Fortification of Milk with Vitamin-D: Strategy To Eliminate Vitamin D Deficiency In India

International Life Sciences Institutes-India

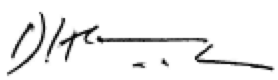
PREFACE

Vitamin D deficiency is a global issue. Many countries have recognized the problem with its adverse fallout and initiated measures to make up the deficiency as a national strategy. There is little appreciation of this problem and consequently no significant action in India possibly in the belief that, being a sunshine country, Vitamin D deficiency among the people may be minimal. That is not so.

The consequences of Vitamin D deficiency go beyond rickets among children and osteoporosis among adults. It is now accepted that Vitamin D strengthens the immune system and reduces the risk of multiple sclerosis, diabetes mellitus, tuberculosis, hypertension and common cancers. It is, therefore, vital that remedial measures are taken to eliminate or at least reduce Vitamin D deficiency in India as a public health mission.

The best option to make up the deficiency is to fortify milk with Vitamin D since other means are either impractical or costly. Milk is the best medium for fortification is widely consumed and can, therefore, reach the largest number of people. It would be preferable to make milk fortification compulsory, like in many other countries, but considering that dairy industry is not well organized, a beginning can be made with voluntary fortification by organized industry. Food Safety and Standard Authority of India (FSSAI) and the Ministry of Health should, therefore, initiate policy action which will facilitate and encourage fortification of milk with Vitamin D.

This Monograph is the outcome of collective work and offers the relevant supportive information on Vitamin D and the means to address the issue in the interest of public health. I express my gratitude to DSM Ltd and others for financial support, to Major General Dr. Raman Kumar Marwah (retd.) for the efforts he put in as Principal Investigator of the ILSI-India Efficacy Project, to Col. M.K. Garg for the initial draft of the Position Paper and the members of the Drafting Committee and other experts for their contributions.



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CONTENTS

Abbreviations And Definitions

Abbreviations

DACH	Germany, Austria and Switzerland
DRI	Dietary ReferenceIntake
FAO	Food And Agriculture Organization
WHO	World Health Organization
FDA	Food And Drug Administration
FSSAI	Food Safety And Standard Authority of India
Gms	Grams
IICDS	Integrated Child Development Services
IU	International Units
MDM	Mid-Day Meal
Nmol/L	Nanomoles Per Liter
Ng/Ml	Nanograms Per Milli Liter
NDP	National Diary Plan
NOC	No Objection Certificate
RDA	Recommended Dietary Allowance
RNI	Reference Nutrient Intake
Serum 25 (OH)D	25 hydroxyvitamin D
VDD	Vitamin D Deficiency
Vitamin D_2	Ergocalciferol
Vitamin D_3	Cholecalciferol

Definitions

Nmol/L and Ng/ml

These are units measuring Vitamin D. Serum concentration of 25 (OH) D is reported in both nanomoles per liter (nmol/L) and nanograms per milliliter (ng/ml). 1 nmol/L= 0.4 ng/ml.

Recommended Dietary Allowance (RDA)

A Recommended Dietary Allowance (RDA) is the average daily dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life-stage and gender group.

The Dietary Reference Intakes (DRIs)

The Dietary Reference Intakes (DRIs) are a set of scientifically based nutrient reference values for healthy populations. It is an umbrella term that describes four types of reference values:

- Estimated Average Requirement (EAR)
- Recommended Dietary Allowance (RDA)
- Adequate Intake (AI)
- Tolerable Upper Intake Level (UL)

DRIs are established using an expanded concept that includes indicators of good health and the prevention of chronic disease, as well as possible adverse effects of excess intakes of nutrients. Each type of DRI refers to the average daily nutrient intake of healthy individuals over time.

Reference Nutrient Intake (RNI)

RNI stands for Reference Nutrient Intake and is the amount of nutrients that is needed to meet the dietary needs of 97% of people within the population.

Section 1. CURRENT STATUS OF VITAMIN D DEFICIENCY: GLOBAL

Vitamin D is a sunshine hormone, which is necessary for optimal human health. It is primarily obtained via sun exposure and food and dietary supplements and is vital for bone health. The evidence regarding it's beneficial role in extra-skeletal systems such as improving immune health, common cancers, diabetes, metabolic syndrome and autoimmune disorders, is accumulating from different parts of the world. The incidence of Vitamin D deficiency is rising worldwide and remains the most common under-diagnosed and untreated medical problem because of it's silent nature.

This emerging pandemic involving more than 2.6 billion people of all age groups (including neonates, infants, school children, pregnant/lactating women, adults and elderly), sex, race and ethnicity has primarily resulted from poor sun exposure, dark skin complexion, vegetarian food habits, sedentary life style and lack of Vitamin D food fortification program.

