NFI BULLETIN
Bulletin of the Nutrition Foundation of India
Volume 37 Number 3
July 2016

Basis of current allowances of nutrients in food fortification in India

K.Madhavan Nair* and Little Flower Augustine**

Food fortification is considered to be one of the most feasible and time tested strategies to tackle micronutrient deficiency in India. According to the World Bank, "probably no other technology available today offers as large an opportunity to improve lives and accelerate development at such low cost and in such a short time"[1]. Fortification is the addition of one or more essential nutrients to a food whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups[2]. The goal of any food fortification programme is to achieve a desirably low prevalence of dietary nutrient inadequacy through supply of micronutrients in amounts that approximate to those provided by a well-balanced habitual diet. Consequently, fortified staple foods will contain "natural" or near natural levels of micronutrients. Any fortification programme should be based on a demonstrated need for increasing the intake of an essential nutrient in one or more population groups, clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients, or possible deficiencies likely to develop because of changes taking place in food habits. This article is based on the presentation made at the first meeting of the Tolerable Upper Level (TUL) committee of nutrients in food fortification at National Institute of Nutrition, Hyderabad, Telangana on 28th April, 2016.

Advantages of fortification

Food fortification can potentiate rapid improvements in micronutrient status of population at a reasonable cost[3]. When properly regulated, it carries a minimal risk of chronic toxicity. With the existing technology and local distribution networks, fortification can readily achieve results because it does not require any modification in existing food habits and does not depend on an individual for compliance.

Public health impact of food fortification

This depends mostly on the quantity of micronutrients recommended for fortification and the daily consumption of the fortified food which serves as the vehicle for the nutrient(s). The quantity consumed should be sufficient to match the dietary requirements of micronutrients and the bioavailability of the fortificants.

The quantity of micronutrients recommended for fortification

The level of micronutrient/s recommended for fortification of staple foods is country-specific. It largely depends on the habitual diet of the population in a region. A data base of micronutrient compositions of various foods and information on bioavailability are powerful tools to facilitate the process of arriving at the quantity of micronutrients required for fortification. It is also necessary to keep in mind the nutrient requirements and recommended dietary allowances of micronutrients for Indians[4].

Common concepts: Nutrient requirements, EAR and RDA

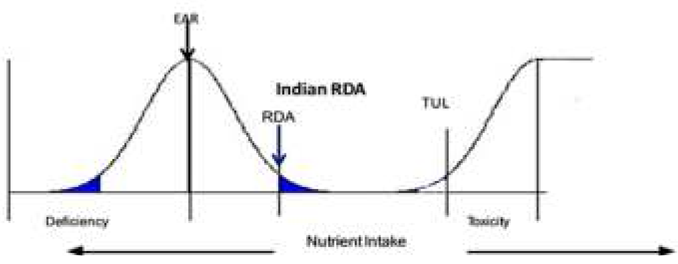
Figure1 shows the common concepts of nutrient requirements used internationally.

Nutrient Requirement: This term indicates the least amount of the absorbed nutrient that is necessary for maintaining the normal physiological functions of the body of practically all healthy people. In any given population group, it follows a normal distribution.

Estimated Average Requirements (EAR): This is the average daily intake of a nutrient that will meet the nutritional needs of 50% of healthy individuals in each life stage and gender group. That is, if healthy children 4-8 years of age received the EAR for iron for their

CONTENTS

Figure 1. Concept of Estimated Average Requirement (EAR), Recommended Dietary Allowance (RDA) and Tolerable Upper Limit (TUL)



age group, the requirement would be satisfied in about 50% of these children.

Recommended Dietary Allowances (RDA): This is the daily dietary intake level of a nutrient which is considered sufficient to meet the requirements of 97.5% of healthy individuals in each life stage and gender group.

Adequate Intake (AI): Like the RDA, the AI is expected to meet or exceed the nutritional needs of almost everyone in the group.

Tolerable upper levels of intake (TUL): This is the highest level of daily consumption at which, according to current data, there are no side-effects in humans when used indefinitely without medical supervision.

While 'requirement' is the least amount of the absorbed nutrient that is necessary for maintaining the normal physiological functions of the body of practically all healthy people, RDAs are based on the amount of the nutrient needed to prevent symptoms of the corresponding nutrient-deficiency disease. The availability of RDAs is a boost to food fortification programmes aimed at eliminating many vitamin and mineral deficiency disorders. TUL figures are used as a guidance to decide on the number of fortified products that can safely be in the market simultaneously, and do not refer to fortification levels of individual foods per se.

Basis of setting fortification levels: FAO/WHO recommendations

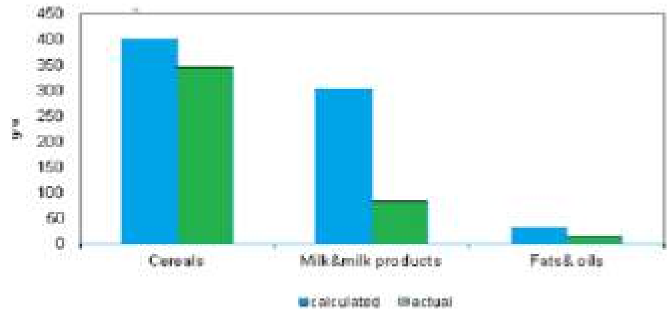
The key micronutrients identified internationally are iron, folic acid, zinc and vitamin A. Defining nutritional goals based on appropriate requirement criteria, EAR or RDA is a pre-requisite for fixing fortification limits. Biochemical and clinical evidence of specific micronutrient deficiencies, dietary patterns and usual dietary intakes are major factors that should be considered. National-level data on the needs of vulnerable segments of the population at risk of deficiency, and bioavailability of the nutrient of interest are also important considerations.

