Workshop Report on Scaling Up the Use of Micronutrient Powders to Improve the Quality of Complementary Foods for Young Children in Latin America and the Caribbean

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Conclusions and Next Steps² – Final, 11 October 2010–

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ACRONYMS

ССТ	Conditional Cash Transfer
CDC	Centers for Disease Control and Prevention
ECD	Early Child Development
FANCAP	Fundación para la Alimentación y Nutrición de Centro América y Panamá
GAIN	Global Alliance for Improved Nutrition
HF-TAG	Home Fortification Technical Advisory Group
IDB	Inter-American Development Bank
INCAP	Instituto de Nutrición de Centro America y el Caribe
INSP	Instituto Nacional de Salud Pública
IYCF	Infant and Young Child Feeding
IYCN	Infant and Young Child Nutrition
LAC	Latin America and the Caribbean
LNS	Lipid-based Nutrient Supplements
MCH	Maternal and Child Health
MDG	Millennium Development Goals
MI	Micronutrient Initiative
MNP	Micronutrient Powder
RCT	Research Control Trial
SGHI	Sprinkles Global Health Initiative
UNICEF	United Nations Children's Fund
WFP	World Food Programme
WHO	World Health Organization

1. Workshop summary

Extensive research shows that Micronutrient Powders (MNP) **work** (efficacy), are **acceptable** and **safe**. MNPs are particularly attractive for their ease of use. MNPs fortify and improve the quality of complementary foods prepared at home and, as the micronutrients are in a powder, tasteless form, their use does not alter the taste or look of the complementary food. Based on current evidence MNPs can be safely and effectively administered under programmatic conditions, and can be feasibly and cost-effectively implemented at scale. Successful public health scale up of MNPs requires that it is integrated within Infant and Young Child Nutrition (IYCN) and Early Child Development (ECD) programmes. Under these conditions, MNPs have the potential not only to improve the micronutrient content of complementary food and decrease the burden of anaemia, but also to improve complementary feeding and care practices of young children. This, in turn, will lead to better growth and development outcomes for young children.

Many countries in Latin America and the Caribbean (LAC) are poised to scale up the use of MNPs as part of integrated IYCN and ECD strategies. Furthermore, a unique aspect of the Latin American experience is the use of MNPs as part of an integrated package of services included under social protection schemes such as Conditional Cash Transfer (CCT) programmes to reduce social inequities. In June 2010, UNICEF and the U.S. Centers for Disease Control and Prevention (CDC) co-hosted a workshop designed to support countries with their plans to introduce and scale up MNPs. Workshop participants representing 15 countries in LAC engaged in this opportunity to discuss the current status of MNP activities in their respective countries, and improve the design of these interventions. Countries exchanged experiences in a way that contributed to strengthening their programme design, which in turn has the potential to substantially contribute to the body of evidence on the effectiveness of MNPs in programmatic settings.

2. Background

MNP and the nutrition agenda

The evidence that undernutrition jeopardizes children's survival, health, growth and development, and impedes countries' progress towards the achievement of the Millennium Development Goals (MDGs) is irrefutable. Stunting, which reflects chronic nutritional deficits, is the most prevalent form of undernutrition and affects an estimated one third – close to 200 million – of children in developing countries³. Furthermore, children with iron and iodine deficiencies have impaired physical and mental development, which in turn affects school performance and productivity in adult life. Good nutritional status contributes significantly to improvements in the rate of under-five mortality, burden of disease, maternal health and gender equality. Thus, improving the nutritional status of children is essential for achieving all the MDGs and securing the rights of children.

Experience shows that marked reductions in child undernutrition can be achieved through improvements in women's nutrition before and during pregnancy, early and exclusive breastfeeding, and good-quality complementary feeding for infants and young children, of which appropriate micronutrient interventions form an essential part. Large-scale, integrated nutrition programmes – including the promotion, protection and support of exclusive breastfeeding, providing vitamins and

³ UNICEF, Tracking Progress on Child and Maternal Nutrition. A Survival and Development Priority, 2009 at <u>http://www.unicef.pt/docs/Progress on Child and Maternal Nutrition EN 110309.pdf</u>

minerals through fortified foods and supplements, and community-based treatment of severe acute malnutrition – have been successful in many countries. Improving child and maternal nutrition is not only feasible but also affordable and cost-effective. In fact, nutrition interventions are among the most cost effective programmes and best development investments countries can make⁴.

