

Workshop Report on Scaling Up the Use of Multiple Micronutrient Powders to Improve the Quality of Complementary Foods for Young Children in Asia

Organized by UNICEF Headquarters and UNICEF Asia Pacific Shared Service Center
Co-sponsored by the US Centers for Disease Control and Prevention

28 April – 1 May 2009
Bangkok, Thailand

Summary – Outcomes, Conclusions and Next Steps¹
– FINAL, 3 June 2009 –

1. Background

In most developing countries, stunting and micronutrient deficiencies are highly prevalent. Infants and young children aged 6-24 months and pregnant and lactating women are the most affected. Treating and preventing these deficiencies are among the biggest challenges nutrition and public health programmes face today.

Among the vitamin and mineral deficiencies affecting these high-risk groups, deficiencies of vitamin A, iron, iodine, zinc and folate are known to be highly prevalent and have important adverse consequences. While significant progress has been made in reducing the prevalence of iodine and the consequences of vitamin A deficiencies through improved household use of iodized salt and the periodic provision of high-dose vitamin A supplements to young children and lactating women, there has been limited success in reducing the burden of other micronutrient deficiencies and iron deficiency anemia in particular.

In the last decade, significant efforts have been made to develop alternative ways of providing iron to young children and reproductive age women. Numerous new and innovative products with proven impact are increasingly available to deliver iron and other essential vitamins and minerals to young children ranging from multiple micronutrient powders (e.g. *Sprinkles*, *Vitashakti*, *Anuka*, *MixMe*), spreads (e.g. *Nutributter*), and crushable tablets (e.g. *Foodlet*). Of the various products recently developed, multiple micronutrient powders (MNPs) are particularly attractive due to the fact that they are advanced in terms of research, and acceptability of use in field settings. They are affordable, and easy to use. Furthermore, there are a number of commercial suppliers with the ability to meet programme needs. MNPs fortify and improve the quality of complementary foods prepared at home and contain a number of micronutrients in a relatively “tasteless” powder form. A number of studies have been conducted showing that MNPs are efficacious in addressing iron deficiency anemia and based on current evidence can be safely and effectively administered under

¹ This summary was prepared by the workshop facilitators. Facilitators of the workshop included: Akoto Osei, Arnold Timmer, Christopher Grasset, Deepika Chaudhery, Elviyanti Martini, France Begin, Genevieve Begkoyian, Jan Komrska, Jee H. Rah, Karen Codling, Laird Ruth, Luc Laviolette, Malia Boggs, Nita Dalmiya, Noel Marie Zagre, Prakash V Kotecha, Rafael Flores-Ayala, Rita Bhatia, Roland Kupka, Sadhana Bhagwat, Saskin de Pee, Siti Halati, Sonja Y Hess, Stanley Zlotkin, Tommaso Cavalli-Sforza, Tom Schatzel, Vilma Tyler and with additional comments from Juan Pablo Pena-Rosa and Werner Schultink.

programmatic conditions. There is emerging evidence that MNPs can contribute to improving complementary feeding practices if programs are designed with that goal in mind. MNPs have the potential to contribute to the health and development of young children, their school performance and productivity in later life. As an integral component of improved complementary feeding, MNPs contribute to the nation's human capital development and impact positively on the Millennium Development Goals especially MDG1 – eradicate severe poverty and hunger. Therefore, MNPs can, as a component of improved young child nutrition, be included in national development plans such as national Poverty Reduction Strategies and Sector Wide Approaches.

It follows therefore that a joint WHO/WFP/UNICEF statement² on the importance of addressing micronutrient status of children 6 to 59 months, pregnant and lactating women in emergencies advocates for the use of multiple micronutrient preparations, such as MNPs. Scaling-up of MNPs are a high priority for all organizations that were represented at the meeting.

