

**WHO MEETING ON ESTIMATING
APPROPRIATE LEVELS OF VITAMINS
AND MINERALS FOR FOOD
FORTIFICATION PROGRAMMES:
THE WHO INTAKE MONITORING,
ASSESSMENT AND PLANNING
PROGRAM (IMAPP)**

GENEVA, SWITZERLAND, 22 JULY 2009



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Declarations of Interest

Participants of the WHO Meeting on Estimating Appropriate Levels of Vitamins and Minerals for Food Fortification Programmes: The WHO Intake Monitoring, Assessment and Planning Program (IMAPP) reported the following:

A. Seal declared a patent, trademark or copyright that might be enhanced or diminished by the outcome of the meeting. This relates to the development of NutVal spreadsheet application (a non-commercial free-ware). P. Guinot declared that within the past three years he was employed by Roche Pharmaceuticals, who has an interest related to the subject of the meeting. The other participants declared they had no conflicts of interest.

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ABBREVIATIONS

| | |
|-----------|--|
| AI | Adequate Intake |
| ARS | Agriculture Research Service of the United States Department of Agriculture |
| A2Z-USAID | A2Z: The USAID Micronutrient and Child Blindness Project |
| CDC | US Centers for Disease Control and Prevention |
| CV | Coefficient of Variation |
| DRI | Dietary Recommended Intake |
| EAR | Estimated Average Requirement |
| EU | European Union |
| FAO | Food and Agriculture Organization of the United Nations |
| FBF | Fortified Blended Foods |
| HANR | Harmonized Average Nutrient Requirement |
| HNRV | Harmonized Nutrient Reference Value |
| HUNL | Harmonized Upper Nutrient Levels |
| IOM | Institute of Medicine |
| NHD | Department of Nutrition for Health and Development |
| NRV | Nutrient Reference Value |
| PAHO | Pan American Health Organization |
| RDA | Recommended Dietary Allowances |
| RNI | Recommended Nutrient Intake |
| t | tonne |
| UL | Tolerable Upper Intake Level |
| USAID | United States Agency for International Development |
| USDA | United States Department of Agriculture |
| WHO | World Health Organization |

1. INTRODUCTION

Food fortification with vitamins and minerals is currently considered as one of the main approaches to improve vitamin and mineral intake in populations. In 2006, *Guidelines on Food Fortification with Micronutrients* were published by the World Health Organization (WHO) in collaboration with the Food and Agricultural Organization of the United Nations (FAO) to provide technical guidance for the implementation of food fortification programmes as a public health intervention.

In designing an effective food fortification programme, calculating the vitamins and minerals to add to foods to be fortified, as well as the amounts, is a complex task that requires knowledge about usual dietary intakes, potential food vehicles, and other micronutrient-related interventions being implemented simultaneously. When defining nutritional goals, it is important to assure that the levels of micronutrients added are both safe and efficacious for all population groups consuming the fortified food vehicle. A meeting convened in Washington DC, United States of America in 2006 organized by A2Z, United States Agency for International Development (USAID), the US Centers for Disease Control and Prevention (CDC), and WHO/PAHO on *The Use of Food Intake in Designing, Monitoring and Evaluating Mass Fortification Programs* identified that food consumption data can be useful for establishing the nutrient gaps, assessing the contribution of fortified foods to the total intake of vitamins and minerals, selecting potential food vehicles to be used, and monitoring and evaluating ongoing programmes.

To facilitate use of the methodology described in the WHO/FAO *Guidelines on Food Fortification with Micronutrients* for determining the appropriate level of vitamins and minerals to add to a food vehicle, WHO is working in collaboration with the University of Hawaii, Iowa State University, and the United States Department of Agriculture, Agriculture Research Service's (USDA, ARS) Western Human Nutrition Research Center in Davis, California, to develop a software tool that will enable public health managers to calculate the optimal level of additional micronutrients for food fortification with user-friendly software, using locally available data.

The Department of Nutrition for Health and Development (NHD) convened a meeting to present a draft the WHO Intake Monitoring, Assessment and Planning Program (IMAPP) and solicit feedback from potential users.