However, progress has been uneven. While close to 60 percent of infants 6 to 9 months old receive complementary foods in developing countries, significant deficits remain in the timely introduction, quality, frequency of these foods and caring practices. Furthermore, meeting standards of dietary quality is a challenge in many developing-country settings, especially in areas where there is household food insecurity. In many cases, children do not receive complementary foods at the right age (often either too early or too late), are not fed frequently enough during the day, and/or the quality of the foods provided may be inadequate. In this respect, MNPs can provide an important entry point to improve complementary feeding practices; evidence shows that their use can prevent anaemia in young children, and also improve care around complementary feeding when programmes are designed with this goal in mind. A comprehensive approach to improving complementary feeding includes counseling for caregivers on feeding and care practices and on the optimal use of locally available foods, improving access to quality foods for poor families through social protection schemes and safety nets, and the provision of micronutrients and fortified food supplements when needed.

Among products recently developed to provide iron and other vitamins and minerals to young children and women of reproductive age, MNPs are considered particularly promising; studies have found they may reduce anaemia in young children by as much as 45 per cent^{5,6,7,8}. It should be noted that 45 percent is the highest reduction found under study conditions; therefore it is very probable that the impact on anaemia is lower during programmatic conditions. MNP sachets contain a blend of vitamins and minerals in powdered form that can be mixed into home-prepared foods, enabling families to improve the quality of complementary foods.

Workshop objectives, methods and outcome

Given the recent interest in MNP activities among countries of LAC region, it is important that countries are supported with the requisite programmatic framework that can guide implementation plans for MNPs. With this objective in mind UNICEF together with the CDC, organized a 4-day workshop in Mexico City, Mexico. Delegations from 14 countries participated in the event (Belize, Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Haiti, Honduras, Ecuador, El Salvador, Mexico, Nicaragua, Peru, and Uruguay). Participants included teams responsible for design and management of MNP interventions with representatives from government, nutrition research institutes, and national and international partners. Global and regional agencies that participated and provided technical support in the facilitation of the workshop include the Global Alliance for Improved Nutrition (GAIN), the Inter-American Development Bank (IDB), the Micronutrient Initiative (MI), the Sprinkles Global Health Initiative (SGHI), the World Food Programme (WFP) and the World Health

⁴ Bhutta ZA, Ahmed T, Black RE, et al.; Maternal and Child Under-nutrition Study Group. What works? Interventions for maternal and child undernutrition and survival. *Lancet* 2008;371:417–40.

⁵ Zlotkin S, Arthur P, Antwi KY, Yeung G. Treatment of anaemia with microencapsulated ferrous fumarate plus ascorbic acid supplied as sprinkles to complementary (weaning) foods. *Am J Clin Nutr* 2001; 74: 791–95.

⁶ Hirve S, Bhave S, Bavdekar A, et al. Low dose 'sprinkles'—an innovative approach to treat iron deficiency anaemia in infants and young children. *Indian Pediatr* 2007; 44: 91–100.

⁷ Menon P, Ruel MT, Loechl CU, et al. Micronutrient Sprinkles reduce anaemia among 9- to 24-mo-old children when delivered through an integrated health and nutrition program in rural Haiti. *J Nutr* 2007; 137: 1023–30.

⁸ Dewey KG, Brown KH. Update on technical issues concerning complementary feeding of young children in developing countries and implications for intervention programs. *Food Nutr Bull* 2003;24:5-28.

Organization (WHO); at the regional level the Foundation for the Nutrition of Central America and Panama (FANCAP), the Institute of Nutrition of Central America and Panama (INCAP) and the National Institute of Public Health in Mexico (INSP) also participated in the workshop.

The workshop had the following objectives:

- 1. Provide a common programme design framework for the scale up of MNPs for young children;
- 2. Strengthen and improve plans for implementation of MNP programmes such that they are more effective, scalable and sustainable; and
- 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 also intended to:

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

All participating countries developed or strengthened programme frameworks during the workshop for the introduction and scale up of MNPs. Extensive preparatory work was carried out by all country delegations prior to the workshop. Questionnaires were completed providing the current status of MNP plans and use, the national policy and regulatory environment, as well as coordination and management systems. Using the programme framework, countries went through a step-by-step process covering all the main programme components to develop or improve an existing plan on how to position, plan and implement the distribution and use of MNPs in the broader context of improving infant and young child nutrition. The workshop was also an opportunity for country teams to share lessons learned and challenges. Each country team was assigned a facilitator.

Prior to the workshop, a two-day pre-workshop was conducted with all workshop facilitators and presenters. The specific aim of the pre-workshop was to review the presentations to be given during the workshop and to discuss and address existing unresolved issues, align approaches and identify gaps in the workshop content and materials. As a result, the workshop format, content and guidance to countries were optimized. Facilitators also met at the end of each day to review progress, and to highlight key issues that required clarification. This approach ensured an inter-agency collaborative effort that would be a platform for continued collaboration and coordination for countries in the region.

