GUIDING PRINCIPLES FOR THE USE OF MULTIPLE VITAMIN AND MINERAL PREPARATIONS IN EMERGENCIES

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The purpose of these guidelines produced by UNICEF on behalf of the Task Force is to provide guiding principles for the use of vitamin and mineral (VM) preparations for pregnant and lactating women and for children 6-59 months of age in emergency situations and other settings or areas where micronutrient deficiency vulnerability is considered to be a public health problem.

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FOREWORD

Vitamin and mineral deficiencies (VMD) are highly prevalent in low-income communities worldwide. When these populations are affected by an emergency, such as a major natural disaster or internal conflict, they may face food shortages or deterioration in the quality of the diet that can cause both new VMD or worsening of pre-existing VMD. Although food rations including fortified foods are distributed as best as possible within these situations, vulnerable groups, specifically children under-five and pregnant and lactating women, may still have inadequate intake of some vitamins and minerals (VM) and therefore require supplementation with multiple VM.

The World Health Organization (WHO), the United Nations Children's Fund (UNICEF), and the World Food Programme (WFP) have issued a joint statement recommending supplementation of children aged 6 to 59 months and pregnant and lactating women with multiple VM during emergencies, due to the critical role of VM in health and development [1]. The Global Consultation on the Use of Multiple Micronutrient Preparations in Emergencies (WHO/UNICEF/WFP) was held in Panama City on November 11 and 12, 2005, the objectives of which were to develop program recommendations on the use of multiple VM preparations in emergencies with consideration for recommendations in non-emergency settings, and to develop a framework of a work plan with partners to implement the recommendations at the country, regional and global level. The 8 guiding principles contained in this document are based on the joint statement and the discussion that took place during that meeting and are intended for use by those working to address the nutrition and health needs of populations affected by emergencies worldwide.

Acronyms

HKI	Helen Keller International
IUGR	intra-uterine growth retardation
IYCF	infant and young child feeding
LBW	low-birth weight
M&E	monitoring and evaluation
NGO	non-governmental organization
RDA	recommended dietary allowance
RNI	recommended nutrient intake
RUTF	ready-to-use therapeutic food
UN	United Nations
UNICEF	United Nations Children's Fund
VM	vitamins and minerals
VMD	vitamin and mineral deficiencies
WFP	World Food Programme
WHO	World Health Organization

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Guiding Principles for the Use of Multiple Vitamin and Mineral Preparations in Emergencies

Background

Vitamin and mineral deficiencies: Causes and consequences

Vitamin and mineral deficiencies (VMD) are a global public health problem affecting 2 billion people worldwide, the majority of whom are children under-five and women in developing countries. VMD emerge when the diet lacks vitamin and mineral rich foods (e.g. animal products, fruits, vegetables, and fortified foods) because they are unavailable, inaccessible, expensive, or culturally unacceptable. Increased physiological need (for development, pregnancy or lactation), repeated episodes of infectious disease and inappropriate infant and young child feeding (IYCF) also contribute to the high prevalence of VMD in developing countries.

Most of what is known about the health consequences of VMD is related to specific outcomes of inadequate iron, iodine, and vitamin A status because these are the most common VMD, affecting one-third of the world's population. Iodine deficiency can cause goitre and mental retardation; vitamin A deficiency can cause xeoropthalmia and blindness; and iron deficiency leads to anaemia. Additional effects of VMD are adverse pregnancy outcome, sub-optimal or delayed child development, growth failure, poor school-performance, and reduced productivity.

Moreover, VMD weaken immune defences and increase susceptibility to infectious disease. The contribution of VMD to infectious disease and death, largely due to the most common diseases of pneumonia, diarrhoea, measles, and malaria is such that VMD are among the 10 leading risk factors contributing to the global burden of disease [2]. The relationship between VMD and morbidity is cyclical because morbidity also contributes to deteriorating vitamin and mineral status.

Vitamin and mineral deficiencies during emergencies

Many factors contribute to increased risk of VMD during emergencies. Emergencies are defined by disorganization or destruction of community infrastructure and resources, and population displacement, and may be natural or man-made. VMD are almost always a key characteristic of the outcome because a loss of crops and livestock and a disrupted food supply mean access to food is limited to that available through relief programs. Morbidity (which contributes to VMD) can also increase considerably during emergencies due to inadequate housing and overcrowding, a lack of clean drinking water and an unhygienic environment.

Nutritionally vulnerable groups

Children aged 6-59 months

Vitamins and minerals (VM) are a necessity for health and well being throughout the entire life cycle, but certain groups are more susceptible to VMD and their consequences, especially during emergencies. Because of the known relationship between VMD and morbidity and mortality, ensuring adequate vitamin and mineral status of under-fives is a priority. While infants are protected from VMD during the first 6 months of life by neonatal stores of VM and by exclusive breastfeeding (the nutritional and immuno-enhancing properties of which ensure optimal health, growth and development), several factors contribute to greater vulnerability of children aged 6-59 months:

First, they have relatively high requirements for VM because of rapid development, particularly from age 6-23 months. During this period, growth and brain development are peaking and more severe negative outcomes are suffered if requirements are not met.

Second, increased episodes of infectious disease often cause anorexia, vomiting, and/or damage to the intestinal surface, which lower overall intake and absorption of VM. At the same time, need for VM is increased for physiological processes such as fever and cell repair.

Finally, inappropriate feeding (especially IYCF) reduces intake of VM, even when vitamin and mineral rich foods are available. From age 6-23 months, continued breastfeeding (critical both for supplying dietary VM and for protecting against infection) should be accompanied by consumption of appropriate complementary foods. In addition to being nutritionally adequate, complementary foods must be prepared and fed hygienically (to prevent infectious disease) and offered at appropriate intervals using proper feeding methods, practices that are often highly compromised in an emergency situation. From age 24-59 months, VMD can arise if family foods are low in VM. The importance of appropriate feeding (particularly IYCF) to health and development should not be underestimated and should always be supported during emergencies [3].