Objectives of the meeting

- i. To present the WHO IMAPP software for estimating the amount of micronutrients to be used in food fortification.
- ii. To understand the synergies of this software tool with the existing USAID Food Fortification Formulator program.
- iii. To solicit feedback on the software program from potential users.
- iv. To review plans for finalizing and disseminating the software program and the feasibility of conducting training workshops.

2. OVERVIEW OF THE WHO INTAKE MONITORING, ASSESSMENT AND PLANNING PROGRAM (IMAPP)

(PRESENTED BY A. CARRIQUIRY)

The primary purpose of this software program is to estimate if a given fortification strategy would be safe and efficacious for most individuals of the population groups consuming food vehicles targeted for fortification. In addition, the program could be widely used for monitoring and evaluating the adequacy of nutrient intakes of populations. WHO IMAPP is being developed in collaboration with Dr Alicia Carriquiry of Iowa State University, Dr Lindsay Allen of the USDA, ARS Western Human Nutrition Research Center, and Dr Suzanne Murphy of the University of Hawaii. The software program is a user-friendly tool that does not require extensive expertise in statistical calculations from the users. Default values are available for many of the statistical and nutritional parameters. All aspects will be clearly documented in the user's manual.

To evaluate intakes accurately, the user can provide estimated daily dietary data (e.g. from 24-hour recalls or food records) for individuals from a representative sample of the population of interest (the presenter considered that at least 100 individuals per population subgroup would be sufficient to provide an acceptable estimate). For each person, the data must contain daily nutrient intakes as well as daily intakes of potential food fortification vehicles. All food mixtures containing the potential food vehicles (e.g. flour in bread) must be disaggregated by the user prior to the analysis to ensure that total intake of the food vehicle is accurately captured. Bioavailability factors may be specified by the user for iron and zinc, or may be based on dietary patterns as described in the documentation. Using this information, the program calculates the predicted prevalence of inadequate and excessive intakes of each nutrient before and after fortification.

The nutrient parameters used for these calculations are average nutrient requirements [such as Estimated Average Requirements (EAR) from the USA/Canadian Dietary Recommended Intakes (DRI)] and safe upper levels of intake [such as the Tolerable Upper Intake Levels (UL) from the USA/Canadian DRI]. These parameters may be specified by the user or the user may choose to use the reference values available as options in the program, which have been developed for each age/gender/reproductive group. To apply the correct nutrient parameter, the user must specify the age, gender, and reproductive status (pregnant, lactating, or neither) for each person in the population. The IMAPP software then produces estimates of the prevalence of inadequate and excessive intakes for each of these groups.

To accurately estimate the usual daily intakes and therefore the prevalence of inappropriate intakes, it is crucial to adjust the intake distributions for within-person day-to-day variation of nutrient intakes. Without this adjustment, both the prevalence of inadequacy and the prevalence of excessive intakes will typically be overestimated, often by 100% or more. For this adjustment there should be multiple (two or more) days of dietary data for at least a representative subsample of the population (no fewer than 35

individuals, but preferably more). Using these data, the software can calculate the ratio of the day-to-day variation (the within-person variation) in nutrient intakes to the between-person variance, and use this ratio to adjust the intake distribution. Although not ideal, if only one day of intake is available, the software provides an option to use variance ratios from other intake data sets.

The first output of the software program is a tabulation of the prevalence of inadequate intakes and the prevalence of excessive intakes for each of the age/gender/reproductive groups before fortification. The program also can estimate the additional amount that would be necessary to add to the diet (through several fortified foods, and even several interventions) to reach the specified target prevalence of adequacy. The user may then specify the level of fortification for a food vehicle, and the software will recalculate the estimates. If the estimates are too high (exceeding upper levels) for any of the nutrients in any population subgroup, the user may specify a different level of fortification and rerun the program. If no level of fortification provides satisfactory results, then the user may wish to consider fortifying a different food vehicle, or multiple food vehicles, and repeat the above process until the expected results are obtained.

The software also provides several output data files that may be used for further analyses, such as usual nutrient intakes at each percentile from 1 to 100, estimated usual intakes before and after fortification, and other statistics associated with the usual intake distributions.