Table 1 Prevalence of major micronutrient deficiencies

Micronutrient deficiency	Prevalence rate (%)
Anaemia	45-78
Vitamin A deficiency	60
Iodine deficiency disorders	3.8
Hypovitaminosis D	70-90

Sources: References 6,7,8

Figure 2. Cereal, milk and visible fats and oils in adult male



Note Calculated based on balanced diet for a reference man RDA 2010 and reported intake based on NNMB survey data 2006

The extent of consumption of the food vehicle among different food groups is by far the most important criterion. The fortified food should be one that is habitually consumed in adequate amounts by the target population. If the chosen vehicle is not widely consumed, the impact will be too slow or negligible to measure. It is preferable to have centrally processed food vehicles for fortification. This is a challenge that India would face while planning and rolling out a fortification programme. It is imperative to use a technology which would keep the fortificants stable in the vehicle and at the same time would not affect the sensory properties of the foods. Finally, an enabling environment has to be created for an effective partnership between government and the food industry[5].

On the basis of intake and estimated absorption of the nutrient, the margin of deficit can be fixed, and this would be the basis for fortification. However, all these guidelines have to be contextualized, and any factor which could potentially influence the programme needs to be considered (locally) even when not considered internationally[2]. Other factors to consider when deciding fortification levels are safety limits, technological limits, and cost limits. Monitoring and evaluation are crucial components as well. Regulatory monitoring has been identified as essential. However, household monitoring is also considered essential to evaluate outcomes. Appropriate selection of outcome measures (intake

Table 2. Consumption of Cereals by different Age Groups

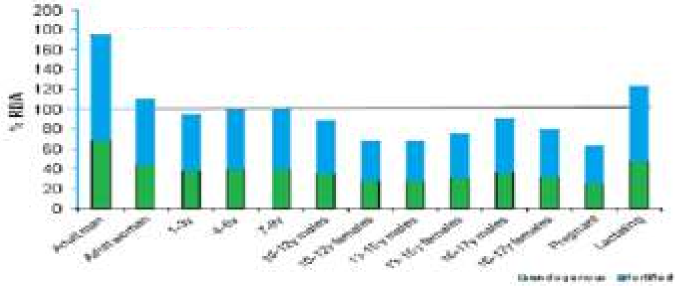
Age Group	Number	Cereal intake (g/day)	
		Mean	SD
1-3y (Boys & Girls)	2895	131	82
4-6y (Boys & Girls)	2915	209	97
7-9y (Boys & Girls)	2963	262	110
10-12y Boys	1654	301	124
10-12y Girls	1577	289	124
13-15y Boys	1529	347	133
13-15y Girls	1538	324	131
16-17y Men	898	386	148
16-17 y Women	991	346	144
Adult Men	11274	444	166
Adult Women	6118	391	141
Pregnant Women	322	354	138
Lactating Women	693	395	152

Source: Reference 10

Table 3.Consumption of Cereals in different States-Adult Men, Moderate Activity			
States	**N**	**Mean (g/day)**	**SD**
Kerala	756	325	133
Tamil Nadu	982	424	146
Karnataka*	1302	481	191
Andhra Pradesh	1119	494	190
Maharashtra*	1343	378	160
Gujarat*	1322	431	145
Madhya Pradesh*	1407	480	120
Orissa	1044	501	81
West Bengal	968	363	84
Pooled	11274	444	166

***Habitual diet consists of millet as staple**
Source: Reference 10

Figure 3.Contribution of iron from endogenous and fortified sources in different age groups.



Note TUL for iron is 45 mg which corresponds to 2.65 times RDA. None of the groups exceeded this level

measures vs more invasive and often more expensive biochemical indicators) and how often these need to be carried out also needs to be specified.

Approaches for fixing fortification levels for micronutrients – India

There have been intensive discussions and consultations on the relative merits of using RDA or TUL as the primary yardstick for fixing fortification levels. TUL is the guiding principle for preventing excessive intake. It, therefore, serves as a guideline to arrive at the number of fortified food products that can safely be in the market at a given point in time. RDAs have been determined as being more appropriate for fixing fortification levels, especially in India which is still at a nascent stage in its food fortification programme and would benefit by having more diversity in fortified products. The Indian RDAs are context-specific and consider factors such as dietary habits and bioavailability, intake and deficiency, and processing losses. The RDAs are provided in the context of the natural habitual food form of the nutrient and therefore, when translated to the synthetic form, would be a higher level than what has been envisaged as requirement in the food form.