Vitamin D deficiency is a global issue. It has been estimated that 20–100% of U.S., Canadian, and European elderly men and women are Vitamin D deficient. Children and young and middle-aged adults are at equally high risk for Vitamin D deficiency worldwide. Vitamin D deficiency is quite common in Australia, the Middle East, India, Africa, and South America.

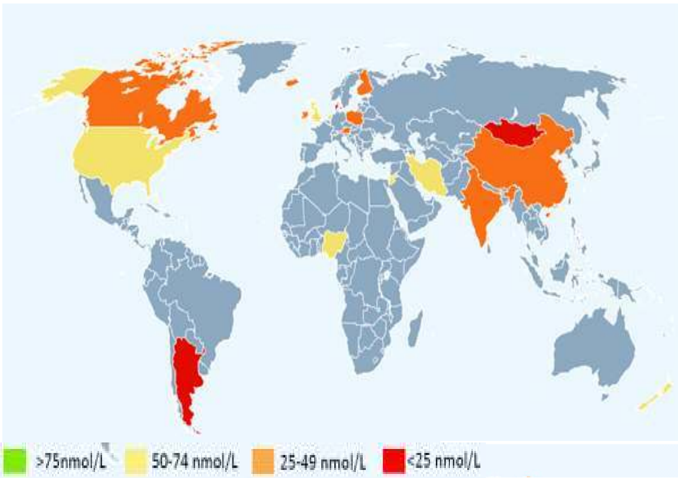
Vitamin D deficiency can be assessed based on serum 25 (OH)D level as given in the following Table:

Table 1: Assessment of Vitamin D Levels

	Severe Deficiency	**Moderate Deficiency**	**Mild Deficiency**	**Insufficient**
nmol/L	< 12.5	12.5-25	25-50	50-75
ng/ml	<5	5-10	10-20	20-30

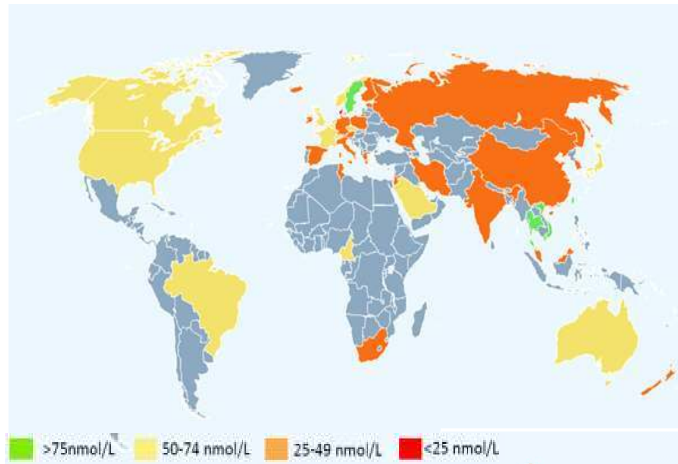
The prevalence of global Vitamin D status in children, adolescents and adults is given in Map 1 and Map 2 and Chart 1 gives the Vitamin D status in Asian countries.

Map 1: *Global Vitamin D Status In Children & Adolescents*



Source: http://www.iofbonehealth.org/facts-and-statistics/vitamin-d-studies-map

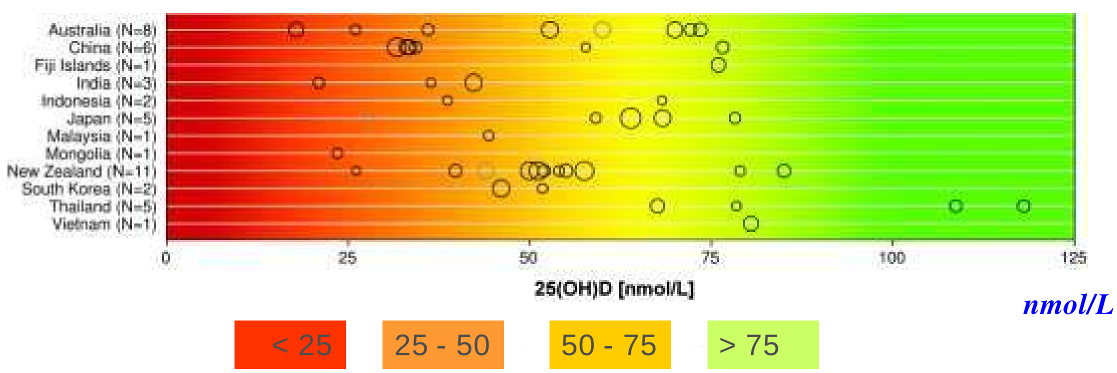
Map 2: Global Status of Vitamin D Deficiency in Adults (<50 nmol/L or 20 ng/ml)



Source: http://www.iofbonehealth.org/facts-and-statistics/vitamin-d-studies-map

Among Asian countries India has distinction of having second lowest levels of Vitamin D (25 OHD).