Summary of discussion on the presentation

Participants discussed how the WHO IMAPP would be applied to specific settings, such as in urban and rural areas, in countries where there is wide variability in nutrition intake for specific age groups, and during particular seasons. Using the example of iron fortification of corn *masa* flour tortillas in Mexico, participants discussed the relevant steps in using the software, including assessment of iron intake by age and gender groups, collection of information on corn *masa* flour tortilla consumption, targeting specific populations, using the WHO IMAPP software to estimate the amount of iron to be used, and adjusting the values.

Participants discussed the strengths, weaknesses, and assumptions of different survey design methods for dietary consumption in populations. National surveys were considered to be ideal in order to ensure that fortification with a specific micronutrient does not reach undesirably high levels for some groups in countries where there is great variability in intakes. However, it was recognized that national surveys with good survey design can be useful even with small sample sizes. It was emphasized that the WHO IMAPP is intended for use with individual level intake estimates but might be useful for household or population level estimates as well; however, further validation of the software would be required for this application.

3. OVERVIEW OF THE USAID Food FORTIFICATION FORMULATOR (PRESENTED BY O. DARY)

Vitamin and mineral deficiencies can occur due to low dietary intake, impaired biological utilization (low bioavailability, parasitism), and/or increased losses (sickness). Estimating micronutrient intakes involves summing the nutrient content of foods (obtained in food composition tables) multiplied by the amount consumed and the frequency of consumption of those foods. An equilibrium between meeting nutrient needs and allowing for the safe consumption of micronutrients for most individuals of the population must be reached. It is important to seek information on how to estimate the nutrient intake gap and the percentage of people with inadequate nutrient intakes. To close the nutrient intake gap, additional intake of micronutrients is needed, along with good coverage of those who benefit from the additional micronutrient intake. If the micronutrient deficiency is due to inadequate intakes, several strategies can be used for providing additional intakes of micronutrients including: 1) improving dietary diversity, 2) food fortification, and 3) supplementation with vitamins and minerals.

Food fortification is the practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements), in a food so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health¹. Three types of food fortification have been identified: mass fortification that is usually instigated by the government and that uses staple foods and condiments to deliver additional vitamins and minerals to the population at large; targeted fortification that might use the same food vehicles but because the serving size and the benefited population are strictly controlled higher fortification levels can be used in order to provide most of the micronutrients needed in only one vehicle; and market-driven fortification, which is a business-oriented initiative that adds micronutrients to commercially distributed foods to increase the perceived value to consumers. Both mass fortification and market-driven fortification deserve careful formulation because the usual consumption pattern is not controlled. The WHO IMAPP focuses mainly on mass fortification.

Intake data can be collected at several levels: country-level (food availability data), household level, and individual level. IMAPP uses individual-level intake data, while the USAID Food Fortification Formulator uses country-level or household-level data. An example of how to proceed if only food availability data is known can be found in Annex 1.

The USAID Food Fortification Formulator² uses the proportional adult energy requirements for each age and gender group of the family to approximate

¹ Allen L et al., eds. *Guidelines on food fortification with micronutrients*. Geneva, World Health Organization and Food and Agricultural Organization of the United Nations, 2006. (http://whqlibdoc.who.int/publications/2006/9241594012_eng.pdf, accessed 21 May 2010).

²Dary O, Hainsworth M. *The Food Fortification Formulator: Technical Determination of Fortification Levels and Standards for Mass Fortification*. A2Z: The USAID Micronutrient and Child Blindness Project, Academy for Educational Development, 2008.

the possible intake values by each family member. In a vegetable oil fortification example, if adult women are 0.79 adult equivalents (i.e. they require 79% of the energy intake of the adult males), then the corresponding vegetable oil intake values would be 5th percentile P5 = 7 g/day, 50th percentile P50 = 14 g/day, and 95th percentile P95 = 28 g/day. Likewise, for children 4-6 years of age with an adult equivalent proportion of 0.47, the approximate intake values for P5, P50 and P95 would be 4 g/day, 8 g/day, and 17 g/day, respectively.

For example, if 20 mg vitamin A/kg is selected as the fortification level for vegetable oil, the USAID Food Fortification Formulator estimates the following median intakes: adult males 360 µg (20 x 18); adult females 280 µg (20 x 14); and children 4-6 years of age 160 µg (20 x 8). The Formulator also expresses those intakes in terms of the corresponding EAR values of each one of the different age/gender groups, because the EAR values are different for each one of them. In the example above, the percentage of the EAR for adult males, adult females, and children 4-6 years of age are 84%, 78%, and 50%, respectively.