Current status of MNP interventions in Latin America and the Caribbean

As of this workshop, 15 countries in LAC representing 16 projects support the use of MNPs. Most countries support MNP programming at a sub-national level, while others efforts are still in the pilot or demonstration project phase. At this time, one country – Bolivia – had national distribution; three other countries including Belize, Brazil, and the Dominican Republic are considering the introduction of MNPs. The size of projects and the number of beneficiaries vary widely ranging from a few hundred children in Argentina to a large proportion of the 1 million children in Haiti. In all instances, MNPs are provided as part of wider programmes for the prevention of micronutrient deficiencies (anaemia specifically), improvement of infant and young child feeding (IYCF) or as part of a

comprehensive Maternal and Child Health (MCH) package. The majority of countries target children 6 to 59 months. Only two countries, Haiti and Guyana also target the use of MNPs for pregnant and lactating women.

In most of the projects, MNPs are distributed free of charge through public health services. One of the distinctive features of programmes in the region is the inclusion of MNPs in social protection schemes such as CCTs to promote the use of health, nutrition and social services among the most disadvantaged populations. There is currently no experience with the application of social marketing strategies exclusively for MNP distribution in the region. Experiences with social marketing of MNPs in other regions may prove useful in informing their introduction in Latin America. These experiences, while also limited, indicate that social marketing of MNPs is feasible although it may be too early to assess its impact, sustainability and coverage. Opportunities may exist to expand the availability and use of MNPs to higher income groups where anaemia also constitutes a significant public health problem.

Clearly, the multitude of MNP projects in the region will significantly contribute to both the regional and the global body of evidence and experience. Successful projects that achieve high coverage and adherence will likely inform the introduction of MNPs by other countries.

3. Outcomes of the workshop

The evidence base for MNPs

MNPs represent an important public health approach to prevent and control micronutrient deficiencies in young children. MNPs were designed as an alternative delivery strategy for providing iron to infants, thereby eliminating issues associated with the use of paediatric iron through drops or syrups. In controlled trials, MNPs have yielded comparable reductions in anaemia as iron drops or syrups. Acceptability studies have demonstrated that MNPs are particularly attractive due to their ease of use. Furthermore, MNPs fortify and improve the quality of complementary foods prepared at home and contain a number of micronutrients in a relatively "tasteless" powder form.

Numerous studies (preventive and therapeutic) have evaluated the efficacy and effectiveness of MNP (i.e. Sprinkles - one brand of MNPs) in thousands of children in Africa, Asia and the Americas. These research studies show that:

- MNPs have been shown to be as efficacious in treating and preventing anaemia as iron syrup but are better accepted and cause fewer side effects. However, effectiveness of iron syrup (i.e., use in programme settings) is low;
- Based on acceptability studies, MNPs were found to be well accepted and appreciated by children and caregivers;
- MNPs have been found to reduce anaemia in young children (between 6 and 24 months) by about 45%. In two studies (Bangladesh and Haiti), the impact of MNPs on anaemia was maintained during the six month period following supplementation (i.e. children having received MNPs daily for 2 months remained non-anaemic in the 6-7 months following the study);
- Generally, no significant adverse events were reported. Less than 1% of caregivers reported an increase in vomiting, hard stools or upset stomach (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 growth⁹. Evidence suggests that adherence to MNPs is much better than to iron drops or syrups.

 Based on existing evidence, provision of micronutrients alone through MNPs have not been demonstrated to reduce stunting or wasting.

Based on current evidence MNPs can be administered safely and effectively under programmatic conditions, and can be implemented feasibly and cost-effectively at scale. Participating countries and organizations subscribe to the scaling-up of MNPs as a feasible and effective way to improve the quality of complementary food, which in turn has the potential not only to reduce anaemia, but also improve the growth and development of children.

Relevant recommendations regarding MNPs

Numerous recommendations exist which are relevant to the use of MNPs in young children (6 to 24 months). The *Global strategy for infant and young child feeding*¹⁰ recommends the use of daily fortified complementary foods or vitamin-mineral supplements for the child as needed. Poor complementary feeding practices among LAC countries have been documented, particularly among vulnerable populations, which, therefore, necessitate the use of MNPs. Another recommendation¹¹ relates to the prevention and control of iron deficiency anaemia and states that when the prevalence of iron deficiency anaemia exceeds 40%, universal, daily iron supplementation should be provided to pre-school age children (6-59 months). Most, if not all, LAC countries meet this cut-off for universal, daily iron supplementation, particularly among the most vulnerable population groups (poorest, indigenous, and rural). In 2007 WHO, WFP and UNICEF issued a *Joint Statement on preventing and controlling micronutrient deficiencies in populations affected by an emergency*¹², which recommends the provision of a daily multiple micronutrient formula for pregnant and lactating women and for children 6 to 59 months. The recommendation does not specify the type of preparation to be used i.e. powder, tablet or spread form.