Prevalence of specific micronutrient deficiencies

Iron deficiency anemia (IDA), vitamin A deficiency (VAD) and iodine deficiency disorders (IDD) continue to be significant public health problems in India. Apart from the well documented deficiencies of iron, iodine and vitamin A, emerging evidence points towards a widespread prevalence of low plasma levels of vitamin D (Table 1)[6-8]. NNMB reports on dietary intake indicate inadequate intake of many nutrients across all age groups[9-10].

Choice of vehicle -existing dietary habits of the population

Habitual Indian diets are predominantly cereal-pulse-vegetarian ones with low amounts of flesh foods. This has been used in computation of RDA and therefore no extra allowance has been made while computing the fortification levels[4]. Data on per capita consumption of different foods have been obtained from the NNMB Technical report[10]. An intake of 400g of cereal is calculated to meet the requirement of calories and certain micronutrients for a reference man. This amount is close to the actual intake reported from rural NNMB surveys across the country (Tables 2 and 3)[10]. Though the cereal consumption is region-specific, it is unlikely to exceed the limits even in the context of consumption of rice and wheat together.

Based on the existing dietary habits in India, and on intake data from NNMB 2006[8] (Figure 2), three vehicles were identified during a brainstorming session[11]. They are cereals, milk and oil. Cereal intakes appeared to be adequate and had been considered as the major vehicle for fortification. Milk and oil, were consumed daily across population groups but the intakes were insufficient (only 80 mL/d of milk as against 300mL suggested and visible fat intake was only 13 g/d as against 30g recommended). Considering the universal usage of these two vehicles, the deliberations also included consideration of fortification with vitamin D and vitamin A. In addition to the above vehicles, salt which has been a universal vehicle for iodine for decades; has been considered for fortification with iron also.

Per capita consumption of identified food vehicles in adult male

A successful fortification programme needs to consider the entire spectrum of intakes including both extremes. While ensuring

Table 4. Studies on rice fortified with iron in India

Design	Duration	Source of iron and dose	Impact		
			Change in prevalence	Hemoglobin (g/dl)	Ferritin (mg/L)
RCT, Bangalore	7 months Dewormed	Extruded rice fortified with	Control	-0.6	+2.3
School lunch Iron depleted children N=184	at Baseline and at 3.5 months	Micronized ferric pyrophosphate / 20 mg	Fortified	- 0.2	+9.5
RCT Hyderabad	12 months Dewormed	Extruded Ultra rice fortified	Control	1.15	- 3.0
MDM Anemic children N= 164	at baseline	with ferric pyrophosphate/ 18 mg	Fortified	0.99	+8.2

Source: References 15, 16

Table 5 Recommendation for micronutrient levels in rice fortification (mg/100g)

Nutrient	Compound	<75 (g/d)	75-149 (g/d	150-300 (g/d)	>300 (g/d	EAR
Iron	Micronized ferric pyrophosphate	12	12	7	7	Not specifiable
Folic acid	Folic acid	0.50	0.26	0.13	0.10	0.192
Vitamin B12	Cyanocobalamine	0.004	0.002	0.001	0.0008	0.002
Vitamin A	Vitamin palmitate	0.59	0.3	0.15	0.1	0.429
Zinc	Zinc oxide	9.5	8	6	5	11.7
Thiamine	Thiamin mononitrate	2.0	1.0	0.5	0.35	1.0
Niacin	Niacin amide	26	13	7	4	12
Vitamin B6	Pyridoxine hydrochloride	2.4	1.2	0.6	0.4	1.1

Source: Reference 2

adequate intake of the nutrient to vulnerable segments, it is also necessary to ensure that those who are already getting adequate intake should not be at risk of any adverse effects of excess intake. In the Indian context, the group which could probably fall into the latter category is that of adult men because they consume the greatest quantity of the identified vehicles, especially cereals (Table 2)[10]. For a majority of the micronutrients, the highest recommended intakes apply to adult males (zinc: 12 mg, iodine: 150 µg, vitamin B1: 1.4 mg, niacin: 18 mg, vitamin C: 40 mg, folate: 200 µg, vitamin B12: 1 µg per day). The exception is iron (17 mg/d). Adult males face the lowest risk of micronutrient deficiencies because their overall food intake is high enough to supply the relatively small micronutrient requirements per unit body weight. At most risk of not meeting their micronutrient requirements are infants, young children and women of reproductive age, especially pregnant and lactating women. It is for this reason that the requirements of adult men (the higher end of the requirement spectrum) has been chosen while fixing the fortification limits of micronutrients.

Reference man: The adult man here refers to the 'reference man', defined by the RDA committee as 18-29 years of age, weight 60 kg, height 1.73 m, BMI 20.3, free from disease, and physically fit for active work. On each working day, he spends 8 hrs in moderate work activity, 2 hrs in walking, physical recreation and household activities, 4-6 hours in sitting or moving about, and 8 hours in bed[4].

Stability of the nutrient in the food being fortified

Stability characteristics of nutrients, especially vitamins, need to be considered while planning fortification of foods. In order to compensate for the deterioration of added nutrients in the food vehicle, overages are suggested. An overage of 10% of the required levels for minerals such as iron and zinc and 20-30% in the case of vitamins may be considered[12].

Chemical sources: The chemical source of the nutrient added can influence the extent of absorption and thereby the level of fortification. For example, in the case of iron, sodium iron EDTA has higher bioavailability than ferrous sulphate, ferric pyrophosphate, fumarate, electrolytic iron, etc[2].