Other functions of the USAID Food Fortification Formulator include estimation of the micronutrient levels that are expected to be found in the factory and retail stores, considering losses during production, storage and transportation, as well as technical variability in the fortification process. The latter is useful to estimate the probable minimum and maximum levels in individual samples. The USAID Food Fortification Formulator assumes an acceptance of 80% around the mean, i.e. the 10th and 90th percentiles of the estimated micronutrient content. For making this estimation, the program computes the minimum level as equal to the average level multiplied by $1 - 1.28 \text{ CV}$ of the process divided by 100. The factor 1.28 is specific for an acceptance of 80%. Thus, if the CV of the process is 15%, then the minimum level is: $20 \times (1 - 1.28(15)/100) = 20 \times 0.81 = 16 \text{ mg/kg}$. The maximum level is calculated similarly, but the variation is added. Thus: $20 \times (1 + 1.28(15)/100) = 20 \times 1.19 = 24 \text{ mg/kg}$. The legal minimum level can be established after considering the estimated proportion lost between processing and the retail level. Thus, if losses are 25% for vitamin A, then the expected minimum level at retail stores is: $16 (1 - 0.25) = 12 \text{ mg/kg}$.

The USAID Food Fortification Formulator can also calculate the micronutrient content of premixes used in food fortification, as well as provide estimates of the probable cost in terms of fortificants, per metric ton of product, and yearly per beneficiary.

For the USAID Food Fortification Formulator program, the following data are needed for input:

1. Per capita consumption of the food vehicle.
2. Proportion of the population utilizing the food vehicle.
3. Intake goals in terms of percent EAR.
4. Assumption about bioavailability of some minerals from the diet.
5. Micronutrient intakes (for those with UL values) from other sources.
6. Price of the food vehicle.

The outputs of the USAID Food Fortification Formulator program include the following estimates:

1. Intake in absolute terms, and percent of EAR and/or percent of Recommended Nutrient Intake (RNI), at percentiles P5, P50 and P95.
2. Expected levels of fortification for food control at factories and retail stores.
3. Premix formulation.
4. Fortification cost of the fortified vehicle (per tonne), and the premix (per kg).
5. Fortification cost per micronutrient.
6. Fortification cost per consumer.

Summary of discussion on the presentation

Participants discussed the strengths of the USAID Food Fortification Formulator program including its ability to consider feasibility and costs. Specific topics discussed included the assumptions to be made related to costs, overage in production costs and manufacturing precision, as well as how often prices should be updated. In addition, participants discussed the importance of the proportion of the population above the UL, and which set of reference values (i.e. WHO/FAO, IOM) could be used.

4. INTERFACE OF THE WHO IMAPP AND USAID FOOD FORTIFICATION FORMULATOR

Participants discussed the possibilities and potential challenges of integrating the WHO IMAPP and USAID Food Fortification Formulator programs. For instance, the WHO IMAPP could provide an estimate for the level of food fortification needed to fill a specific intake gap, and the USAID Food Fortification Formulator program could provide an estimate of costs, and the expected micronutrient levels at factories and retail stores that would be useful for quality control. The WHO IMAPP does not consider feasibility or costs, but the USAID Food Fortification Formulator program does. Participants discussed the possibility of combining (or linking) the two programs in the future and making them freely available on the internet.

5. HARMONIZED NUTRIENT REFERENCE VALUES

(PRESENTED BY L. ALLEN)

The presenter highlighted the need for Harmonized Nutrient Reference Values (HNRV) given that neither WHO/FAO nor Institute of Medicine (IOM) values might be adequate for estimating the prevalence of inadequate or excessive intakes of all nutrients or for developing fortified foods specifications. WHO uses the RNI, covering 97.5% of the population, as the Nutrient Reference Value (NRV). The IOM uses the EAR (average requirement), the Recommended Dietary Allowance (RDA; to cover 97.5% of the population), and the UL (level above which risk of adverse effects increases). EAR values are needed in order to calculate the percent of the population with inadequate intakes. WHO/FAO did not set EAR values in the 2004 *WHO/FAO Vitamin and Mineral Requirements in Human Nutrition*¹ report. A table of EAR values for some micronutrients was published in the *WHO/FAO Guidelines on Food Fortification with Micronutrients*, but these values were calculated using an assumed coefficient of variation (CV) for requirements, and the validity of this approach is questioned. The IOM has some EAR values, but not for all nutrients. UL values are also needed for calculating the percent of the population at risk of excessive intakes. WHO/FAO has no published UL values and although the IOM has UL values, a few are controversial.