WHO does not recommend the universal provision of iron supplements to young children in areas with "intense malaria transmission and high prevalence of infection". A WHO Expert Consultation ¹³ recommended that universal iron supplementation should not be implemented without the screening of individuals for iron deficiency. At the time of the workshop, the safety of providing iron through in-home fortification (powders, crushable tablets, and fat-based spreads) had not been established in malaria-endemic areas.¹⁴. The interpretation of this recommendation in the context of LAC countries and MNP use is as follows:

- Iron deficiency anaemia is a significant public health problem in LAC.
- The decision to use MNPs as a population-wide intervention should be triggered by existing prevalence data on anaemia and iron deficiency.

⁹ Sharieff W, Yin S, Wu M, Yang Q, Schauer C, Tomlinson G, ZLOTKIN S. Daily or weekly administration of micronutrient sprinkles in school has high compliance and does not cause iron overload in Chinese children: A cluster-randomized trial. Public Health Nutrition 2006;9:336-44.

¹⁰ Joint publication by the World Health Organization and the United Nations Children's Fund: Global strategy for infant and young child feeding, 2003 at www.who.int/nutrition/publications/infantfeeding/9241562218/en/index.html

¹¹ Joint Statement by the World Health Organization and the United Nations Children's Fund: Iron Deficiency Anaemia: Assessment, Prevention and Control, 2001 at www.who.int/nutrition/publications/micronutrients/anaemia_iron_deficiency/WHO_NDH_01.3/en/index.html

¹² 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.

¹³WHO Statement on "Iron supplementation of young children in regions where malaria transmission is intense and infectious disease highly prevalent", 2006 at www.who.int/child_adolescent_health/documents/pdfs/who_statement_iron.pdf

¹⁴ Food Nutr. Bull. 28(4):S621-S631, 2007

At the time of writing, a systematic review on the use of MNPs commissioned by WHO is underway and is expected to clarify and serve as the basis to revise all current recommendations. Multiple randomized control trials (RCT) are also being carried out on the safety of iron supplementation in malaria endemic areas. Therefore, at this time, and until sufficient evidence is available, MNPs containing iron should not be distributed in that context.

MNPs in National Policies

MNPs are effective in preventing and treating anaemia in young children, a critical period for growth and development, and therefore have the potential to contribute to their school performance and productivity in later life. MNPs can also be part of an integrated approach to improve complementary feeding, as part of a mitigation strategy in response to an emergency or crisis. In this way, MNPs have the potential to contribute to the nation's human capital development and have a positive impact on achieving the Millennium Development Goals, especially MDG1 (i.e. eradicate severe poverty and hunger). Moreover, from an economic point of view MNPs are very cost effective. Each US dollar spent on MNPs provides a gain in future earnings of 37 US dollars¹⁵.

Therefore, MNPs (as part of the package of nutrition interventions) should be included in national development plans and social protection schemes as a component of improved young child nutrition. The inclusion of MNPs in national development plans can be made both from the evidence base and cost effectiveness. The opportunity and need for carefully crafted advocacy plans and messages to be presented to key decision makers and stakeholder groups emerged in the workshop as an essential element when introducing MNPs. This should be part of an advocacy and communication package at country level.

Social protection programmes have been successfully implemented in a number of LAC countries, a unique feature to this region. The structure of social protection programmes, specifically conditional cash transfers, is particularly well suited to the operational requirements of MNP distribution and administration, making the combination of services a strategy worth examining.

MNP integrated in nutrition strategies

MNP interventions should be included as integral components of complementary IYCF and ECD programmes, and not as 'vertical' stand-alone interventions. It should be part of an integrated strategy using the lifecycle approach to address undernutrition, particularly stunting. Each country should explore in which nutrition programme MNPs can be integrated. Successful implementation of MNPs requires working upstream to ensure that their use is embedded in national policies or strategies (e.g. conditional cash transfer, anaemia reduction strategy), and downstream to ensure distribution and acceptance within communities.