Example: Derivation of fortification level of iron

For a reference man, assuming 20-30% prevalence of iron deficiency and cereal being the food of maximum consumption the following were suggested:

a. Fortification level: one RDA (17mg/d).
b. Vehicle: single vehicle considering cereals as a group (wheat atta/ maida/ rice)
c. Intake: average consumption of rice/wheat atta/maida = 400 g/day

Under these assumptions, the fortification of iron per kg of cereal (rice/wheat atta/maida) = 17/400x1000 = 42.3mg/kg. At this level of fortification, the different groups will receive between 39% (pregnant women) and 100% (adult man) of their RDAs. Considering the presence of endogenous iron in cereals, the overall intake of iron from cereals is presented in Figure 3, showing that all the age groups and pregnant women would meet above 60% of the RDA. However, due allowances were made for the variable intake of cereals in different population groups and the fact that iron requirements are lowest for adult men[13]. On this basis, a higher level of 60 mg/kg which is in concordance with the FAO/WHO guidelines[2] was adopted. This translates to intake of 200% of RDA by an adult man (34 mg/day), which is still well below the TUL level of iron (45 mg/day).

Fortification of iodized salt with iron (double fortified salt)

RDA is also basis for fixing the levels of iodine and iron in double fortified salt (1 RDA of iodine, 150 µg and 50 % RDA of iron, 10 mg) and is based on approximate consumption of 10 g of salt by an adult male.

Basis for fixing fortification level of Vitamin A

On account of the fact that more than one vehicle lends itself to fortification with vitamins A and D (milk and vegetable oil), and also given the tropical climate for vitamin D, 1/3rd of the daily requirement could be fixed as the fortification level. The fortification level recommended for vitamin A is 25 IU per gram, which works out to one-third of RDA at the recommended intake of 25g/d of visible fat. The level of fortification was, therefore, set at 25,000 IU per kg or 7500 µg/kg of oil.

Vitamin D

There is no specific recommendation of RDA for vitamin D in the Indian context. However, under situations of minimal exposure to sunlight, a specific recommendation of 10µg/d is suggested. This will work out to 133.2 IU/ 30g, which translates to 4400 IU/kg of oil. Where milk is used as the vehicle, the fortification level could be 133.2 IU/at the recommended intake of 300mL, which will account for 440 IU of vitamin D/L of milk.

Future directions

Food Safety Standards Authority of India[14] has already provided recommendations for wheat flour fortification. Considering that rice is an equally widely consumed staple cereal in certain parts of India, a concurrent rice fortification strategy needs to be envisaged for a better nation-wide impact. Though the recommended fortification levels may remain the same (considering that the sum total of cereal intake will remain at around 400 g for an adult man), the technological issues need to be solved before rolling out this aspect of fortification in India. Wheat flour fortification involves a simple dry mixing process but rice fortification requires extrusion technology. There have been two studies in India (Table 4)[15,16] which have demonstrated efficacy in the target population within RDA level, and therefore could be taken further for either an effectiveness trial or a direct translation considering the extent of deficiency in India. It needs to be kept in mind that, in India, on account of intake of multiple cereals and the large variations in quantities of intake by various groups, differential fortification suggested by FAO/WHO, ie., different levels of fortification depending on intake levels (Table 5)[2] does not seem to be a feasible option.

Conclusion

The fortification strategies in India have been based on available evidence and international guiding principles. Future research needs to concentrate on country- and context-specific innovations so that food fortification becomes a successful strategy for combating micronutrient deficiencies.

*The authors are from National Institute of Nutrition, Indian Council of Medical Research, Hyderabad, Telangana (*Scientist 'F' (Retd.), Head Micronutrient Research, **ICMR-Post doctoral fellow).*

References

1. The World Bank Enriching Lives: Overcoming Vitamin and Mineral Malnutrition in Developing Countries. 1994.
2. FAO/WHO. Guidelines on food fortification with micronutrients World