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VENEZUELA: An indigenous Wayuu woman breastfeeds her infant.

Pregnant and lactating women

Pregnant and lactating women are at high risk for VMD because foetal development and production of breastmilk increase requirements for VM. Outcomes of VMD during pregnancy and lactation include iron-deficiency anaemia and vitamin A-related night-blindness (which are relatively common in developing countries), as well as increased risk of morbidity.

Protecting against VMD is important not only to the health of pregnant and lactating women, but also to that of their children. Intra uterine growth retardation (IUGR), low-birth weight (LBW) [4], and mental impairment are pregnancy outcomes associated with VMD. Transfer of VM to the foetus is dependent on both maternal nutrient stores and maternal dietary intake, which may be poor during an emergency. Maternal vitamin and mineral status is also a determinant of neonatal stores.

Intake of VM during lactation helps determine the quality of maternal breastmilk. Content of water-soluble vitamins in breastmilk are especially dependent on current maternal dietary intake. This is extremely important during the first 6 months of life when infants rely solely on breastmilk to meet their nutritional needs. Infants of mothers with VMD are more likely to have inadequate intake of VM during the breastfeeding period.

Rationale for supplementation with multiple vitamins and minerals during emergencies

The contribution of food aid rations

Food aid rations provided in emergencies are not meant to address underlying VMD, but are aimed at preventing deterioration in the nutritional status of a population. They should be nutritionally adequate and well balanced, and include diverse commodities. Because highly refined cereals are low in B vitamins, iron, and other minerals, fortified foods (i.e. corn-soya blend, biscuits, vegetable oil enriched

with vitamin A, and iodized salt) form an integral part of the WFP basic ration. In the best of circumstances fresh foods are even provided, but in most emergency situations this is not feasible. Ideally, food aid is accompanied by promotion of beneficial food-preparation practices.

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INDIA: A child holds a package of fortified biscuits on remote Car Nicobar Island. The biscuits, provided by the World Food Programme (WFP) were distributed by UNICEF.

Need for supplementation with multiple vitamins and minerals

A ration that includes fortified foods will help ensure that daily recommended intakes of VM are met, but it may not fully meet the needs of children aged 6-59 months and pregnant and lactating women [5] because of their relatively higher requirements. Therefore, delivery of multiple VM to these groups, in addition to distribution of food aid, is needed during emergencies. The objective of intervention with multiple VM is to help prevent incidence of previously non-existing VMD while protecting against worsening of existing VMD (which populations affected by emergencies have often experienced prior to the acute crisis).

Supplementation with multiple VM ensures that daily requirements for all VM, rather than just those of any specific nutrient, are met. VMD rarely occur in isolation and treating specific deficiencies will never completely address the nutritional needs of a population, nor have the power to eliminate the adverse outcomes that can be traced to multiple VM rather than one specific vitamin or mineral.

Second, providing multiple VM makes certain that response to any one nutrient is not limited by coexisting deficiencies that lead to similar adverse outcome. Both vitamin A and zinc deficiencies are associated with morbidity in children. Supplementation with vitamin A alone may help reduce length and severity of sick episodes, but if the requirements for zinc are not being met, sick episodes may continue

to be grave. Supplementation with both vitamin A and zinc will ensure that neither deficiency is contributing to morbidity, and may even have a positive synergistic impact [6].

Third, supplementation with multiple VM prevents nutrient-nutrient interactions from interfering with adequate utilization of any nutrient. For example, vitamin A has been shown to mobilize stored iron and promote production of red blood cells [7]. As a result, vitamin A deficiency may prevent adequate treatment of anaemia with iron because iron is more likely to be sequestered in the liver and unavailable for erythropoiesis.

The rationale for supplementation with multiple VM in emergency situations is clear; that multiple VM will be beneficial to the health, survival and development of under-fives and pregnant and lactating women [8]. Any program that distributes multiple VM in emergency situations should ideally include a monitoring and evaluation component to assess the impact on health and nutritional outcomes.

Guiding principles

Populations affected by emergencies are at high risk of VMD. An emergency will most always lead to disruptions in the food supply and limit access to vitamin and mineral rich foods. Incidence of infectious disease, which contributes to the development of VMD, increases in an emergency because of overcrowding, a lack of clean water, poor waste disposal, and because delivery of community services such as health care is interrupted. Supplementation with multiple VM should occur as part of an emergency-response. The following 8 principles should be used to guide delivery of multiple VM to affected populations.

1. Children aged 6-59 months and pregnant and lactating women should receive multiple VM during emergencies because these groups are particularly vulnerable to VMD and their consequences.

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I**NDIA:** (Centre) Naomi Felix, holding her one-year-old son Titus, speaks with Dr. Mahesh D. Srinivas (right), at a health outreach centre in Arong Village on remote Car Nicobar Island. With fresh food scarce, Titus has eaten only milk and rice and is now suffering from malnutrition. His treatment plan includes Vitamin A and iron supplementation, fortified food and deworming.

2. Children aged 6-59 months and pregnant and lactating women should receive a daily supplement of one recommended nutrient intake (RNI) of essential VM. Young children who are consuming fortified foods should only receive two RNI each week.

3. Implementation of any additional nutritional interventions should continue alongside supplementation with multiple VM.

4. Multiple VM preparations currently available for distribution as supplements in emergencies include powders, crushable tablets and spreads. The type of preparation to be used must be chosen by carefully weighing the advantages and disadvantages of each product, within the context of each particular situation.

5. Distribution of multiple VM should represent a minimum increase in the workload of health and emergency workers in the field, and be cost-efficient.