Approaches to improving micronutrient intake of young children include dietary diversification through education, improving feeding practices through counselling, fortification of processed complementary foods, micronutrient supplements and home fortification (including MNPs and Lipid-based Nutrient Supplements (LNS)). Combining ECD activities and recommendations and tools for family stimulation can indirectly increase the impact of MNPs on children's cognitive development. Also, the idea of improving "smartness" has been known to motivate many caregivers to participate in MNP and ECD interventions.

¹⁵ Sharieff Horton Zlotkin 2006 -Can J PH -Economic Gains of a Home Fortification Program

Design of MNP interventions

In the design of the MNP interventions, important decisions need to be made regarding the product (packaging, messaging, and composition), distribution channels, communication messages, duration and frequency of providing the MNPs to children. There is no established evidence base on what the ideal MNP dose frequency and distribution channels should be. These decisions are context specific but lessons learned and best practices should be utilized to design the best possible intervention.

The first step, prior to any planning or design activity, is to conduct qualitative studies to assess the acceptability of MNPs. As a second step, formative research must be conducted to develop an appropriate communications strategy for the use and promotion of MNPs. Thirdly, a pilot intervention must be carried out, including a pilot of the monitoring system. This step is when the implementation of the intervention is designed, tested and adapted as in a real life programme situation. Only after this is conducted should the intervention be scaled up. Some considerations include:

- The use of MNPs as a potential incentive to encourage the use of other health and nutrition services and the need to set in place the necessary considerations to support adherence with MNP administration and dosage recommendations at the household level;
- Management of an MNP intervention requires sufficient budgets, good supply planning, distribution, operational engagement and motivation, all coordinated and managed through a central unit;
- Good programme monitoring will provide the necessary feedback for corrective action and also to show impact.

MNPs and other interventions to improve micronutrient intake

The micronutrient levels of the two standard formulations take into account the recommended daily micronutrient requirements for children of this age group in developing countries. The formulations were developed after careful consideration of the availability of micronutrients from other sources including ongoing nutrition programmes, and the upper level of individual micronutrients. Therefore,

- MNPs can be safely provided to children that receive bi-annual high dose 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;
- MNPs containing iodine can be safely provided even when iodized salt is also consumed at 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 established upper level for children in this age group;
- Fortified staple foods and condiments (e.g., flour, sugar, soy sauce) are intended to meet the needs of adult populations and do not cause a safety concern for the child's micronutrient intake when provided at the same time.
- The presence of complementary interventions (other than MNPs, for instance fortified complementary foods) that target the same age group (6 to 24 months or 6 to 59 months) must also be considered. When these interventions are already in place, MNPs can be introduced if those interventions are not effective. For example, this may be the case when fortified complementary foods are shared with other children and therefore do not fully benefit the intended child.

In sum, there are minimal safety concerns for nutrient intake above the upper limit with use of MNPs alone or in the situations described above. In the context of fortified complementary food interventions, it is important to assess the effectiveness of these programs and whether there is risk of exceeding the intake of any micronutrients if MNPs are introduced in this context.

Choice of MNP formulation

It is recognized that research is rapidly evolving, and that there are multiple options in terms of micronutrient preparations for use in young children. It is also recognized that modifications of the existing formulations are available and in use by countries (such as the inclusion of vitamin D where this deficiency is highly prevalent).

Two standard MNP formulations exist, a 5 and a 15 micronutrient component. Countries are recommended to adopt one of these two 'standard' formulations to address iron deficiency anaemia and guarantee that the micronutrient needs of young children in the vast majority of countries are met. The 5 component¹⁶ formulation is a so-called "anaemia formulation" tested in numerous trials and a 15¹⁷ component multiple micronutrient formulation which was primarily developed to meet the daily vitamin and mineral requirements of young children, particularly in emergency settings.

The decision on which formulation to use depends on programme objectives. Either one of the formulations could be used to address iron deficiency anaemia in young children. However, if the objective were to improve the quality of complementary feeding to ensure the provision of the recommended daily vitamin and mineral requirements, then the 15 component formulation would be optimal. Since there is only a marginal cost-difference between the two formulations, it is recommended to use the 15-micronutrient formulation.

Multiple aspects should be considered 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. 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. Decisions on in-country production should similarly be made based on commercial feasibility.

Target groups for MNPs

In routine infant and young child feeding programmes, the priority target age group is children from 6 to 24 months as this is the period of rapid growth and development and highest nutrient requirements. Depending on the context and if resources are available, the provision of MNPs could be extended to children 6 to 59 months, as in emergency situations¹⁸. In food insecure contexts, MNPs may not be the best approach. In these settings, the use of a lipid-based spread may be more appropriate.

