, therefore, helps countries to prioritize essential commodities for procurement and ensuring they are available throughout their health system.

WHO GUIDELINE AND RECOMMENDATIONS FOR MNP

Recommendations for the use of MNP are supported by the *WHO guideline: Use of multiple micronutrient powders for point-of-use fortification of foods consumed by infants and young children aged 6-23 months and children aged 2–12 years*. Point-of-use fortification is often referred to as "home fortification" in which various foods prepared in the home can be fortified using MNP.[2]

The adoption of home fortification using MNP has increased significantly over the past few years, largely replacing iron supplements such as liquid ferrous sulphate drops, also listed in the EMLc. WHO's second Global Nutrition Policy Review (GNPR2), undertaken between 2016–2017, reported that among the 167 countries surveyed, the most common micronutrient supplements provided to children were MNP.

WHY MNP?

In settings where access to nutritious diets is limited and complementary feeding practices are poor, MNP improve the nutrient content of children's diets, prevent micronutrient deficiencies, such as iron deficiency and anaemia, and support growth and development.

Packaged in single-serve sachets containing iron, zinc, vitamin A and other essential vitamins and minerals, MNP are a proven public health intervention, which allow direct fortification of all types of semi-solid foods for children 6–23 months of age, and up to the age of 12 years. Easy to use, with fewer side-effects compared to liquid iron supplements, MNP can promote better complementary feeding practices when integrated into existing infant and young child feeding programs and improve the quality of the diet in early childhood development and school feeding programs.

REGULATORY CLASSIFICATIONS FOR MNP

In addition to being included on the national EMLc, countries are recommended to register MNPs with their national regulatory agency. The regulatory classification of MNP can have implications for how the product is imported, packaged, distributed, and/or promoted, and therefore deciding whether to classify MNPs as either pharmaceuticals or food products, needs careful consideration. Classification as a pharmaceutical has sometimes exempted MNP from import taxation, particularly in instances where MNP has been included on the national list of essential commodities.[3] Countries have also reported greater flexibility and/or availability of government or donor funds for the procurement and purchase of products listed in WHO's Model EMLc. Products listed in the EMLc can also be managed by national central medical stores and tracked using Health Management Information Systems. When a food-related classification is used for MNP, regulatory standards may be lower compared to those for medicines, which may facilitate integration into food systems; however, there is the consideration as to whether national budgets can be allocated to such products. Notwithstanding, countries have the option of deciding whether to register MNP as a medicine, food, or other type of product based on what is considered most appropriate and feasible in the context of their own regulatory and policy environments.

INTEGRATION OF MNP IN INFANT AND YOUNG CHILD FEEDING, EARLY CHILDHOOD DEVELOPMENT AND SCHOOL FEEDING PROGRAMS

While the inclusion of MNP into the EMLc confirms that MNP should be considered as an essential product for public health impact, it is also a step towards making MNP more accessible and cost-effective for delivery through national health systems. This includes integration of MNP into infant and young child feeding programs, early childhood development, and school feeding programs, where they can have an effective role in improving the diets of children and complementary feeding practices. Other approaches for MNP distribution include integration within food systems, water sanitation and hygiene (WASH), and social protection programs. Regardless of the approach, programs should include a behaviour change strategy that promotes awareness and correct use of this product, proper and hygienic preparation, promotion of diverse and nutrient-dense foods, feeding of complementary foods for children older than six months and a healthy diet for children older than two years. Recommended breastfeeding practices, hand washing with soap, prompt attention to fever in malaria settings, and measures to manage diarrhoea should also be included.

DOSING SCHEME AND SPECIAL CONSIDERATIONS

Current formulations of MNP include up to 15 micronutrients depending on the needs of the target population. A suggested base formulation and dosing schedule for MNP, as listed in the EMLc, is presented in Table 1, below, for infants and young children 6–23 months of age, based on the WHO guideline. Other special considerations for program planning should consider the malaria situation and other nutrition interventions being implemented in the same population, including for the treatment of severe to moderate malnutrition, distribution of fortified foods (including iron and vitamin A fortified complementary foods for infants and young children), and large-scale fortification.

TABLE 1: Suggested scheme including dose forms/strengths for home fortification of foods with MNP consumed by infants and young children aged 6–23 months[2]

Scheme for fortification	Target group: infants and young children aged 6–23 months
Composition per sachet	Iron: 12.5 mg of elemental iron (preferably as coated ferrous fumarate)[a] Vitamin A: 300 µg retinol Zinc: 5 mg elemental zinc With or without other micronutrients to achieve 100% of the RNI[b,c]
Regimen	Program target of 90 sachets/doses over a six-month period
Settings	Areas where the prevalence of anaemia in children under two years or under five years is 20% or higher

a 12.5 mg of elemental iron equals 37.5 mg of ferrous fumarate or 62.5 mg of ferrous sulfate heptahydrate or equivalent amounts in other iron compounds. In children aged 6–12 months, sodium iron EDTA (NaFeEDTA) is generally not recommended. If NaFeEDTA is selected as a source of iron, the EDTA intake (including other dietary sources) should not exceed 1.9 mg EDTA/kg/day.