The use of HNRV is justified by the following:

- All nutrient reference values have a degree of uncertainty.
- Some recommendations differ substantially between WHO/FAO and IOM, although sometimes WHO/FAO uses those of IOM.
- There is large uncertainty about the true bioavailability of micronutrients across different diets (and fortificants).
- Food intake and composition data are not always accurate.
- In the absence of harmonized values, little effort can be made to estimate nutrient intake gaps and excesses, or to formulate interventions appropriately.

¹ *Vitamin and mineral requirements in human nutrition*. Report of a Joint FAO/WHO Expert Consultation on Human Vitamin and Mineral Requirements, Bangkok, Thailand, 21–30 September 1998. 2nd ed. Geneva, World Health Organization, 2004. (<http://whqlibdoc.who.int/publications/2004/9241546123.pdf>, accessed 21 May 2010).

For the *WHO/FAO Guidelines on Food Fortification with Micronutrients*, a temporary solution to the lack of HNRV was to create EAR values. Since NRV from WHO/FAO meet the needs of 97.5% of a population group, they are set at ≈ 2 CV above the average requirement. The USA/Canadian DRI published some CV values (2 CV=20-40%), and therefore WHO subtracted 20%-40% from the NRV to produce an “EAR” as they appear in the publication. However, this was not possible for nutrients with no NRV (≈ 8 nutrients), or where the CV was not available (9 nutrients).

The current approach suggested by the author for establishing Harmonized Average Nutrient Requirements (HANR) would be:

1. If the difference between the RDA from IOM and the RNI from WHO/FAO is $\leq 10\%$, they are defined as “similar” and EAR from IOM’s could be used as the HANR.
 - This includes B vitamins, vitamin D, iodine (except for lactation), magnesium (except for adults), calcium (except for adolescents), and zinc (with modifications suggested by the International Dietary Zinc Consultative Group, IZiNCG).
Note that IOM values for vitamin D are Adequate Intakes (AI).
2. For nutrients lacking any recommendations by WHO/FAO, EAR from IOM’s could be used as the HANR as an option in the software.
 - This includes vitamin E, choline, phosphorus, and all trace minerals except for selenium, iron, and iodine.
3. Where IOM only has an AI and not an EAR, the HANR will be estimated as the AI minus 2 estimated CV of the requirement. These were compared for reasonableness with EAR values from the United Kingdom.
 - This includes calcium, pantothenic acid, biotin, choline, chromium, and manganese.
 - The method may overestimate the prevalence of inadequate intakes, but these are not nutrients of major public health importance, except for calcium.
4. For nutrients with an RDA and RNI that are substantially different ($\geq 10\%$), an HANR was developed based on specified scientific considerations. United Kingdom values were also referred to.
 - This includes vitamins A, C, and K, magnesium and selenium.

For example, WHO/FAO RNI values for vitamin C are 50-65% lower than the RDA from IOM except for young children where they are 200% higher. WHO/FAO used the average intake needed. EAR values from IOM were used as the HANR for all age groups, resulting in HANR that are slightly higher than the RNI.

For vitamin E, WHO/FAO has no recommendation (insufficient data). In the United Kingdom, requirements are based on the intake of polyunsaturated fatty acids and a “safe intake” is set at 3–4 mg α -tocopherol/day. IOM’s EAR is 12 mg/day. This causes 79% of school-age children in the USA to have an inadequate intake of vitamin E, although there is no evidence of deficiency. In developing countries, much “vitamin E” intake is γ -tocopherol, which may not have vitamin E activity. Therefore, the author decided to use IOM’s EAR as the HANR. This may overestimate the prevalence of inadequate intakes where most intake is from α -tocopherol.