The workshop focused on the use of MNPs in infants and young children; it did not address the use of MNPs among other population groups such as school-age children, adolescent girls, and pregnant

¹⁶ Iron, Folic acid, Zinc, Vitamin A, Vitamin C

¹⁷ Vitamin A, Vitamin D3, Vitamin E, Vitamin B1, Vitamin B2, Vitamin B6, Folic acid, Niacin, Vitamin B12, Vitamin C, Iron, Zinc, Selenium, Copper, Iodine ¹⁸ 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.

and lactating women. However, the importance of addressing the micronutrient needs of these population groups and the interest of various countries and partners to expand MNP use to other age groups was noted and its importance is recognized. Evidence regarding the use of MNPs in pregnant and lactating women is currently developing. Available information shows that MNPs are efficacious but that some studies suggest lower acceptability vis-à-vis tablets. Until further evidence is available, the recommendation coming out of the workshop 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.

Distribution channels

MNPs can be distributed through free public distribution or market-based channels when targeting specific socio-economic (but not the poorest) population groups. The latter requires a developed private sector and a significant consumer market.

In considering distribution channels, it is important to take into account the target population's (particularly most vulnerable) access to products and social/health services, community structures, geographic access, costs, the possibility of subsidization by government, and policies to improve access. Governments can improve access through the ways they classify and register MNPs, through their national policies on optimal infant young child feeding practices, and interpretation of the International Code of Marketing of Breast-Milk Substitutes. In order to determine the best distribution mechanism to reach the different population groups/market segments, all available models need to be explored. Social protection programmes typically target the very poor through free distribution, while subsidized services are available for some of the groups in other segments. The middle and higher income segments can be targeted using market-based strategies. It is probable that semi-private sector channels may be feasible for LAC, particularly for the middle and higher income population approach was used, followed by social marketing and private sector involvement and eventual take over once they see the market opportunity created by social marketing.

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, and required frequency of contact with the family, logistics and reporting capacity.

MNP in acute emergencies (as part of Relief and Recovery Operations)

MNPs are widely used in emergency situations. In fact, emergency experiences have facilitated the introduction of MNPs in routine programmes. However, while use and purpose of MNPs is similar across programme settings, the distribution mechanism, timing and monitoring and evaluation structure can vary according to the context. The main attention points for use of MNPs in emergencies include:

- Typically, MNPs are not provided in the initial phases of an emergency, especially if the product has not been previously used.
- MNPs should be introduced at a later stage, when the required communication activities can be implemented alongside the distribution of the product. Recent experiences show, most notably in Indonesia during the tsunami response but also in other countries, that large-scale distribution of MNP in early phases of emergencies is feasible.

- Faster roll out of MNP distribution can be done when MNPs have been previously used in the affected area or country. If MNPs are already in use, the project timeline can be shortened because product has already been approved, sachet design is available and the existing social marketing strategy can be used.
- The use of a universal sachet design ensures a faster roll out in both emergency and development programmes.
- In emergency-prone countries, it is important to include the provision of MNPs as a component of the early warning and preparedness plan. Guiding tools include the WHO/WFP/UNICEF joint statement¹⁹.
- Strong partnerships and good collaboration between government, humanitarian agencies and the community are essential for the rollout of the plan.
- A well-designed and executed social marketing strategy is equally important for an efficient roll out.
- Focus on programme implementation and acceptance building is a priority in an emergency, however building and implementing a monitoring system is not always feasible from the onset.

Schedule of administration (duration and frequency) of MNPs

The optimal frequency of distribution and duration of MNPs usage in a specific programme should be determined based on what works best within the context, i.e. the population and programme environment characteristics. This includes the prevalence of the deficiency, food patterns and intake, acceptability of the product, types of foods provided to children and utilization, sharing within the household, the cost of the MNP intervention, and other factors.

Based on the current evidence, the minimum number of sachets that has proven to be efficacious in reducing anaemia in study settings is 60 sachets every 6 months for each child. However, in public health settings, the number of sachets can be increased according to the country context e.g. one sachet per day (for 60, 90 or 120 days) or 60 sachets over a period of 90 or 120 days, with no more than one sachet per day. There are advantages and disadvantages with each of these options. The decision regarding distribution options should be based on the best obtainable adherence in each programme context. One study²⁰ 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. Typically, the use of MNPs should start at the age of 6 months and distribution should be repeated every 6 months, at a minimum, until a child reaches 24 months inclusively (so 4 distributions between 6 and 24 months). However, frequency varies when distributed 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 and 24 months receiving every 6 months at different ages) or a combination thereof. It is vital that messages regarding MNPs distribution and use are consistent and based on what works best in the specific country context.