Health Organization and Food and Agriculture Organization of the United Nations 2006:98.
3. Horton S. The economics of food fortification. J Nutr. 2006. 136(4):1068-71.
4. ICMR, Indian Council of Medical Research. Nutrient Requirements and Recommended Dietary Allowances for Indians. Indian Council of Medical Research, New Delhi. 2010.
5. Griffiths M. Communicating the benefits of micronutrient fortification. Food Nutr Bull. 2003, 24:S146-50.
6. International Institute of Population Sciences: National Family Health Survey. National Report. (NFHS-3). IIPS. Mumbai:2007.
7. National Nutrition Monitoring Bureau. National Institute of Nutrition, Hyderabad. 2003.
8. Harinarayan CV, Shashank R J, Vitamin D Status in India – Its Implications and Remedial Measures, JAPI, 2009; http://www.japi.org/january_2009/R-1.html
9. National Nutrition Monitoring Bureau. Technical Report 24, National Institute of Nutrition, Hyderabad. 2006.
10. NNMB, National Nutrition Monitoring Bureau. Diet and Nutritional Status of Rural Population and Prevalence of Hypertension. Third Repeat Survey. NNMB Technical Report Series 26. Hyderabad: National Institute of Nutrition). 2012.
11. National Institute of Nutrition. DBT-NIN Brainstorming session on fortified foods. 17- 18April 2007. Held at NIN. Recommendations and Network projects. 2007.
12. de Pee S, Kraemer K, van den Briel T, Boy E, GrassetC,Moench-Pfanner R, Zlotkin S, and Bloem MW. Quality criteria for micronutrient powder products: Report of a meeting organized by the World Food Programme and Sprinkles Global Health Initiative, Food and Nutrition Bulletin, 2008. 29, 232-241.
13. National Institute of Nutrition. Minutes of the stake holder consultation on regulation for food fortification. National Institute of Nutrition, Hyderabad, India. 2011.
14. FSSAI, Food Safety and Standards Authority of India. Ministry Of Health And Family Welfare, Government of India. 2010.
15. Moretti D, Zimmermann MB, Muthayya S, Thankachan P, Lee TC, Kurpad AV, Hurrell RF. Extruded rice fortified with micronized ground ferric pyrophosphate reduces iron deficiency in Indian schoolchildren: a double-blind randomized controlled trial. Am J ClinNutr. 2006 Oct;84(4):822-9.
16. Radhika MS, Nair KM,Rao HK, Rao MV, Ravinder P, Reddy CG, Brahmam GNV. Micronized ferric pyrophosphate supplied through extruded rice kernels improves body iron stores in children: a double-blind, randomized, placebo-controlled midday meal feeding trial in Indian schoolchildren. Am J ClinNutr. 2011 Nov; 94(5):1202-10. doi: 10.3945/ajcn.110.007179.

Arriving at Tolerable Upper Limits (TUL) for Indian Population

B. Sesikeran

Micronutrient deficiencies are the most common nutritional deficiencies in the world. In India, prevalence of micronutrient deficiencies is very high; this is mainly due to low dietary intake of fruits and vegetables. For the last three decades, nutrition scientists have been intensively engaged in nutrition education aimed at improving fruits and vegetables intake in the population. However, there has not been substantial improvement; the segments of the population who have high levels of micronutrient deficiencies are either unable to or unwilling to access and consume micronutrient rich fruits and vegetables in adequate quantities. Food fortification is increasingly being used in many countries to improve micronutrient intakes and combating public health problems due to widespread micronutrient deficiencies. In many countries, several food products are fortified with multiple micronutrients. Several natural sources of nutrients with better bioavailability have greater than RDA quantities of nutrients. There are segments of population among whom micronutrient intake from food is sufficient to meet their requirements; they also consume fortified food products. Under these circumstances, their micronutrient intake may be higher than the requirements.

Micronutrient intakes below the recommended daily allowances (RDA) are associated with the risk of deficiency disorders. At the other end of the spectrum, intakes of some of the nutrients beyond the upper limits have also been shown to have adverse effects on health. Upper limits (ULs) or tolerable upper limits (TULs) may be defined as habitual intake level from all sources (food and supplements) that is unlikely to lead to adverse health effects in humans when consumed unsupervised for the entire life time[1]. This article describes international best practices[2-4] in arriving at TUL for some major nutrients and how the process of arriving at TUL in the Indian context has to be initiated.

Adverse impact of excessive micronutrient intake

The limits both lower (RDA) and upper (TUL) apply to consumption of nutrients both through food sources and as nutrient supplements[1]. Between RDA and TUL is considered the safe range of nutrient intake. Examples of adverse effects happening at both extremes of intakes are given in the Table.

Steps to arrive at TULs:

Step 1: Hazard Identification

Evaluation of all published information relative to the nutrient's potential to cause harm in humans is the first step in risk assessment. Analysis of the nature of adverse effect, severity, and its persistence or chronicity should follow. If the excess nutrient intake has resulted in multiple adverse effects of a varied nature, the most critical i.e. in severity and persistence at Lowest Intake is considered.

Step 2- Dose Response Assessment

A quantitative evaluation of relationship between the level of intake and any adverse effect is done to fix the "no observed adverse effect level" (NOAEL). The highest level of intake with no adverse effect, is the "no observed adverse effect level" (NOAEL); the "lowest observed adverse effect level" (LOAEL) is the lowest intake level where adverse effects have been reported. Uncertainty factor (UF) is a factor used as a denominator applied to keep the TUL at a level lower than the actual level where adverse effects were observed; UF provides the allowances for possible uncertainties due to a variety of reasons like robustness of the research and data, number of studies, sample size, human versus animal data and other inherent variations and limitations of the published evidence. If the data is robust then the UF is low and vice versa. The Institute of Medicine USA used a range of UF from 1 to 5.