Several countries in Asia are supporting the distribution of MNPs or have done so in the recent past. Currently, MNPs are distributed in at least 32 projects across 14 Asian countries, most of which form part of routine development programmes. Two of these are national in scale; the majority are at a sub-national or large-scale level and some are pilots or demonstration projects. In all cases MNPs are provided as part of a wider programme such as for reduction of anaemia or micronutrient deficiencies, improvement of IYCF or as part of a comprehensive MCH package. The majority of countries target young children 6-24 months; several have expanded the target group to older children up to 59 months. MNPs are distributed without charge (free) through public health services in most of the projects. There are two large and one small scale example of social marketing of MNPs in the region. These experiences, while limited, indicate that social marketing of MNPs is feasible although it may be too early to assess their impact, sustainability and coverage. Clearly, the multitude of MNP projects in the region will significantly contribute to both the regional and the global experience. Successful projects which achieve high coverage and adherence will likely inform MNP implementation by other countries.

This workshop brought together the 14 Asian countries which have developed plans to start MNP distribution in the near future or have started to implement MNP distribution. Given the urgent need to assist these countries, UNICEF organized a workshop, co-sponsored by U.S. CDC, to introduce a common programme framework for scaling up MNPs for young children in Asia. Delegations of the 14 countries, including members from government, and nutrition institutes, participated in the workshop: Bangladesh, Cambodia, China, East Timor, India, Indonesia, Kyrgyzstan, Laos, Mongolia, Nepal, Pakistan, Philippines, Sri Lanka, and Viet Nam. International agencies with an interest in supporting MNP scale-up also participated including the World Health Organization (WHO), United Nations High Commissioner for Refugees (UNHCR), World Food Programme (WFP), United Nations Children's Fund (UNICEF), United States Agency for International Development (USAID), Sprinkles Global Health Initiative (SGHI), Global Alliance for Improved Nutrition (GAIN), Helen Keller International (HKI), U.S. Centers for Disease Control and Prevention, Swiss Red Cross, Sight and Life/DSM and the Micronutrient Initiative (MI).

² Joint Statement by the World Health Organization, the World Food Programme and the United Nations Children's Fund: Preventing and Controlling micronutrient deficiencies in populations affected by an emergency – multiple vitamin and mineral supplements for pregnant and lactating women, and for children aged 6 to 59 months. WHO, WFP and UNICEF: 2007.

Specific workshop objectives were to:

1. Provide a common programme framework for planning the scale up of multiple micronutrient powders for young children
2. Strengthen and improve plans for implementation of MNP programmes such that they are more effective, scalable and sustainable
3. Identify, prioritize and address the fundamental challenges for planning sustainable, scalable and effective MNP approaches, in the context of a country's current and evolving stages of social and economic development

Furthermore the workshop was designed to also:

1. Develop intra- and inter-country technical and programme support mechanisms
2. Replicate scalable models for MNP programming
3. Strengthen collaboration between international agencies
4. Identify research and programme implementation questions
5. Develop a basis for programme guidance, reporting and documentation

2. Outcomes

Extensive preparatory work by country delegations formed the point of departure for the workshop which provided guidance on how to position, plan and implement the use and distribution of MNPs in the broader context of improving infant and young child feeding practices. For countries that have already introduced MNPs, the workshop was an opportunity to share their plans, lessons learned – both successful practices and implementation challenges with other countries, and to further improve programmes. For countries that have not yet started distribution, draft plans were reviewed and strengthened. All participating countries developed programme frameworks to support the introduction and scale up of MNPs.

The discussions covered the main components entailed in a successful programme. As with any new intervention, current guidance falls short and an abundance of experiences and knowledge from countries is accumulating. As a result, many issues require more work and need further clarification. The sections below summarize the main observations and try to clarify issues that can help guide programmes provisionally. The Home Fortification Technical Advisory Group (HF-TAG) with representation of international agencies (UN, NGO), research/academic institutions, and suppliers, will provide advice on MNP interventions while normative guidance will be provided by WHO.