¹⁹ 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.

²⁰ Ip H, Hyder SM, Haseen F, Rahman M, Zlotkin SH. Improved adherence and anaemia cure rates with flexible administration of micronutrient Sprinkles: a new public health approach to anaemia control. Eur J Clin Nutr. 2009 Feb;63(2):165-72.

Communication

The provision of MNPs requires a change in the behaviours and practices of caretakers. MNPs can create opportunities to improve complementary feeding practices. Country experiences demonstrate that MNPs have the potential to facilitate the timely introduction of complementary feeding, make complementary feeding an important care practice, and encourage increased frequency of feeding, increased portion sizes and responsive feeding. Direct contact with beneficiaries is therefore key to ensure the use of MNPs. Once the acceptance of MNPs by the potential target population has been established through acceptability studies, a communications strategy for this product, as part of the broader IYCF communication messages and strategy, needs to be developed to raise awareness, and promote behaviour change among caregivers to ensure the right sustained utilization of MNPs.

Secondary target groups such as medical professionals and other members of society, who influence caregivers' decisions related to the use of products for their children, must be considered in the formative research as well as in the communication activities for awareness raising and behavioural change (their own and as influencers of caregivers).

Formative research for the identification of appropriate messages such as the MNP name, sachet design, box packaging, communication channels and the barriers and opportunities for the appropriate use of the MNPs should feed into the communication strategy. To shorten the time required, formative research can be replicated in different locations, after adjusting its design to local settings. 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).

Secondly, to prevent negative public reporting on MNPs it is crucial (like with other public health interventions) to build public awareness and trust in MNPs targeting providers, beneficiaries, policy makers, media, decision makers, scientists and other opinion builders in the society. In the event that negative reporting occurs, a response plan needs to be prepared.

Supply and procurement of MNPs

Availing and ensuring access to adequate, high quality MNPs at the best price possible in a timely manner is the main goal of the supply and procurement process. However, it is often among the main constraints in MNP programming efforts.

In principle, MNPs should be registered as a food supplement. MNPs do not claim any therapeutic property and therefore do not have to be registered as a pharmaceutical product. Given that registration as a pharmaceutical product might limit distribution only through pharmacies, MNPs are usually not produced by pharmaceutical manufacturers. In cases where the MNP has already been registered as a pharmaceutical product and/or commissioned to a pharmaceutical manufacturer it should not be reason for concern. However, if the registration status (as pharmaceutical) prevents access to caregivers/children, this poses a serious limitation and must be addressed. Countries should also be aware that when MNPs are registered as a food product, they are not subject to the International Code of Marketing of Breast-Milk Substitutes since the Code exempts the use of vitamin and mineral supplements. However, when a national Code of Marketing of Breast-Milk Substitutes exists, any conflict with use of MNPs needs to be reviewed.

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. Ultimately, it is the manufacturer who is responsible for product quality. For example, UNICEF does not put its logo on any of the MNP products it distributes, since the organization cannot be held accountable for the product itself.

As previously discussed, MNPs can be produced by food manufacturers and/or pharmaceutical manufacturers. An important requirement is that all manufacturers must possess a valid manufacturing licence and comply with standard requirements²¹. 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 may not be necessary.

Typically MNPs are obtained from established manufacturers in the initial phase of the intervention. The consideration to produce locally (in-country or in the region) is valid and this decision should be made based on factors such as ability to meet quality standards, price, expected needs and timeliness. Local manufacturing of MNP would mainly involve packaging of premix into sachets. 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. Due to the large volume the MNP package represents relative to its content, it is good to consider local packaging. Developing local manufacturing capacity requires investment and the return on investment could be guaranteed only once a significant sales volume of the product is established. It is therefore better to start pilot projects with imported products and only once the programme has been established and there is demand for the product should the option of local manufacturing be explored. The potential to produce MNPs in LAC is a valid option and technology transfer and quality assurance for premix from other suppliers, through UNICEF Supply Division and through guidelines that are being developed by the Home Fortification Technical Advisory Group²² (HF-TAG).

A certificate of analysis does not guarantee product quality; building quality assurance system into the production and distribution process ensures product quality. An MNP stability study does not have to be conducted on all product components in an initial phase, but selected vitamins known for their quick disintegration could be selected instead (for example: vitamin A, complex B vitamins and vitamin C). Analysis of samples and stability testing of the vitamins and minerals from the field is recommended. No guidelines exist yet how to do this in a structured way. In LAC countries collection and analysis could be supported through a network of labs (e.g. the INSP has lab capable of analyzing samples), and technical support could be obtained from MI in the design of the sample collection strategy.