6. Advocacy and education must occur alongside distribution of multiple VM to ensure successful use by beneficiaries.

7. Careful monitoring and evaluation should be implemented as part of every multiple VM delivery program.

8. Delivery of multiple VM should occur until the emergency phase is over and access to vitamin and mineral rich foods is achieved.

Guiding principle 1: *Children aged 6-59 months and pregnant and lactating women should receive multiple VM during emergencies because these groups are particularly vulnerable to VMD and their consequences.*

Environmental deterioration and limited access to vitamin and mineral rich foods leaves vulnerable groups susceptible to VMD during emergencies. While neonatal vitamin and mineral stores and exclusive breastfeeding protect infants from VMD during the first 6 months of life, relatively high requirements, increased episodes of infectious disease and inappropriate feeding (especially IYCF) leave children aged 6-59 at risk.

Pregnant and lactating women are also at risk because of increased requirements. Growth faltering, delayed development, and increased morbidity and mortality are outcomes of VMD in children aged 6-59 months. Increased maternal morbidity, impaired foetal development and adverse pregnancy outcome are outcomes of VMD in pregnancy, and VMD in lactating mothers may lead to lower concentrations of some VM in breastmilk thus compromising the vitamin and mineral status of infants. These negative outcomes can be prevented in emergencies by supplementation of children aged 6-59 months and pregnant and lactating women with multiple VM.

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SUDAN: A health worker hands a packet of prenatal vitamins to a pregnant woman at a clinic run by the International Rescue Committee, an NGO in the Abu Shouk camp for displaced people, near El Fasher, capital of North Darfur State.

Guiding principle 2: Children aged 6-59 months and pregnant and lactating women should receive a daily supplement of one recommended nutrient intake (RNI) of essential VM. Young children who are consuming fortified foods should only receive two RNI each week.

The recommended nutrient intake (RNI) is the equivalent of the recommended dietary allowance (RDA). The RNI (or RDA) represents the daily dietary intake level of a nutrient that sufficiently meets the requirements of nearly all apparently healthy individuals in an age and sex specific population [9, 10]. Delivery of a daily multiple VM formula containing the RNI of children aged 6 to 59 months (Table 1a) and pregnant or lactating women (Tables 1b), is recommended during emergencies. Pregnant and lactating women should receive 1 RNI supplement daily whether or not they receive fortified rations. Children aged 6 to 59 months should receive a 1 RNI supplement daily when they are not receiving fortified foods, and a 1 RNI supplement twice weekly when food rations include fortified foods that they consume.

The RNI is a small quantity that by definition poses no health threat, but is enough to control and prevent VMD. Among children aged 6-59 months who are consuming fortified foods (either fortified complementary foods or fortified family staples), the recommendation for intervention twice weekly is an additional measure to ensure safety of the supplement, and is at the same time effective. Based on the recommendations for supplementation requirements during emergencies, distribution of two multiple VM formulations, (one for children aged 6-59 months and one for pregnant and lactating women), is required.

The WHO/UNICEF joint statement [11] on iron supplementation for young children states that -- in regions where malaria transmission is intense and infectious disease is highly prevalent -- there is some evidence to suggest that iron supplementation at levels recommended for otherwise healthy children carries the risk of increased severity of infectious diseases. Based on this WHO recommendation, iron supplementation should be targeted to children who are anemic and at risk of iron deficiency, but the supplementation should be given with concurrent protection from malaria and other infectious diseases through effective case management and prevention, provision of insect-treated nets, vector control, prompt recognition and treatment of malaria, as well as promotion of exclusive breast feeding for the first six months, followed by consumption of nutrient-dense complimentary foods.

Although the WHO recommendation for iron supplementation and the policy on prevention and treatment of iron deficiency anemia have not changed, available evidence indicates that providing additional folic acid may interfere with the efficacy of anti-folate anti-malaria drugs (Sulfadoxine/pyrimethamine, SP). At the same time, widespread folate deficiency is not known to be a problem in infants and young children. Therefore, in areas where Sulfur-based anti-malaria drugs are still routinely used, the current formulation of multiple micronutrient should not be given to infants and young children.

Supplementation in the context of HIV/AIDS

The WHO Nutrition and HIV/AIDS secretariat report to the Fifty-Ninth World Assembly [13] (2006) recommended that multiple micronutrient supplementation for people living with HIV should not exceed one recommended daily allowance. This recommendation also supported the 2005 participants' statement endorsed in a consultation on Nutrition and HIV/AIDS in South Africa where it was agreed that micronutrient intakes at daily recommended levels need to be assured in HIV-infected adults and children through consumption of diversified diets, fortified foods and micronutrient supplementation as needed. [14]

Table 1a. Supplementation requirements for multiple vitamins and minerals for children aged 6 to 59 months [1].

	Children (6-59 months)	
	1 RNI	2 RNI
Vitamins		
Vitamin A, ug	400	800
Vitamin C, mg	30	60
Vitamin D, ug	5.0	10
Vitamin E, mg	5.0	10
Thiamine (vitamin B1), mg	0.5	1.0
Riboflavin (vitamin B2), mg	0.5	1.0
Niacin (vitamin B3), mg	6.0	12.0
Vitamin B6, mg	0.5	1.0
Vitamin B12, ug	0.9	1.8
Folic acid, µg	150	300
Minerals		
Iron, mg	10.0	20.0
Zinc, mg	4.1	8.2
Copper, mg	0.56	1.12
Iodine, ug	90.0	180.0

Table 1b. Supplementation requirements for multiple vitamins and minerals for pregnant and lactating women [1].