Efficacy of MNPs and research conclusions

To date 16 studies (preventive and therapeutic) have evaluated the efficacy and effectiveness of Sprinkles (one brand of MNPs) in thousands of children in Africa, Asia and the Americas. These studies show:

- Sprinkles have been shown to be as efficacious in treating and preventing anaemia as iron syrup but are better accepted and cause fewer side effects. Effectiveness of iron syrup (i.e., use in programme settings) is low, however;
- Sprinkles have been found to reduce anaemia in young children (between 6-24 months) by about 45%. In two studies (Bangladesh and Haiti), the impact of MNPs was found to be maintained for the following 6-7 months (i.e. children having received Sprinkles daily for 2 months remained non-anaemic in the 6-7 months following the study);
- Based on acceptability studies, Sprinkles were found to be well accepted and appreciated by children and caregivers;

- Generally, no significant adverse events were reported. Less than 1% of caregivers reported an increase in vomiting, hard stools or stomach upset (including diarrhoea). There was no evidence of iron overload in iron replete or deplete children as measured by serum ferritin and no negative impact on growth.
- Based on existing evidence, provision of micronutrients alone through MNPs have not been demonstrated to reduce stunting and wasting.
- Research supports the use of MNPs to control iron deficiency anaemia (safely) as follows:
 - Daily – one sachet per day for 60, 90 or 120 days OR
 - Flexibly – 60 sachets over a period of 90 or 120 days, with no more than one sachet per day
- Therefore, MNPs can be consumed daily, every other day, every week or ‘flexibly’. There are advantages and disadvantages with all distribution options and should be based on the best obtainable compliance in each programme context. One study suggests that a flexible consumption schedule may be more acceptable as caregivers are less anxious about missing a dose thus leading to better adherence and cost-effectiveness. The choice of the distribution schedule depends on the ability of existing systems to reach the intended target group with the desired frequency, the capacity of personnel to implement, communicate and monitor the distribution, and the cost and sustainability.
- Based on the above, a range of dosing and different distribution schedules and modalities are likely to be acceptable in programme settings. The appropriate schedule should be chosen based on country context (e.g. epidemiology of deficiency) and objectives. Ideally, the use of MNPs should start at the age of 6 months and, at a minimum, distribution should be repeated every 6 months until a child reaches 24 months inclusively (so 4 distributions between 6-24 months). However, distribution frequency may vary to the programme context and be conducted through continuous routine services (each child receiving at the same age) or through events (e.g. child health days every 6 months i.e. every child between 6-24 months receiving every 6 months at different ages). Messages regarding MNPs should be consistent and based on what works best and the specific country context.
- Whereas recommendations for micronutrient intake among other population groups such as school-age children, adolescent girls, and pregnant and lactating women exist, there is no existing data on the efficacy of MNPs among these groups, nor on the relative efficacy compared to multiple micronutrient tablets or capsules or the current WHO recommendation on iron-folate tablets alone. Research is therefore needed to document the impact of MNP use on the micronutrient status and its acceptability and utilization in these population groups.
- Existing WHO recommendations caution against the provision of iron supplements to young children in areas with “intense malaria transmission and high prevalence of infection”. This conclusion however, “should not be extrapolated to fortification or food-based approaches”.³

Positioning of MNPs

Because of their potential to improve child nutritional status and child development and because they can be a mitigation strategy to a food and/or economic crisis by improving the quality of the child’s diet, MNPs contribute to the achievement of the MDGs especially MDG1.

³WHO Statement on “Iron supplementation of young children in regions where malaria transmission is intense and infectious disease highly prevalent” 2006

Through the workshop's discussions the need for advocacy in a planned manner with key decision makers and stakeholder groups emerged as an essential element when introducing MNPs and for its continuation. The need for creation of an "advocacy package" and a communication plan at country level to enable this was emphasised.

Various approaches to improve micronutrient intake of young children include dietary diversification through education, fortification of processed complementary foods, micronutrient supplements and home fortification (including MNPs). Experience with MNPs so far is very encouraging and suggests that programmes that use MNPs are effective, feasible to implement, and should therefore be considered in national infant and young child feeding strategies.

Programmes for scaling up MNP should not be implemented as 'vertical' stand-alone interventions, but should be included as integral components of infant and young child feeding programmes.