At the time of writing, MNPs can be procured by or through UNICEF, WFP, NGOs, or procured directly from the manufacturer. Additionally, the GAIN Premix Facility is currently certifying good quality suppliers and will be able to offer a competitive procurement process for MNPs by the end of 2010. Important decision-making considerations include quality, price, transparency and conflict of

²¹ e.g. HACCP, Codex Alimentarius, ISO 22000:2005 or WHO General Manufacturing Practices

²² The Home Fortification Technical Advisory Group (HF-TAG) is a community of stakeholders involved in home fortification comprised of members from the public, private, academic and non-governmental organization sector. The group's mission is to facilitate implementation of well-designed and effective home fortification projects at scale, based on sound technical guidance and best practices, integrated into comprehensive nutritional strategies for children.

interest, importation requirements, national ownership and capacity, lead-time, reliability of the supply line and the phase the programme is in. Procurement forecasting tools can facilitate accurate planning and assessment of the MNP supplies needed and therefore timely delivery of the product. 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.

There is no major price difference between the 5 and 15 MNP formulation since the major cost driving components are the packaging and transportation of the product. Country-specific layout of the packaging is available from global suppliers, but entails a longer lead-time and increased production costs. A good alternative is presented by WFP who developed a generic sachet with a minimum of instructions packaged in country-specific boxes. Templates for developing these are available.

Recycling and waste management need to be addressed and require a public and private partnership. In LAC, nutrition institutes like INCAP can help, as well as agencies like UNICEF and GAIN, as well as private companies.

Monitoring and Evaluation

Monitoring of MNPs interventions is required to compare how well a programme 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 has achieved the intended purpose. The logical framework (log frame) is a tool used initially to plan and design a programme and in a later stage serves as an excellent programme management tool. Subsequently, it provides a framework for monitoring, evaluation, progress reporting, and briefings.

Within the context of the log frame, 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 the purpose will be met. Performance indicators, monitoring and evaluation (M&E) and assumptions should be delineated using the horizontal logic. MNPs programmes should have outputs related to provision, utilization and coverage of MNPs. The M&E column of the log frame should answer the following questions for each performance indicator:

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

Once programmes achieve adequate provision, utilization and coverage of MNP distribution for a minimum pre determined period of time, then an impact evaluation can be conducted, keeping in mind that:

- 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.

Further key points that merit attention are:

- Developing a system for M&E is necessary and needs to be considered for all programmes, including small-scale projects;
- The monitoring system should be designed bearing in mind the possibility of a large scale programme; thinking ahead will make scale-up of the monitoring system more feasible, sustainable, and easier;
- To the extent possible, programmes should use and build on the monitoring systems that are already in place;
- It is important to convince stakeholders of the importance of impact evaluation and carry them out when the programme progress is significant and/or when management purposes require feedback on programme performance;
- It is important to design an impact evaluation before starting implementation of the programme, as these considerations may impact how the actual evaluation can be carried out; and finally,
- Aligning a log frame for a new intervention can be challenging, particularly in the context of a wider integrated multi-sectoral programme log frame.

4. Conclusions, challenges and areas for follow up

While experience in MNP use and scale up around the world have rapidly increased since 2005, many questions remain unresolved such as:

- What is the recommended use of iron and folic acid containing MNPs in areas with high malaria endemicity?
- What is the environmental impact of MNP packaging and how can this be addressed?
- What are some recommended optimal methods for measuring adherence/utilization?
- Can generic M&E guidelines be provided for different distribution strategies?
- Guidance for adjusting MNP formulations:
 - Modifications of MNP formulations i.e. inclusion/exclusion of nutrients;
 - Agreement to adopt standard formulation or allow adjustments by individual projects;
 - Spell out the process for adoption and translation of evidence into programme policy and obtain consensus (an HF-TAG responsibility).
- Development of a repository for supply and product quality related problems.
- Provision of technical support and quality assurance of planned country programmes.
- Defining the different application criteria for MNPs 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.
- Best strategies for combining MNPs with ECD programmes and messages and the impact of this combination on adherence and child development.

Follow up and support mechanisms

The workshop concluded with country delegations presenting updated plans for MNP interventions and the next steps to be taken to implement these plans. Information exchange and support mechanisms were discussed and suggestions were made including: inter-country exchange of information through information circulars, websites, inter-country exchange visits, tailored country support and documentation of best practices and lessons learned and ad-hoc consultation. Regional and global partners play an important role to facilitate this function.