b Recommended nutrient intake (RNI). Multiple micronutrient powders can be formulated with or without other vitamins and minerals in addition to iron, vitamin A and zinc, to achieve 100% of the RNI[ii], and also taking into consideration the technical and sensory properties.

c Where feasible, likely consumption from other sources, including home diet and fortified foods, should be taken into consideration for establishing the composition of the sachet

As per the WHO guidelines, in malaria-endemic areas, the provision of iron in any form, including MNP, should be implemented in conjunction with measures to prevent, diagnose and treat malaria including the provision of insecticide-treated bed nets and vector-control programs, prompt diagnosis of malaria illness, and treatment with effective antimalarial drug therapy.

In the case of children who are receiving treatment for severe acute malnutrition using ready-to-use therapeutic foods (RUTF) – whether through an in-patient or out-patient community-based approach – MNP should be withheld. RUTF products already contain an adequate amount of vitamins and minerals, including iron. Similarly, children who are being treated for moderate acute malnutrition and receiving ready-to-use supplementary foods (RUSF) or Supercereal Plus, do not require MNP. Children with mild to moderate malnutrition, if being treated in the community and not receiving RUTF, RUSF or Supercereal Plus, should receive MNP. For further information on these topics, please refer to the following HF-TAG publications:

- HF-TAG MNP Implementation Manual
- HF-TAG Technical Brief on the Use of MNP in Malaria Endemic Regions
- HF-TAG FAQ – Technical Considerations of the Provision of MNP

TABLE 2: Suggested scheme including dose forms/strengths for home fortification of foods with micronutrient powders consumed by children aged 2–12 years[2]

Scheme for fortification	Target group: children aged 2–12 years
Composition per sachet	Iron: 12.5 mg of elemental iron (preferably as coated ferrous fumarate) for children aged two-four years; and 12.5 to 30 mg elemental iron (preferably as coated ferrous fumarate) for children aged five–12 years[a] Vitamin A: 300 µg retinol Zinc: 5 mg elemental zinc With or without other micronutrients to achieve 100% of the RNI[b,c]
Regimen	Program target of 90 sachets/doses over a six-month period
Settings	Areas where the prevalence of anaemia in children under five years of age, is 20% or higher

a 12.5 mg of elemental iron equals 37.5 mg of ferrous fumarate or 62.5 mg of ferrous sulfate heptahydrate or equivalent amounts in other iron compounds. In children aged 6–12 months, sodium iron EDTA (NaFeEDTA) is generally not recommended. If NaFeEDTA is selected as a source of iron, the EDTA intake (including other dietary sources) should not exceed 1.9 mg EDTA/kg/day.

b Recommended nutrient intake (RNI). Multiple micronutrient powders can be formulated with or without other vitamins and minerals in addition to iron, vitamin A and zinc, to achieve 100% of the RNI[ii], and also taking into consideration the technical and sensory properties.

c Where feasible, likely consumption from other sources, including home diet and fortified foods, should be taken into consideration for establishing the composition of the sachet

PROCUREMENT INQUIRIES

There exist many MNP manufacturers around the world for standard and custom needs. The standard formulation (12.5mg) for children aged 6-59mo is available in the UNICEF Supply Division catalogue for procurement.[4] UNICEF Procurement Services offers purchasing capacity and logistics expertise to development partners, so that they can use their own financial resources and donor funds to procure supplies for children.

REFERENCES

1 World Health Organization Model List of Essential Medicines for Children, 7th List, 2019. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO. Available at: https://www.who.int/publications/i/item/WHOMVPEMPIAU201907

2 WHO Guideline: Use of Multiple Micronutrient Powders for Point-of-Use Fortification of Foods Consumed by Infants and Young Children Aged 6–23 Months and Children Aged 2–12 Years. Geneva: World Health Organization; 2016. PMID: 28079999. Available at: https://www.who.int/publications/i/item/9789241549943

3 Schauer C, Sunley N, Hubbell Melgarejo C, Nyhus Dhillon C, Roca C, Tapia G, Mathema P, Walton S, Situma R, Zlotkin S, Dw Klemm R. Experiences and lessons learned for planning and supply of micronutrient powders interventions. Matern Child Nutr. 2017 Sep;13 Suppl 1(Suppl 1):e12494. doi: 10.1111/mcn.12494. PMID: 28960875; PMCID: PMC5656916. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5656916/

4 UNICEF Procurement. https://www.unicef.org/supply/procurement-services

OUR MISSION:

To facilitate actions that fill the nutrient gap and reduce malnutrition among children by providing global leadership that supports the integration of home fortification within comprehensive nutrition strategies at the national and global level.

For additional information, please visit www.hftag.org

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