	Pregnant and lactating women
	1 RNI
Vitamins	
Vitamin A, ug	800
Vitamin C, mg	55.0
Vitamin D, ug	5.0
Vitamin E, mg	15.0
Thiamine (vitamin B1), mg	1.4
Riboflavin (vitamin B2), mg	1.4
Niacin (vitamin B3), mg	18.0
Vitamin B6, mg	1.9
Vitamin B12, ug	2.6
Folic acid, ug	600
Minerals	
Iron, mg	27.0
Zinc, mg	10.0
Copper, mg	1.15
Selenium, ug	30.0
Iodine, ug	250

Guiding principle 3: *Implementation of any additional nutritional interventions should continue alongside supplementation with multiple VM.*

As previously stated, children undergoing treatment for acute undernutrition should be excluded from supplementation with iron (and thus multiple VM) during the management phase [12]. Under all other circumstances, multiple VM delivered at the recommended dose and frequency is a safe and effective nutrition strategy, even among populations already exposed to additional nutritional interventions. These interventions include:

- Delivery of food aid rations that contain fortified foods
- Delivery of protection rations to siblings of children being treated for acute undernutrition
- Iron and folic acid supplementation of pregnant women
- Mega-dose vitamin A capsule distribution to young children and post-partum women
- Zinc supplementation of young children as an adjunct treatment of diarrhoea

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Myanmar: Aye Aye Thwe holds her son as he receives his first dose of Vitamin A from a woman health worker in North Okkalapa Township.

Supplementing with multiple VM at the RNI level in combination with other nutritional interventions is both safe and beneficial. It provides an opportunity for children aged 6-59 months and pregnant and lactating women to receive VM that are not distributed under other nutritional programs, which in general aim to address needs related to one specific vitamin or mineral. In addition, delivery of multiple VM ensures intake of key VM by individuals whom might not be covered under other nutritional programs. For example, national policy guidelines on vitamin A supplementation only provide post-partum mothers with capsules because high doses of vitamin A can harm a developing foetus, and because providing alternative doses of the vitamin requires a more complicated and expensive strategy. Delivery of multiple VM during emergency provides an opportunity for vitamin A supplementation of pregnant and lactating women without fear of associated birth defects.

Guiding principle 4: *Multiple VM preparations currently available for distribution as supplements in emergencies include powders, crushable tablets and spreads. The type of preparation to be used must be chosen by carefully weighing the advantages and disadvantages of each product, within the context of each particular situation.*

Planning for provision of multiple VM should ideally be part of a country's emergency preparedness plan so that supplements are ready for distribution at the onset of an emergency, however; this was not common practice at the time these guiding principles were developed. If there is no strategy for supplementation with multiple VM in place, an immediate assessment of the emergency situation needs to occur at its onset (as part of the monitoring and evaluation process), so that an appropriate plan for delivery to children aged 6-59 months and pregnant and lactating women can be designed. Choosing and purchasing a multiple VM preparation should happen rapidly so that distribution can begin as quickly as possible. The following steps will help guide this process:

1. Identification of program beneficiaries

When choosing which multiple VM preparation to distribute in an emergency setting, program beneficiaries must first be identified. Ideally, all children aged 6-59 months and all pregnant and lactating

women should receive multiple VM, as set out in the statement. If cost is a limiting factor, delivery of multiple VM to children age 6-23 months should be prioritized (over both children aged 24-59 months and pregnant and lactating women), as they are most susceptible to deficiencies and their consequences.

2. Identification of the objective of supplementation with multiple VM

The objective of supplementation with multiple VM is the prevention and control of VMD in children aged 6-59 months and pregnant and lactating women. Nutritional rehabilitation and treatment of severe cases of undernutrition are likely to be ongoing in an emergency situation and specific guidelines for what to provide these individuals already exist [12, 15].

3. Identification of an appropriate multiple VM preparation

At the time these guiding principles were prepared, three different multiple VM preparations were available, and hence considered, for use as supplements in emergencies. Two of these preparations contain multiple VM in the forms of a crushable tablet and a powder that is to be added to food prepared in the home. The third preparation is a spread that contains macronutrients as well as multiple VM, and is ready-to-eat. Spreads are generally used for rehabilitation of undernourished children but have the potential to be used with a different formulation to provide multiple VM. Bioavailability of VM in all three preparations is generally good and all have been used safely in young children.

In order to choose which multiple VM preparation to deliver in an emergency, the characteristics of each preparation needs to be weighed (Annex A) and the following questions answered:

- **Objective**
  - What is the size of group to receive multiple VM?
  - How is the population organized (i.e. in camps?)
  - Who will receive multiple VM? Will all children aged 6-59 months and all pregnant and lactating women receive supplements?
  - If not, who will be prioritized?

- **Production**
  - Are any of the preparations available locally?
  - If so, are they being produced under GMP systems including adequate quality control? Is appropriate packaging occurring?
  - If a preparation is not being produced locally, is it available through a central procurement facility such as UNICEF's Supply Division?

- **Availability**
  - How many supplements are needed for distribution?
  - For each preparation, what is the quantity of supplements currently available for use?
  - For each preparation, how long will it take to produce and deliver supplements for emergency intervention?

- **Stability**
  - Are there local environmental factors, such as extreme heat and humidity, which can lead to degradation of VM?
  - Where will storage of supplements occur? Do appropriate storage facilities exist at the emergency site?

- **Acceptability**
  - Is the population already familiar with the multiple VM preparation?
  - Has the multiple VM preparation been accepted in similar populations?
  - Are there any cultural factors that may affect acceptability of the preparation?
  - Does the Implementing Partner have any experience with the particular preparation?

- **Cost**
    - What will the overall cost of the intervention be? Which preparation is most cost-effective?
    - What are the budgetary constraints of the intervention?

4. Purchase of supplements

Once a multiple VM preparation has been selected, supplements should be procured as quickly as possible. Stockpiling of supplements in readiness for emergencies is ideal, and in the future may occur at the central or local level. International agencies may maintain a central stock for delivery to any emergency setting worldwide. Alternatively, willing government or non-governmental agencies may stock in-country. UNICEF is currently moving towards having both a stockpile and regular suppliers of all three multiple VM preparations, who could provide supplements in response to an emergency situation. The use of multiple VM in emergency situations is a relatively new strategy and thus the issue of supply an important concern; as their use becomes more mainstream, procuring supplements should become easier.