Guidance and support for scaling up MNP use within young child nutrition programmes

The "WHO/WFP/UNICEF *Joint Statement on preventing and controlling micronutrient deficiencies in populations affected by an emergency*" provides guidance on provision of micronutrients to children 6-59 months, pregnant and lactating women in emergency situations. Given that emergencies exacerbate existing underlying vulnerabilities it is reasonable to extend the guidance of the Joint Statement to non-emergencies pending a more specific recommendation. WHO estimates of iron deficiency anemia highlight the unacceptably high prevalence among pre-school age children.

Although the Joint Statement provides recommendations on use of multiple micronutrient preparations, several areas need further clarification. The Joint Statement does not specify the type of preparation to be used i.e. MNP, (crushable) tablet or spreads. Also the principles for adjusting the micronutrient formulation and the rationale for prioritizing the 6 to 24 month within the 6 to 59 month age group need clarification. Furthermore, several questions were posed about use of MNPs in other age groups.

Until additional guidance becomes available through the HF-TAG and until WHO provides a recommendation for MNP use in routine programmes, based on the discussions and conclusions from the current workshop, the following provisional guidance was suggested.

Target age-group for MNPs

In emergencies, the Joint Statement recommends the provision of multiple micronutrient preparations for all children 6-59 months.

In routine programmes, the priority target age group is 6-24 months as this is the period of rapid growth and development and highest nutrient requirements. If resources are available, the provision of MNPs could be extended to children 6-59 months.

Choice of preparation

Based on the available evidence and acceptability studies, MNPs are currently the recommended preparation for children 6-24 months. It is however recognized that research in this area is rapidly evolving and that there may soon be other preparations available for field application.

Use of MNPs in other population groups

The workshop did not focus on the use of MNPs among other population groups such as school-age children, adolescent girls, and pregnant and lactating women but recognized the importance of addressing their micronutrient needs and the interest of various countries and partners to expand MNP use to other age groups. Until further evidence is available, the workshop recommendation is to address the needs of other population groups following existing WHO guidance, i.e. iron-folic acid supplements for adolescent girls, and pregnant and lactating women, and multiple micronutrient tablets for pregnant and lactating women in emergencies.

Formulation of MNPs

Two standard formulations are available (the 5 component anemia formulation which has been tested in a number of trials and the 15 component multiple micronutrient formulation).

The decision on which formulation to use depends on programme objectives: either formulation could be used to address iron deficiency anemia in young children; if the objective is to improve the quality of complementary feeding, the 15 component formulation is optimal to ensure the provision of a more complete array of micronutrients. Currently, there is a slight cost-difference between the two formulations which may also factor in when selecting formulations although it is anticipated that the cost-difference would be minimal when volumes of MNPs ordered increase.

Countries are recommended to adopt one of the two 'standard' formulations which should address iron deficiency anemia and the micronutrient needs of young children in the vast majority of countries. Careful consideration should be given before a country embarks on modifying a formulation to suit local needs. The decision to modify a formulation should only be made once the efficacy and safety has been demonstrated. Additional guidance will need to be provided by the HF-TAG. Countries should also consider the supply implications of modifying a formulation as customized formulations may require longer production times, and may also cost more than standard formulations.

Safety of providing MNPs as part of a comprehensive strategy to address micronutrient deficiencies and to enhance the daily nutrient intakes of young children

The micronutrient levels of the two standard formulations take into account that children of this age group in most developing countries have low micronutrient intakes. The formulations were developed after careful consideration of the availability of micronutrients from other sources including ongoing programmes, and the upper limits of individual micronutrients. Therefore,

- MNPs can be safely provided to children that receive bi-annual vitamin A supplementation. Vitamin A supplementation provides pharmacological doses of vitamin A to reduce young child mortality and morbidity whereas the additional vitamin A intake from MNPs helps meet the daily vitamin A requirements.
- Similarly, MNPs which contain iodine can be safely provided when iodized salt is also used by the household. There should be no concern of toxicity because the intake of iodine through MNPs in addition to iodine in salt is very unlikely to exceed the UL for most children.
- These interventions complement (rather than duplicate) each other and form part of a comprehensive approach to young child's health and nutrition.
- If adequately fortified complementary foods, i.e. meeting approximately 50% of the RNI for most or all of the 15 vitamins and minerals per portion, with the appropriate chemical form (i.e. good bioavailability) are accessible and are consumed daily by the majority of the target population, MNPs would not be required.