Table: Adverse effects of low and excess intake of various nutrients

Nutrient	Intakes below RDA	Intakes above TUL
Calcium	Osteoporosis	Hypercalcemia /renal stones
Iron	Anemia	GI side effects
Zinc	Growth Failure	Impaired Cu status
Vitamin A	Increase in morbidity and mortality	Liver damage , teratogenecity
Vitamin C	Scurvy	GI side effects
Vitamin D	Skeletal Deformities	Hypercalcemia
Folic Acid	Megaloblastic anaemia, neural tube defects	Masking of Vitamin B12 deficiency

Step- 3 Derivation of UL

UL = NOAEL ÷ UF or sometimes UL = LOAEL ÷ UF

Some examples of TUL computation are given below:

Vitamin D: Critical adverse effect is hypercalcemia (serum calcium >11 mg/dl). Based on published literature, upto 2,400 IU daily for more than 3 months did not cause any adverse effect, therefore NOAEL was 2400 IU. As the data base was considered to be robust, the assigned UF was 1.2 and an UL of 2000 IU was fixed. Exposure assessment showed that food source was upto 0.01 mg/day (mean=0.0025 mg/day) supplements: upto 0.02 mg/day[2]. UL of 0.05 mg/day also valid for children aged 1 year and older and for pregnant or lactating women. Institute of medicine (IOM), EU and UK, all had recommended similar levels. Recent data showed that up to 5000 IU of Vitamin D did not show any adverse effect; IOM therefore revised the TUL to 4000 IU. The UL for adults was extrapolated computation of UL for children.

Similar exercise was done for **Niacin** where a LOAEL due to flushing was 50 mg. Due to the transient nature of the flushing effect, a small UF of 1.5 was selected and UL was fixed at 35 mg from all sources.

Folic Acid: Since Folic acid can cause progression of neurological symptoms by masking B12 deficiency a LOAEL was found to be 5mg (5000 ug). Millions of people have consumed 1/10 of LOAEL (i.e. 400 µg) in the form of supplements without reported harm. An UF=5 was selected based primarily on severity of neurological complications observed, and for LOAEL to NOAEL extrapolation. The UL was, therefore, 1mg. Total intakes from all sources was found to be less than 1mg. The same UL was applicable to even pregnant and lactating women.

Vitamin B12: According to US-IOM, there appear to be no risks associated with intakes of supplemental B12 that are more than 2 orders of magnitude higher than the 95th percentile of intake. EU - There is no evidence that the current levels of intake from foods & supplements represent a risk. UK- established a guidance level for supplemental intake of 2 mg/day (Guidance level = 2 mg/d ÷ UF of 1 = 2 mg/d).

European Food Safety Authority has categorized the nutrients into 3 groups

a) Group 1: No evidence of risk to human health at levels currently consumed - no UL. Nutrients included under this category are: thiamine – 100mg, riboflavin- 40 mg, biotin – 900 µg, cobalamin – 2000 µg, pantothenic acid - 200 mg, vitamin K -1000µm and chromium III - 10 mg

The remaining which have a defined UL were categorized into two more groups based on quantitative population safety index (PSI). PSI is computed from the mean highest intake from foods (97.5 percentile intake of average adult Male MHI)+ estimated intake from water IW)/RDA (Population Safety Index (PSI) = UL - (MHI + IW)/ RDA)

Group 2 consists of nutrients for which the difference between current highest intake from food and UL is more than 150% RDA (PSI ≥1.5). In this group, the chance of exceeding UL is low. Nutrients included in this group are vitamin B6, vitamin C, vitamin D, folic acid, nicotinamide, phosphorus, magnesium, molybdenum, selenium and potassium.

Group 3: consists of nutrients for which the difference between current highest intake from food and UL is less than 150% RDA (PSI ≤1.5). Supplementation may potentially lead to intakes that approach the UL. Nutrients included in this group include vitamin A, beta carotene (smokers), calcium, copper, iodine, iron, manganese and zinc.

The way forward

There is an urgent need to carry out a literature search for clinical trial data / toxicity reports/ case reports on different levels of nutrient intakes in the Indian population. Data from single large bolus doses may not be suitable to arrive at NOAEL but could be documented and excluded. Studies in experimental animals may also have to be excluded. Data on the characteristics of the study population, study design, observed intake (food and supplements), duration of intake and observes adverse effects have to be tabulated and carefully reviewed by the experts; based on the review NOAEL can be worked out for the Indian population. In view of the rapidly changing dietary intake, lifestyle and intake of supplements, there has to be a periodic review of the data so that emerging problems could be readily identified and appropriate corrective measures initiated.

The author is Former Director, National Institute of Nutrition, Hyderabad.

References

1. Hathcock JN: Safety of Vitamin and Mineral Supplements; Safe levels identified by risk assessment. IADSA publication, 2004.

2. Expert Group on Vitamins and Minerals: United Kingdom Food Standards Agency Safe upper levels for vitamins and minerals, 2003.

3. Hathcock JN: Vitamin and Mineral Safety, 2nd Edition. Council for Responsible Nutrition, Washington, DC, 2004.

4. Scientific committee on Food: Tolerable Upper Levels of Vitamins and Minerals. Scientific panel on dietetic products, nutrition and allergy, 2006. phosphorus, magnesium ,molybdenum, selenium

FOUNDATION NEWS

- Dr. Prema Ramachandran (Director, NFI) participated in the Meeting of Research Advisory Committees at the Central Institute for Women in Agriculture-ICAR, Bhubaneshwar on 11th May 2016 and made a presentation on " Nutrition orientation of production, processing and marketing of food".
- Dr Prema Ramachandran participated in the launch of "Global Nutrition Report 2016" in New Delhi on 14th June 2016 and made a presentation on "Reflections on the World Health Assembly Targets for Nutrition for India".