If supplements have not been stocked centrally, the length of time needed to produce and ship the preparation needs to be considered as supplements produced on demand may not be available for several months. For each preparation, supplements can be purchased from producers in either industrialized or less-developed countries. Locally produced supplements will be considerably less expensive than those purchased from industrialized countries, but quality control needs to be in place to ensure adequate stability and safety of the final product [16]. Proof of quality of locally produced supplements should be assessed by external quality audits.

5. Storage of supplements in the field

An appropriate facility needs to be identified for storage of supplements, based on the characteristics of the preparation, prior to their arrival in the field. Adequate storage ensures maximum stability and shelf-life of VM. This is an especially important consideration if supplements are to be stored locally because an ideal environment (a cool and dry facility) may be more difficult to find in less-developed countries.

Guiding principle 5: *Distribution of multiple VM should represent a minimum increase in the workload of health and emergency workers in the field, and be cost-efficient.*

Delivery of multiple VM should occur within current national health and nutrition programs, or emergency programs, to avoid setting up parallel chains of distribution. This will substantially reduce the workload for health workers, and lower program costs. Distribution can be conducted in intervals. Integration within the national health and nutrition system, (e.g. public health campaigns, or vitamin A capsule distribution programs), will help improve sustainability and success. If routine national and community services have been disrupted, delivery can occur within additional interventions such as food aid programs. After the 2004 tsunami in Indonesia, a relief and recovery program distributed multiple VM, iron-fortified soy sauce, dispersible zinc tablets and vitamin A capsules to affected communities through partners or HKI field teams.

Health workers and/or other community workers that will be distributing supplements should receive training on the key benefits of the multiple VM preparation, proper usage and promotion. Within this training, written guidelines and Q&A for each preparation should be provided. Because of time requirements, manpower that requires limited training is preferred for distribution (those with some knowledge or experience in public health, nutrition, food production, or distribution). Distribution should occur with collaboration from local health staff and partnerships with other NGO's or UN agencies so that coverage is increased rapidly.

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PAKISTAN: Workers load boxes of high-protein biscuits for malnourished children onto a truck at the international airport in Peshawar, capital of North West Frontier Province.

Multiple VM should be distributed with face-to-face contact between the distributors and beneficiaries. Initial face-to-face contact is needed to ensure proper introduction and usage of a new multiple VM preparation. Depending on the situation, a health worker can approach one caregiver or a group of caregivers together. Health workers and/or other community workers must be able to convey information to the beneficiaries on the importance of supplementation with multiple VM, using language that is understandable. Training should be adapted to the emergency situation as well as the local culture (habits and language) in order to access affected communities.

Written guidelines on interpersonal communication should be provided and then followed by the distributor when communicating with beneficiaries. Distributors should communicate with mothers, care takers, local health personnel (e.g. doctors, midwifes, cadre mothers), NGO staff and local leaders. Although written guidelines as well as promotion materials will be distributed, it is important to emphasize dosage and specific instructions regarding use of multiple VM preparations verbally, to avoid low compliance. Distributors should be available regularly at set times to answer any questions that beneficiaries or others might have, particularly when they've just started using the multiple VM preparation.

Guiding principle 6: *Advocacy and education must occur alongside distribution of multiple VM to ensure successful use by beneficiaries.*

If the preparation has not been used prior to emergency, multiple VM must be introduced with appropriate training, education, and advocacy to ensure consumption by beneficiaries, otherwise the program is likely to fail because of the relative newness of the multiple VM preparations in most settings. Families need to understand the importance of multiple VM, how to use the preparation in the home, and how frequently to take multiple VM. The advocacy and education component of the delivery program should include:

1. Appropriate packaging of supplements to promote acceptance and correct use

Supplements need to be packaged appropriately to ensure that they are accepted and used correctly. In some circumstances such packaging may already have been developed, but in many others that may not be the case. In these situations the following guidelines apply to package development:

- Decide on the appropriate package material to ensure adequate stability and safety of the final product.
- Seek out information on the multiple VM preparation or similar products to gather insight on names, colours, graphics, pictures, key promotion messages and directions of use that are being used successfully. When feasible, a small market survey outside the affected emergency area can be conducted.
- A brand/product name should be chosen that is identified with the content of the product itself.
- Directions for use of the preparation, included as part of the packaging, should contain information on the recommended dosage, beneficiaries with age specification, and how to use the multiple VM preparation.
- Content should also be declared on the packaging.

A number of packages can be designed and pre-tested through rapid formative research, using focus-group discussions and in-depth interviews with various members of communities that are comparable to the affected communities. In addition, formative research should assess the perceptions of the beneficiaries of the multiple VM preparation. Based on the outcomes of the formative research, the final package can be designed. The packaging should have attractive colours, graphics and pictures, and simple key promotion messages and directions of use, that are easy to understand. When appropriate packaging is already available it should be used as development requires a substantial amount of time.

2. Training materials

Generic guidelines on how to administer the multiple VM preparations should be available to health workers and community workers for translation in the local language. These generic training materials can be adapted to suit the local culture and the particular emergency situation. In the initial phase of the emergency simple written guidelines (in the local language) should be developed, according to international guidelines (WHO, UNICEF), so that health workers can be trained on how to administer the multiple VM preparations. It is also important to train health/community workers on management of potential side effects, such as darkening of the stool due to unabsorbed iron. It is best to seek both generic training materials and existing training materials that have been developed for previous programs, for immediate distribution to health volunteers, local government officials, local and international NGOs, in the affected areas. More comprehensive training materials (e.g.. a flip chart using graphics and text, training modules) can then be developed to raise awareness and educate health personnel about the multiple VM preparations.