Phases of MNP Distribution

There are typically three potential stages for MNP in a programme development in a country. A typical scenario in a country evolves a 'start-up' phase which includes one or more demonstration projects followed by scale-up which involves widespread free public distribution for a large group of social beneficiaries. This stage may be followed by distribution through social marketing mechanisms or through market based channels targeting specific socio-economic (but not the poorest) population groups which require a developed private sector and a significant consumer market.

It is not necessary and nor is it the role of public health organizations to build social or commercial markets. However, if a public distribution system builds awareness and demand for MNPs, the private/social market may enter if they perceive an opportunity for profit. As a result, the burden of the public health system will be reduced, enabling the public health system to focus on meeting the universal rights of poor and hard to reach children for nutrition security.

Planning of programmes to scale up MNPs is multi-dimensional, including the intervention with continued improvement and integration; supply, distribution and financing; and behaviour change, operational engagement and motivation, all coordinated and managed through a central unit.

Distribution Strategies

The public health distribution channel should be selected on the basis of considerations such as coverage, capacity to deliver at community level, motivation of personnel, frequency of contact and logistics and reporting capacity. The choice of distribution strategy should also consider the dosing schedule, for example if the chosen dosing schedule is daily for two months followed by a four month 'break', a bi-annual distribution strategy could be chosen. However, if the dosing schedule is flexible through the period of a child's age between 6-24 months, distribution through a routine service with frequent contact with the child and caretaker might be more appropriate.

Supplies

- Accessing adequate, high quality supplies of MNPs in a timely manner was identified as the most common constraint by countries either planning or implementing programmes
- Adoption and adherence to a standard formulation would facilitate large scale production, timely delivery of orders and the lowest possible price.
- MNP can be produced by food manufacturers and/or pharmaceutical manufacturers. An important requirement is that manufacturers must possess a valid manufacturing licence and comply with standard requirements (e.g. HACCP, Codex Alimentarius, ISO 22000:2005 or WHO GMP).
- Certificate of analysis for each batch of manufactured MNP issued by the manufacturer confirms product compliance with the specification and further analytical testing of the product by the national authorities is redundant.
- Centralized procurement offers certain advantages in the form of expertise (in particular establishing product specifications and assessing compliance of manufacturers with quality requirements), cost savings and better lead times due to higher volumes.
- Supply from local manufacturers may be preferable for countries that envisage large scale up of the use of MNP since large and regular orders could be generated. UNICEF is able to provide capacity building support for local manufacturers, which in most cases entails support for mixing and packaging.

- Country specific layout of the packaging is available from global suppliers, but entails longer lead time and increased costs. The WFP strategy of using a generic sachet with a minimum of instructions packaged in country-specific boxes presents a good option.
- Programme planners and national regulatory authorities should ensure that government ownership is retained over logos, product names, and branded images, for products distributed through public health services.
- Procurement forecasting tools can facilitate accurate planning and assessment of the MNP supplies needed.

Communications and Training

MNPs are a new approach which requires behaviour change of the caretaker. Communications to ensure acceptance and correct utilization are essential. Based on the experience of a few countries, the communications strategy should ideally involve inter-personal communication in the community, complemented by reinforcing messages delivered by the mass media. Depending on the approach both public and/or private sector should be trained in the use of MNPs as a component of IYCF to improve quality of complementary feeding and control iron deficiency anaemia.

Formative research is necessary to identify which messages and communication channels are the most appropriate. Materials and messages need to be designed for the target communities, pre-tested and potentially adapted for different communities or local conditions.

Local names for MNPs increase community acceptance and positive messages on improved function are more appealing than negative nutrition/health messages (e.g. healthier and stronger vs. cure anaemia).

MNPs create an opportunity to improve complementary feeding practices. Country experiences (e.g. Nepal) demonstrate that MNPs have the potential to facilitate the timely introduction of complementary feeding, make complementary feeding an 'important' care practice, encourage increased frequency of feeding, and increased portion sizes and responsive feeding.