In developing the Harmonized Upper Nutrient Levels (HUNL), because WHO/FAO has no established UL values, UL values from the IOM can be equated to HUNL, except for zinc where IZiNCG’s recommendations are used¹.

The presenter recommended that WHO/FAO/IOM review and consider the use of these harmonized values (perhaps after modifications). This approach, i.e. harmonization among WHO/FAO and IOM values, checking with other countries values as appropriate, would be a very cost-effective approach to developing HANR and HUNL (and Harmonized Recommended Intakes) that are globally useful. They can be updated and modified as needed.

The presenter suggested that HNRV can be used to estimate the prevalence of inadequate nutrient intakes within and across populations, to identify the size and type of nutrient gaps in different population groups, to simulate the effect of fortifying with specific amounts of micronutrients on the percent of individuals with intakes less than the EAR and percent greater than the UL, and to simulate the effects of other nutrient interventions. IMAPP could potentially take the HNRV and correct for differences in bioavailability, and even requirements, across populations.

Summary of discussion on the presentation

Most participants welcomed the proposal to harmonize reference values, and urged the publication of a paper with the rationale for the calculations. Specific topics discussed included overestimation and underestimation of cut-off values, bioavailability, and UL values and whether or not going above the UL was a serious problem.

One suggestion to achieve global harmonization and support was to broaden the review to include recent UL values from the European Union (EU). However, some participants highlighted that the different agencies in various countries and WHO may use similar evidence but they all had different targets for different purposes. Participants then discussed whether requirements should vary from one country to another or whether they should be the same around the world. Participants also suggested that a help function be added to the IMAPP software to explain the harmonized values, if these were to be included.

¹ IZiNCG. Assessment of the risk of zinc deficiency and options for its control. *Food and Nutrition Bulletin*, 2004, 25 (Supplement 2):S94–S204.

6. PRESENTATION OF ADDITIONAL DETAILS OF THE WHO IMAPP

(PRESENTED BY A. CARRIQUIRY)

Details about the WHO IMAPP

Necessary components of the input files:

1. Subject ID
2. Recall or record number (if more than one day per person)
3. Gender
4. Reproductive status, if appropriate
5. Age
6. Daily intake for the nutrient(s) of interest
7. Daily intake for each food vehicle after disaggregating mixed dishes into their constituent ingredients (grams per day).
8. Files can be in Excel format or in plain text format.

Other factors used by the analysis:

1. Users may specify their own average nutrient requirement value or use the Allen harmonized values provided by the program for each age/gender/reproductive status group, and each nutrient of interest.
2. Users may specify the safe upper level of intake or use the Allen harmonized values provided by the program for each age/gender/reproductive status group for each nutrient of interest.
3. When defining subject groups for nutrient standards, users can select the groups defined by the IOM of the National Academy of Sciences or can aggregate these groups.
4. Bioavailability factors may be specified by the user for iron and zinc.
5. External variance ratios may be used if only one day of dietary data is available.

Process of calculating intake resulting from the fortification of the specified vehicle food:

1. After the above information is entered into the program, the software calculates and displays (on screen) the baseline prevalence of inadequacy (without fortification) for the nutrient(s) of interest, as well as the prevalence of intakes that are considered excessive.
2. The user can then enter fortification levels for nutrients in the food vehicle. The new prevalences are then calculated and displayed on screen.
3. This process is repeated until a satisfactory level of fortification is identified.

Summary of discussion on the presentation

Participants requested that the WHO IMAPP software include guidance regarding use of the program. Suzanne Murphy will be creating a users manual that will accompany the software program. Using an example from food commodities in the Philippines, participants were shown how the WHO IMAPP software could adjust for survey design factors. Some participants had reservations about some of the adjustments used.

Bioavailability was also discussed, and participants agreed that it would be useful to show the bioavailability of the fortificant in the software. However, participants worried that using an algorithm to estimate bioavailability may not provide accurate estimations. Participants discussed how much of the data needed to calculate bioavailability was missing or not currently collected in surveys.

Finally, participants discussed how to estimate dietary intake from breast milk. Some strategies may not account for breast milk while others make assumptions to estimate intake from breast milk. This issue was an ongoing discussion yet to be resolved.