3. Social marketing materials to help promote use of multiple VM

Social marketing materials can be used to help increase acceptance and use of the multiple VM preparations. The most appropriate medium (e.g. face-to-face, community mobilization or mass media) for program beneficiaries will have to be selected. The formats of materials (e.g. flyers, brochures, posters, radio spots) will also have to be chosen. Social marketing materials should include the following:

- Concept messages developed based on theory and research expertise in nutrition and health
- Summarized information in simple language on who should consume the multiple VM preparation, how to use it, its benefits, and how to manage potential side effects
- Key messages that are short and simple

After materials have been developed, they should be pre-tested among the beneficiaries to determine whether the materials are understood or have to be revised. Based on the outcome of the pre-testing, the design of the materials can be finalized and materials produced in sufficient quantities. The developed materials should be distributed effectively to the beneficiaries, health workers, NGO staff, partners and health officials to promote acceptance of the multiple VM preparation.

Guiding principle 7: *Careful monitoring and evaluation should be implemented as part of every multiple VM delivery program.*

The monitoring and evaluation (M&E) component of a program is essential for assessing efficacy and effectiveness of multiple VM. Data can be used to monitor distribution, acceptance and compliance, changes in the population's vitamin and mineral status, and to determine when delivery of multiple VM is no longer necessary. Analysis of collected data should occur rapidly so that implications can be used to modify intervention activities.

An initial assessment should be made following the onset of an emergency so that an appropriate delivery strategy can be developed. The initial assessment should include an evaluation of the food security and health and nutrition status of the population pre-emergency, using all available data sources. Demographic and socioeconomic data, information related to community infrastructure, and information about any cultural and dietary habits that might affect program implementation, can also be gathered. Available data should be collected as quickly as possible and when necessary, a rapid assessment at the emergency site can be conducted [17]. In addition, an estimation of the number of children aged 6-59 months and pregnant and lactating women who require intervention needs to be made.

After the initial assessment is complete, M&E of the intervention can begin. Components of the program that need to be monitored include:

1. Program coverage and distribution

Program coverage and adequate distribution are necessary for intervention with multiple VM to be effective. Delivery of the supplement to the field, effectiveness of the distribution point locations, and distribution at the individual level can be monitored.

2. Acceptability and compliance

Once supplements have been distributed it is up to individuals to consume or administer them to their children, or the benefits of multiple VM will be lost. This requires that the individuals and households covered under the program accept the multiple VM preparation and comply with the intervention protocol. Acceptance and compliance require education and advocacy to communicate the health benefits and management of side effects associated with supplementation with multiple VM. Acceptability data will be

qualitative and consist of information about how individuals feel regarding the protocol for intake, consumption (i.e. taste), perceived health benefits, and side effects.

3. Nutritional and health impact

The objective of intervention with multiple VM is to reduce negative outcomes associated with VMD, such as growth faltering, delayed development, and increased morbidity and mortality, given limited access to vitamin and mineral rich foods in an emergency situation. An evaluation of food security, morbidity and mortality, and prevalence of undernutrition, will indicate whether access to vitamin and mineral rich foods has been achieved, if health and nutrition status is improved, and if further supplementation of the population with multiple VM is needed.

Health and nutrition status of the population is usually evaluated as part of the overall M&E of an emergency, and information from these general assessments should be used for impact monitoring. If a specific M&E strategy needs to be designed, the available guidelines should be followed [13, 15-17].

Guiding principle 8: *Delivery of multiple VM should occur until the emergency phase is over and access to vitamin and mineral rich foods is achieved.*

M&E will help determine the duration of delivery of multiple VM to children aged 6-59 months and pregnant and lactating women. The joint statement issued by WHO/UNICEF/WFP reads:

"The multiple micronutrients should be given until the emergency phase is over and access to nutrient rich foods is achieved. Then an assessment of the micronutrient status of the population would be required to decide whether further interventions to prevent and control micronutrient deficiencies are still required" [1].

Access to vitamin and mineral rich foods and vitamin and mineral status of the population may often be compromised pre-emergency. Therefore, the minimum program objective should be to deliver multiple VM until the emergency phase is over and access to vitamin and mineral rich foods is back to what it was pre-emergency. A return to normality may take a long time, especially if the population has been displaced. Each situation should be judged uniquely in order to identify at which point delivery of multiple VM, as an emergency intervention, is no longer necessary. If VMD were already highly prevalent pre-emergency, additional interventions may be necessary after the population has achieved non-emergency status. Non-emergency developmental programs to address the nutritional needs of the population should follow emergency interventions.

Logistics and Supplies

UNICEF Supply Division is currently reviewing its multiple VM product range and specifications so that it can respond better to the supply requirements that will be generated by the WHO/UNICEF/WFP joint statement on multiple VM supplementation of children aged 6-59 months and pregnant and lactating women in emergencies. As there will be numerous options on the market, it is particularly important that multiple VM preparations, whether in the form of crushable tablets, powders or spreads, be carefully checked for quality and conformity with the recommended minimum composition listed in the statement. UNICEF Supply Division technical and procurement experience with nutrition products over many years will therefore be placed at the disposal of not only its own country programmes but to those of other partners. For countries that depend totally on external sourcing, the supplements that are received will be subject to normal clearance procedures based on their national laws and policies. In acute emergencies rapid clearance and distribution procedures are essential. To save costs on logistics, existing structures (e.g. government distribution chains, WFP logistics systems, NGO distribution systems) should be utilized.