NUTRITION NEWS

Forty eighth Annual National Conference of Nutrition Society of India will be held on 4th & 5th November 2016 (Friday & Saturday) at St.John's Research Institute, St. John's National Academy of Health Sciences, Bangalore. Along with the main conference, three pre-conference workshops will be organized on 3rd November 2016 (Thursday).

Home Based New-born Care Plus: Innovative approach to address nutrition, health and development of infants in four EAG states in India

Harish Kumar

Nutrition in the first 1,000 days of life (during pregnancy and the first two years) is critical for child growth and survival. The WHO recommends exclusive breastfeeding in the first six months of life, followed by extended breastfeeding for two years or beyond, coupled with timely, nutritionally adequate, safe and appropriately fed complementary foods for optimal growth of the child. The global strategy on infant and young child nutrition (IYCN) highlights that adequacy of knowledge about proper foods and feeding practices is often a more important determinant of malnutrition than the availability of food. It is estimated that interventions that promote optimal breastfeeding and complementary feeding could prevent about a fifth of the under-five deaths in countries with high mortality rates[1] . At the same time, there is the recognition that achieving a substantial impact requires preventive action beyond the immediate health and food interventions[1]. Non-initiation, delayed initiation, and inadequacy of complementary feeding, and inappropriate feeding practices are important reasons for growth faltering at 6-7 months of age[2,3], the period of the infant's life when there is no scheduled contact with the health system currently.

Home-based infant care or home visits during the first year of life using the community worker platform is an unexplored opportunity for making quantum improvements in child survival in areas with high infant mortality rate (IMR), poor nutritional indices and low intervention coverage for community diarrhoea and pneumonia management. Home-based Care for Infants or HBNC + designed and piloted by Norway India Partnership Initiative (NIPI) in 2014 aims to expand the efforts of community health workers (ASHAs) to include the post-neonatal period till age 1 year. Home-based newborn care plus (HBNC+) follows a population approach, i.e. delivering HBNC+ programme and services to the whole community, with particular emphasis on the preventive rather than curative aspect of health care.

Why home based new born care plus?

India has been operationalizing home-based newborn care or HBNC since 2011 through a series of home visits by community workers called ASHA[4]. This is likely to ensure better access to essential newborn care and provide positive health outcomes in terms of reduced newborn mortality. Currently 6-7 home visits are provided, ending at 6 weeks; the basic premise of HBNC + is to extend this continuum of care throughout the period of infancy. It aligns well with the concept of 'first 1000 days' as a unique window of opportunity to make a lasting impact on overall nutrition, growth and development of infants.

Diarrhoea, Acute Respiratory Infections (ARI or pneumonia) and underlying malnutrition continue to be major causes of death in children under five years of age. Under-nutrition contributes to more than a third of all under-5 child deaths. Malnutrition commonly affects children between 6 months and 2 years of age, with inappropriate and delayed complementary feeding being one of the most common reasons for it. Anaemia affects as many as half to three-fourths of all children in most States. Most of these causes of morbidity and mortality among children under 5 are preventable with timely intervention. HBNC+ is designed to address these major causes of childhood mortality through reinforcement of preventive health messages and optimal childcare practices as well as by ensuring the availability of commodities to enable this.

Implementation of the innovation

Implementation of Home Based Newborn Care Plus (HBNC+) builds upon the concept of home-based newborn care of the Government of India, leveraging the existing service delivery platform and personnel available under the National Health Mission (NHM). HBNC+ envisages bringing together evidence-based interventions that have a proven impact on reducing child mortality and are recommended by the World Health Organization[5].

Objectives of HBNC+: Promoting growth and development of infants

Home visit schedule under HBNC+: 4 Visits - 3 months, 6 months, 9 months and 1 year of age.

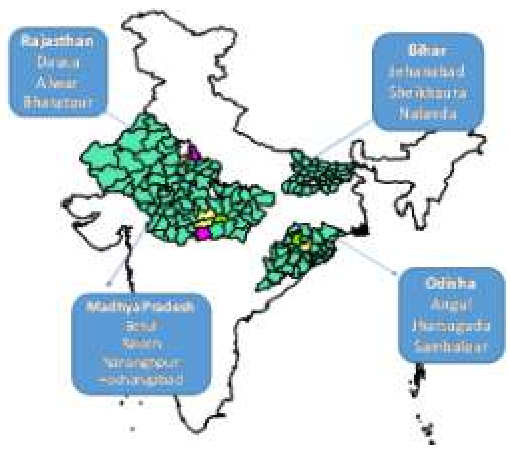
Tasks envisaged for community health worker (CHW):

- Ensuring growth monitoring and recording it in MCP card,
- Promoting exclusive breastfeeding till 6 months of age, initiation of complementary feeding at 6 months and continued breastfeeding for at least 2 years,
- Promoting hygiene, especially hand washing,
- Promote iron and folic acid (IFA) supplementation, starting at 6 months of age (ensure availability of IFA syrup ; demonstrate IFA administration),
- Providing oral rehydration solution (ORS) packets to the family and demonstrating ORS preparation,
- Promoting play and communication for Early Childhood Care and Development (ECCD)
- Ensuring full immunization

After the completion of 4 scheduled visits and fulfilment of specified conditions, the ASHA is paid Rs 500 per infant, in line with all the other incentives to ASHAs by State NHMs.