7. MICRONUTRIENT SIMULATION MODEL FOR DESIGNING FOOD AID PRODUCTS

(PRESENTED BY L. TURNER
AND L. FLEIGE)

The challenge for this project was to design fortification programmes for food aid products when individual dietary data are not available. The resulting micronutrient simulation model is described in a publication which provides further details of the process used, and its assumptions¹.

When planning a fortified blended product for food aid, the theoretical method of choice is the EAR cut-point method to estimate the current prevalence of inadequacy, and then design the product to address these inadequacies (as IMAPP does). However, this approach requires detailed knowledge about the following:

- Percent of daily energy supplied by fortified blended foods (FBF)
- Composition of total diet, including portion not supplied by food aid
- Distribution of typical micronutrient intakes
These data are not available for typical groups of food aid beneficiaries (global distribution)

¹ Fleige LE, Sahyoun NR, Murphy SP. A new simulation model estimates micronutrient levels to include in fortified blended foods used in food aid programs. *Journal of Nutrition*, 2010, 140:355-65.

As a result of these limitations, the RDA and RNI values were chosen as most appropriate targets to use on an interim basis for establishing fortification levels of FBF.

A micronutrient simulation model was developed by SUSTAIN to determine the most appropriate micronutrient composition of FBF using some of the concepts from the IOM's theoretical approach of planning for populations¹. This model can be used to estimate micronutrient levels in food aid products when data required for the EAR cut-point method are unavailable.

Two models were developed to test the effect of different assumptions on the percent of the RNI for individual micronutrients, and percent of energy, to be supplied by the FBF. One model was for an FBF product intended for children 6-36 months of age, and the other model was for an FBF product for older children and adults.

The models used several sources of nutrient guidelines, including the RNI values from WHO/FAO, AI values from IOM for sodium, potassium, and phosphorus; the FAO/WHO/UNU guidelines on Human Energy Requirements; and UL values from IOM.

The objective was to develop an FBF that would provide 75% of the RNI in a product that was consumed to provide 25% of daily energy requirements, and without exceeding the UL even if consumed at 50% of energy needs. A nutrient density approach was used to ensure that the needs of all age groups would be met. Several assumptions were made:

- FBF supplies 25%, but seldom more than 50%, of daily energy requirements (all groups).
- People with higher energy requirements will consume more of the product.
- Complementary model assumed "worst case", that infants would consume no breast milk.
- Remaining 75% of the diet consists mainly of staple cereals and is inadequate in key micronutrients.
- Remainder of the diet would contain at least 25% of the nutrient targets (RNI).

Development of the two FBF products was an iterative process involving the following steps:

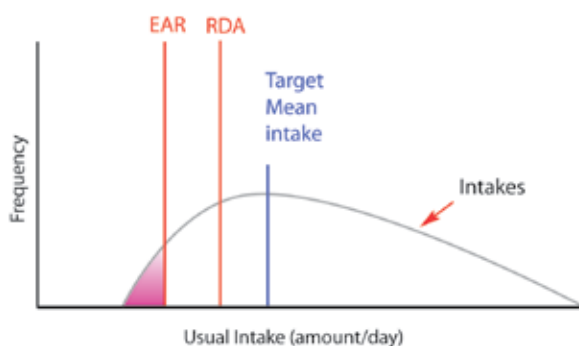
- Step 1: Determine the energy and nutrient requirements for the age and gender groups of interest.
- Step 2: Determine the age group with the highest nutrient requirement relative to energy requirement, i.e. the highest nutrient density of requirement or "limiting group."

¹ Institute of Medicine (IOM). *Dietary reference intakes. Applications in dietary planning*. Washington DC, The National Academies Press, 2003:89-106.

- Step 3: Simulate the effect of adding 100%, 75%, or 66% of the limiting group's RNI to FBF if FBF supplies 25%, 50%, or 100% of daily energy intakes.
- Step 4: Calculate the absolute quantity of each micronutrient that would be consumed per day under different assumptions.
- Step 5: Compare estimated intakes to the UL.
- Step 6: Convert values from step 4 to quantity of each micronutrient per 100 g FBF.
- Step 7: Subtract intrinsic micronutrients, naturally present in FBF, from simulation model results to estimate premix levels.