For more information on UNICEF's procurement and supply of nutrition-related products, especially for use in emergencies, please contact:

- Essential Medicines and Nutrition Unit
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Annex A. Multiple vitamins and minerals preparations available for use in emergency situations

Powder preparation

Multiple VM powders are usually presented as single-dose sachets of VM in powder form that can be mixed into semi-solid food prepared in the household. Multiple VM powder can be added to porridge, mashes or gruels made from any grain or starchy roots and tubers. They can also be added to fortified or non-fortified food aid rations (e.g. corn-soy blend or wheat-soy blend). The sachet is mixed into the individual bowl/plate of each beneficiary and is not to be mixed into family foods eaten from a communal bowl/plate. The powder does not significantly change taste, colour, or texture of foods to which it is added. Several formulations have been developed and the content can be varied to meet the recommendation for use in emergencies.

The stability of the powder preparation is due to its dry form, which gives good physical resistance. Stability data show 80% of the content in the label claim after 24 months, which is the reported shelf-life with storage at 60% humidity and 25°C. The current formulation includes an overage to compensate for degradation over time.

Supplements of multiple VM powder are packaged individually in foil sachets. They have a bland taste that deters out-of-package consumption by young children, and prevents potential overdosing. In community-based efficacy trials, no adverse events have been reported, and no evidence of iron overload in either iron-replete or iron deficient children has been observed. Packaging should be tailored towards each specific population, such that pictures on the sachet, and instructions on how to use the preparation are culturally appropriate, to promote acceptability and use.

Multiple VM powders are largely manufactured on a cost-recovery basis through organizations that engage in public-private partnerships that support the sustainability of a low-cost, high quality supply. A manual outlining quality and manufacturing standards for multiple VM powder has been developed by such organizations. Multiple VM powders are manufactured under Good Manufacturing Practice (GMP) either as a food supplement or pharmaceutical dietary supplement depending on the regulatory requirements of the country in which it is distributed. Raw materials and ingredients for multiple VM powder must meet specific quality standards and have been tested to demonstrate efficacy and safety. Technology transfer for the manufacturing of multiple VM powder is feasible; local producers should demonstrate a need for the product (i.e. have a high prevalence of VMD deficiency), demonstrate commitment to reaching vulnerable populations, have a credible distribution program, and have a robust financial model to support sustainability. The local companies must meet quality and manufacturing standards dictated by the manual, meet international and local regulatory requirements and product registration, and agree to annual audit. Suppliers in Canada, India, Pakistan and Indonesia have been approved, and approval of production in Bangladesh, and Guyana is in process.

The cost of multiple VM powder will be reduced with increasing volumes. The estimated cost of production in industrialized settings is $U.S. 0.025 to 0.03 per sachet while those produced in India cost $U.S. 0.013 per sachet. A minimum order quantity of 1 million sachets is required for orders customized in terms of packaging label, language, and formulation, however smaller volumes may be feasible in a standard format. These cost estimates consider only production of the multiple VM powder and do not take into account the cost of shipping, insurance and ground delivery to the distribution centre which may represent an additional financial cost. Depending on the method of freight, (air or sea freight), the cost of freight and handling from a centralized, as opposed to local, manufacturing facility can be up to 50% of the product cost. In addition, one must consider the regulatory and importing restrictions for the import of multiple VM powder, including any applicable taxes and duties related to customs clearance. Production of multiple VM powder generally takes a minimum of 12 weeks for custom orders.

Acceptability of multiple VM powder is good, with caregivers reporting they are easy to use at home, that there are no noticeable changes in the taste or smell of infant food to which multiple VM powder is added, and they perceive improvements in the health of their child upon supplementation [20].

Crushable tablet preparation

The crushable multiple VM tablets can be taken as a chewable tablet or crushed and mixed into food, which is the delivery method recommended during emergencies. Crushable tablets are made with a high proportion of milk powder that is compressed to a soft, crushable texture, then sweetened and flavoured. A crushable tablet was recently used successfully to conduct research on supplementation with multiple VM in infants and young children [21]. The tablet is crushed and mixed into the individual bowl/plate of each beneficiary and is not to be mixed into family foods eaten from a communal bowl/plate.

The stability of the crushable tablet preparation is due to its dry form, which gives good physical resistance. Vitamins in crushable tablets are stable for 24 months, and the formula includes an overage to compensate for VM loss over time. Crushable tablets stored under tropical conditions were found to have no decrease in VM content after 18 months, which suggests relatively good stability. An advantage to this preparation is that oxidation produces spotting of the tablet, allowing for easy identification of unusable product. Although consumption of spotted tablets is not hazardous to health, it indicates a loss of VM and is an inbuilt monitoring system.

The crushable tablets are usually packaged individually in blister packs of moulded plastic film sealed with aluminium foil. Another successfully used strategy is packaging of 10 tablets in plastic tubes that have moisture-absorbent elements in the lid. The packaging helps prevent ingestion of a toxic overdose. There have been no reports of adverse effects in young children. Packaging should be tailored towards each specific population, such that pictures on the blister pack, and instructions on how to use the product are culturally appropriate.

Production of crushable tablets uses widely available and standard technology. They can be produced locally using either with a "final blend" which is fed into the tableting machine, or a concentrated “premix” of vitamins-minerals, which requires that the excipients be purchased locally and increases production process locally, but lowers cost of shipping. Quality control must include monitoring of the production environment, of the final product (weight, hardness, brittleness), quality packaging, and documentation of inspection of all aspects of production.

The cost of production of a crushable tablet is dependent on which technology (final blend or premix) is used, and the location of production. Tablets produced in Europe cost approximately $U.S. 0.55 per packet of 10 and those produced in Asia cost approximately $U.S. 0.023 each ($U.S. 0.23 per 10 tablets). These cost estimates consider only production of VM and do not take into account any cost of shipping, delivery, and advocacy. Production, processing and shipping of 300,000 10-pack tablets takes approximately 10-12 wks. The cost of freight and handling can reach up to 50% of the product cost.