Training of ASHA: The ASHA's skills to provide additional care and services to children is built over a three-day period using theory and field practice sessions. A cascade training model was used, with training of trainers followed by training of ASHAs. Training packages including audio-visual tools have been developed under the project with engagement of domain experts.

Handholding and supervisory support are provided by the existing ASHA supervisory chain comprising of ASHA facilitators at field level, Location of 13 districts where HBNC+ is being implemented



(1 for every 20 ASHAs) supported by a Block Community Mobilizer (BCM) and a District Community Mobilizer (DCM). These are being leveraged for the supportive supervision of HBNC+. Supervisors are paid based on the same norms as for HBNC scheme of the Government of India.

Monitoring and evaluation

In order to track the progress of HBNC+ coverage and quality, a comprehensive Monitoring and Evaluation (M&E) Framework has been developed under NIPI new born project. It uses data from various sources including data generated through routine programme monitoring; periodic validation exercises; and data from external evaluation agencies. Home visits were initiated as a pilot study in 13 districts in 2014. During a period of two years (April 2014-April 2016) a total of 4,24,651 infants have received home visits of which 2,45,942 infants have received all 4 visits. Data from MCTS (Mother and Child Tracking System) is used for registering children as well as estimating coverage in the 13 pilot districts. In order to achieve this, 20,327 ASHAs and 856 supervisors have been trained using the packages developed under the project.

An independent evaluation of HBNC+ intervention package was conducted in Rajasthan in 2015 adopting a case control design (three intervention districts and 3 control districts[6]. The assessment observed that for children in the age group 0 to 5 months, the project districts had higher current exclusive breastfeeding rates when compared to the non-project areas. This difference was also statistically significant, at 5%. That there is a decrease in current exclusive breastfeeding rates with increase in age of the child has been shown by NFHS data. The ASHA, by providing counselling and motivation during home visits can help ensure that the mothers continue exclusive breastfeeding till 6 months of age. The assessment also showed that a higher percentage of families with children above 6 months of age in project areas received IFA syrup as compared to those in non-project areas. The differences between project and non-project districts were found to be statistically significant (5% level of significance), proving the better status of project areas in terms of IFA syrup supplementation[6].

Implications for scale up

Home-visitation programmes can be an effective early-intervention strategy to improve the health and well-being of children, particularly if these programmes are embedded in comprehensive community services to families at risk[7]. The initial results and field experiences from the pilot studies show a lot of promise for HBNC+ and reveal the scope of implementation across districts with high infant mortality. The HBNC+ intervention leverages existing community platforms and public health cadres, and with the involvement of the health system at every level (from national to district and block level), makes its sustainability in the public health system more likely. While there is a lot of published data about home visits in the newborn period, there are no published studies and evidence regarding its use in the post-neonatal period, specifically for addressing child health and nutrition. HBNC+ pilot studies will provide data from a significantly large population base. An operational research project is currently under way in one of the pilot districts to evaluate the possible strategies in terms of policy refinement and development of monitoring and accountability framework, and to overcome the barriers of programme delivery so as to develop a scalable model. Results are expected by the end of 2016.

The author is Project director, NIPI Newborn Project, New Delhi.

References

1. Murage K, Elizabeth W, Kyobutungi C, Ezeh AC, Wekesah F et al. Effectiveness Of Personalised, Home-Based Nutritional Counselling On Infant Feeding Practices, Morbidity And Nutritional Outcomes Among Infants In Nairobi Slums: Study Protocol For A Cluster Randomised Controlled Trial. Trials 14 (1): 445. doi:10.1186/1745-6215-14-445, 2013.
2. Zongrone A, Winskell K, Menon P. Infant and young child feeding practices and child undernutrition in Bangladesh: insights from nationally representative data; Public Health Nutrition. 2012. 15(9), 1697–1704.
3. Menon P, Bamezai A, Subandoro A, Agyoya M, Aguayo V. Age-appropriate infant and young child feeding practices are associated with child nutrition in India: insights from nationally representative data 2013. Maternal and Child Nutrition. 2015. 11, 73–87.
4. MOHFW, GOI: Home Based Newborn Care Guidelines, 2014. nrhm.gov.in/nrhm-components/rmnch-a/child-health.../child.../guidelines.htm Accessed on 15.6.2016.
5. WHO: Packages of Interventions for Family Planning, Safe Abortion care, Maternal, Newborn and Child Health WHO 2010. whqlibdoc.who.int/hq/2010/WHO_FCH_10.06_eng.pdf. Accessed on 15.6.2016.
6. Rapid Assessment of HBNC+ conducted by Sambodhi Research and Communications Pvt. Ltd., 2015 - Report in print.
7. The Role of Home-Visitation Programs In Improving Health Outcomes For Children And Families. PEDIATRICS 101 (3): 486-489; 1998. doi:10.1542/peds.101.3.486.

Edited by Dr. Anshu Sharma for the Nutrition Foundation of India, C-13, Qutab Institutional Area, New Delhi - 110016, website : www.nutritionfoundationofindia.res.in
Designed & Printed by Himanshi Enterprises