Monitoring and Evaluation

Monitoring of MNPs interventions is required to compare how well a programme/project is being executed so managers can implement timely remedial actions when needed. Impact evaluation of MNPs interventions is considered necessary to document if the programme/project achieved the intended purpose.

The Logical framework (logframe) is a tool used initially to plan and design programme/projects. Subsequently, it provides a framework for monitoring, evaluation, progress reporting, and briefings. MNPs programme/projects are encouraged to develop their own logframes.

Within the context of the logframe the Goal, Purpose and Outputs should be defined taking into account the vertical logic, meaning that if Outputs are delivered, and Assumptions hold true, then Purpose will be achieved. Performance Indicators, M&E and assumptions should be delineated using the horizontal logic.

MNPs programme/projects should have Outputs related to provision, utilization and coverage of MNPs.

The M&E column of the logframe should answer the following questions for each Performance Indicator:

- For whom the indicator will be collected (stakeholders)?

- How the indicators will be collected (source of verification, methodology)?
- How often the indicator will be collected (frequency)?
- Who will report the indicator?
- Who does what based on the information?

The impact evaluation of MNPs programme/projects should be done when the monitoring system indicates:

- Adequate provision and utilization.
- Adequate programme coverage for a minimum period.

If a decision is made to do an impact evaluation:

- The evaluation questions must be clearly defined at the onset of the process.
- The evaluators should take into consideration the different types of impact evaluation.
- The necessary resources should be available and sound evaluation standards should be applied.

3. Conclusions

There has been extensive research on **MNPs** showing that they **work** (efficacy), that they **are acceptable** and that they are **safe**. Their successful use, within IYCF programmes, has the potential to improve the quality of home-prepared complementary foods and essential young child feeding practices. This in turn will lead to better outcomes - growth and development - for young children. When used as recommended, MNPs can decrease the burden of anemia and improve micronutrient intake of other vitamins and minerals in young children. Many Asian countries are poised to scale up the use of MNP as part of an integrated IYCN strategy. Participants at the workshop revealed the current status of country-programmes. Best practices were shared and as a result of the workshop individual countries are in a better position for scaling up MNP programmes. The large scale projects in Asia will substantially contribute to the body of evidence on effective distribution channels and the effectiveness of MNPs in programmatic settings. In order to ensure documentation of this experience, it is imperative that MNP distribution is well monitored and evaluated.

Annex: MNP topics identified for HFTAG

Given the many complex technical components of 'home fortification' approaches and programmes, a Home Fortification Technical Advisory Group (HF-TAG), with representation of international agencies (UN, NGO), research/academic institutions, and suppliers, has been formed to provide technical advice and programme guidance. It is important to note that the HFTAG is not a normative agency, such as WHO. Therefore, its advice is to be regarded as guidance based on best available knowledge and experience

HF-TAG will provide guidance on various aspects of MNPs.

Specifically HFTAG will:

- Publish standards and recommend practices for quality control/quality assurance in production, packaging and storage of MNPs
- Develop programme guidance and monitoring and evaluation tools
- Develop advocacy tools related to home fortification
- Provide guidance to appropriate supply sources
- Facilitate sharing of programme experiences

Unresolved issues/follow up for the HF-TAG and/or WHO

- Use of iron and folic acid containing MNPs in areas with very high prevalence of malaria
- Environmental impact of MNP packaging
- Optimal methods for measuring adherence
- Statement on use of MNPs in non-emergencies
- Provision of generic M&E suggestions for different distribution strategies.
- Guidance on formulations:
 - Modifications of MNP formulations i.e. inclusion/exclusion of nutrients;
 - Guiding principles for changing the formulation (use of fortified foods, supplements, vitamin D deficiency)
 - Agreement within HF-TAG on whether to adopt standard formulation or adjustments by individual projects. Spell out the process for adoption and translation of evidence into programme policy and obtain consensus among HFTAG members.
- Development of a repository for supply and product quality related problems
- Technical support and quality assurance of planned country programmes
- Defining the different application criteria for MNP in an immediate crisis versus chronic emergency versus non-emergency.
- Defining quality requirements for MNP products and manufacturers.
- Further guidance on requirements for manufacturers of MNP.