Crushable tablets for use in emergencies should be crumbled over food because delivery of iron via food is less likely to produce side effects. In all situations the acceptability of tablets is good, and the preparation is generally perceived as easy to use.

Spread preparation

Spreads are generally used as ready to use therapeutic foods (RUTF) for rehabilitation of undernourished children. They could also be used to provide multiple VM, but experience with this application is limited. Spreads are ready-to-eat and do not need to be mixed into foods prepared in the household. Spreads contain dry powder ingredients and vegetable fat, and are made without water. The fat-base spreads mask the metallic taste of minerals and have been well accepted by undernourished children. They can contain between 10 g and 100 g of product and can deliver a large amount of energy, protein, and VM in a small volume (92 g of spread can contain 500 kcal). If prepared with peanut butter, spreads look and taste like peanut butter. In infants aged 6-8 months it may help to mix the spreads with other complementary foods because the thickness makes consumption in this age group difficult.

Spreads are completely different from the other two preparations due to their macronutrient content. They contain dry powder ingredients and vegetable fat, and are made without water to prevent proliferation of bacteria. Industrially manufactured spreads can be stored for two years and have no

special temperature and humidity conditions for storage, except to avoid very high temperature. Once the wrapper is opened, the spread can be stored two weeks at room temperature (up to 32-34°C) with no change in stability or nutritive value. Spreads are packaged individually in foil; however even locally made spreads which are not packaged in foil, can simply be stored 3 months in a container which is properly sealed. Packaging should be tailored towards each specific population, such that pictures on the foil wrapper, and instructions on how to use the product are culturally appropriate. An advantage to spreads is they require no need of special conditions for storage given appropriate packaging. The high fat content of a spread limits the amount a child can eat so that toxicity is not an issue.

Spreads are made from peanuts, oil, powdered milk, sugar, and multiple VM, and a final 500 kcal product weighs 92 g. Local production of spreads is ongoing in Malawi, Niger, and the Democratic Republic of Congo, with provision of technical support and quality control. Local production is easy because it only requires simple mixing (using bakery equipment) of powdered, and then fat ingredients. Quality needs to be ensured. Packaging poses the most difficult part of production, but this is not an issue if locally produced spreads are to be used within 1-2 months, because they can simply be stored in a sealed container. One disadvantage to the spread is that technological constraints limits iron content (0.5 mg iron per g spread). This is mainly an issue for meeting needs of pregnant and lactating women. Increasing iron content increases cost because in order to meet iron requirements during pregnancy (60 mg iron per day), spread intake increases to 120 g per day.

The cost of a spread is not standardized and will depend heavily on its' macronutrient content, but will be around US $3.5 per kg of spread ($U.S. 0.32 per 92 g spread), which is relatively high compared to the other two multiple VM preparations. Cost of locally produced spreads is dependent on cost of ingredients. These cost estimates consider only production of the VM and do not take into account any cost of shipping, delivery, and advocacy. The cost of freight and handling can reach up to 50% of the product cost.

Spreads are easy to use because they ready-to-eat and acceptability has been high among families and children in regions where peanuts are a local food.

Table 1. Composition of three preparations of multiple vitamins and minerals for children aged 6 to 59 months

	Powder	Crushable tablet	Spread (92g)
Energy (kcal)	--	--	500
Protein (g)	--	--	12.5
Lipid (g)	--	--	32.9
Vitamin A, ug	375	375	840
Vitamin C, mg	35	35	49
Vitamin D, ug	5	5	15
Vitamin E, mg	6	6	18.4
Thiamine, mg	0.5	0.5	0.55
Riboflavin, mg	0.5	0.5	1.66
Niacin, mg	6	6	4.88
Vitamin B6, mg	0.5	0.5	0.55
Vitamin B12, ug	0.9	0.9	1.7
Folic acid, ug	150	150	193
Calcium, mg	--	--	276
Iron, mg	10.0	10	10.6
Zinc, mg	10.0	10	12.9
Copper, mg	0.6	0.6	1.6
Selenium, ug	--	--	27.6
Iodine, ug	50	50	92

Table 2. Characteristics of three multiple vitamin and mineral preparations

	Powder	Crushable tablet	Spread
Impact	• Improved VM status • Reduction in anaemia	• Improved VM status • Reduction in anaemia	• Improved VM status • Reduction in anaemia • Improved growth
Bioavailability of VM	• Good	• Good	• Good
Stability of preparation	• Dry form gives good physical resistance • Overages added to compensate for degradation over time • 24 mo shelf life	• Dry form gives good physical resistance • Overages added to compensate for degradation over time • 24 mo shelf life	• Made without water prevents proliferation of bacteria • 24 mo shelf life if produced commercially
Storage requirements	• Low humidity and temperature ideal for warehousing • Storage under ambient conditions is acceptable within the family dwelling	• Low humidity and temperature ideal for warehousing • Storage under ambient conditions is acceptable within the family dwelling	• No special requirements
Packaging	• Foil sachets	• Foil blister packs • Tubes	• Foil wrapper
Safety	• Packaging forms first barrier • Bland taste prevents over-consumption	• Packaging forms first barrier	• Packaging forms first barrier • High fat content and volume of the food limits the amount a child can eat
Production	• Industrialized setting • Local settings, production requires licensing and technology transfer, • Or non-licensed production	• Industrialized setting • Local settings, can be produced with a pre-mix or final blend locally	• Industrialized setting • Local settings, low technology allows production under license, • Or non-licensed production
Cost	• Industrialized setting: US $0.025-0.03 per sachet • Local setting: US $0.013 per sachet	• Industrialized setting: US $0.055 per tablet • Local setting: US $0.023 per tablet	• Industrialized setting: $0.34 per 92 g spread • Local setting: US $3.50 per kg ($0.32 per 92 g)
Acceptability	• Well accepted	• Well accepted	• Well accepted

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