Limitations associated with the Food Aid model

- EAR cut-point method usually results in a mean intake target above the RDA/RNI; therefore, using the RDA/RNI as a target could increase the risk of under-fortification.



- RNI values were developed for healthy individuals; nutrient guide lines for malnourished populations are not available.
- Nutrient requirements and health status of beneficiaries varies significantly in population subgroups.
- Uses two nutrient standards: RNI values from WHO/FAO and UL values from IOM.

SUSTAIN wishes to acknowledge Suzanne Murphy, Kathryn Dewey, and Nadine Sahyoun for their valuable contribution to the development of the Micronutrient Simulation Model.

8. CONCLUSIONS It was noted that Rosalind Gibson authored a background paper that discusses advantages and disadvantages of collecting different types of food intake data. The feasibility of having this paper made available as part of the IMAPP software would be explored.

Participants recommended possibly testing the WHO IMAPP in a few countries before implementing globally. One participant proposed finding test countries through the International Union of Nutritional Sciences (IUNS), which is made up of 78 different nutrition societies. This would empower technical and academic personnel from within a country to become involved. In addition, participants recommended that a help desk be created for the program on a permanent basis, so that someone could be contacted for questions about the program.

Participants recommended that cost-effectiveness of assessing dietary consumption in populations every five or ten years, as it would be too costly to assess twice yearly. Participants had questions about an estimated budget for data collection. Some participants cited examples of surveys that went over their estimated budget, while others referred to a movement to share data and collaborate across countries to lower costs.

The meeting identified the need for practical guidance on recommended survey methods for practitioners on the ground. Participants recommended that a document be produced with recommended survey methodologies as a result of the meeting, and that handbook/guidance materials be subsequently produced for field practitioners.

9. NEXT STEPS On 23 July 2009, the software developers (A. Carriquiry, S. Murphy, L. Allen) met with representatives of WHO (L. Rogers, JP Pena-Rosas) to discuss the next steps for finalizing and distributing IMAPP.

1. L. Allen is developing a background paper on Harmonized Nutrient Reference Values (HNRV). This paper will be circulated among the software developers and then externally for review. The paper will be published in a journal.
2. Time Line
 October - November 2009: If possible, have a demonstration of the IMAPP software at International Congress of Nutrition (ICN) and/or Latin American Congress of Nutrition (SLAN).
 December 31, 2009: Version 0.5 will be supplied to WHO
 January - March 2010: Version 0.5 will undergo beta testing by 3-4 external users who are familiar with statistics and large nutrient data sets.
 June 2010: Release of Version 1.0
 Late 2010: If additional funding is available:
 - Training workshops to be conducted with countries who have just completed a national survey or who are planning a national survey.
 - Additional components to the software program to be added and new versions released and updated regularly.
3. Following testing of the software capabilities, and following WHO clearance processes, the IMAPP software would eventually be available on the WHO website.

ANNEX 1**How to proceed with the
USAID Food Fortification
Formulator program if
only per capita intake
data is available**

If only food availability data is known, the per capita intake of a potential vehicle for the fortificant is calculated as the total availability in tonnes (t with 1 t equal to 1 000 kg or 2 204.622 62 lb) divided by the population in millions of inhabitants. If the percentage of users of the food vehicle is known, the per capita intake value could be refined by dividing it by the proportion of the population that consumes it. The new value is then used in the USAID Food Fortification Formulator as the median intake of the adult equivalent (using adult males as the reference). The 5th and 95th percentiles (P5 and P95) of intake can be approximated by dividing the estimated median intake by a factor of 2 to 4, and multiplying by a factor of 2 to 4, respectively. For example, if the total availability of table vegetable oil in a country of 25 million people is 100 000 tonnes (1 t = 1 million grams), then the per capita annual intake of oil is: 100 000 million g/25 million persons = 4 000 g/year per person or 11 g/day. However, if only 60% of the population uses table vegetable oil, then the estimated median intake per adult equivalent would be $11/0.6 = 18$ g/day. If one assumes that P5 is $\frac{1}{2}$ of the median, and that P95 is twice the median, then the corresponding oil intake values would be 9 and 36 g/day, respectively.

ANNEX 2

List of Participants

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