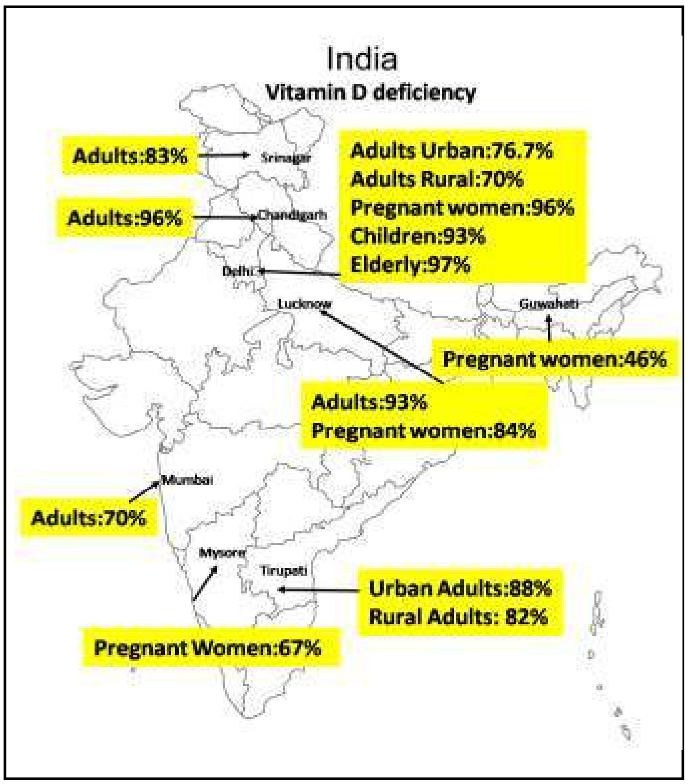
Chart 1: Global Vitamin D Status In Adults In Asian Countries (N=46 Studies in Asia)



Section 2: CURRENT VITAMIN D DEFICIENCY STATUS: INDIA

The Indian subcontinent is situated between 8.4° N and 37.6° N latitude and has adequate sunshine throughout the year. Several studies over last decade from all across India have revealed high prevalence of Vitamin D deficiency in all age groups and both sexes. This is probably the result of poor sun exposure, dark skin complexion, atmospheric pollution, vegetarian food habits, absence of food fortification with Vitamin D, usage of sun screens and poor intake of Vitamin D supplements.

Map 3: Vitamin D Deficiency: India (Select Studies)



As regards pregnant and lactating women studies from different parts of India like Delhi, Lucknow, Mysore and Guwahati have shown high prevalence of Vitamin D deficiency ranging from 46% in Guwahati (East) to 67% in Mysore (South) and 84% -96% in Delhi and Lucknow (North).

Goswami R et al from Delhi and Sachan et al from Lucknow showed mean cord blood 25(OH)D concentrations of the new born to be significantly lower than the mean maternal serum(25OH) D and that cord blood 25(OH)D strongly correlated with maternal values ($R=0.79$, $p<0.001$).

Bhalala et al from Mumbai and Anju & Marwaha et al from Delhi, corroborated the above observations in significantly larger number of study subjects.

Another study evaluating the role of Vitamin D deficiency in causation of neonatal hypocalcaemia seizures also revealed a strong positive correlation of serum 25 (OH)D levels between mother and their infants presenting with hypocalcaemia seizures. The study concluded that infants born to vitamin D deficient mothers are at a significantly higher risk to develop hypocalcaemia seizures.(Aneja and Marwaha et al).

Unlike adults, there is limited data on clinical and subclinical vitamin D deficiency in Indian children. Marwah RK et al have demonstrated the prevalence of bow legs/ knock knee in 10.8%-11.6% and low serum 25(OH)D i.e. <20ng/dl in 84 to 93% apparently healthy school children and adolescents in Delhi.

In children of Indian origin residing in South Africa, the prevalence of knock knee and bow legs was reported to be between 6.1% to 19.4%. Similarly, in Indian migrants in UK, the prevalence of clinical Vitamin D deficiency in children and adolescents was shown to be 5%-30%, while studies using biochemical and radiological variables, showed prevalence at 12.5% to 66% (69,82,83).

Studies from all corners of India have reported Vitamin D deficiency ranging from 70%-94% among adult population. A study from Kashmir reported presence of Vitamin D deficiency in 83% of adults while Delhi reported Vitamin D deficiency in 76.7% -94% in urban and 70% in rural areas in NCR region. Similar high prevalence of Vitamin D deficiency (93% and 96%) was noted in Lucknow (Central India) and Chandigarh. Southern part of India, where maximum sunshine is available being near to the equator, also revealed Vitamin D deficiency in 82%-88% among urban and rural population with slight female predominance. Vitamin D deficiency was also noted to be present in 70% of adults residing in Mumbai (West).

Till recently, there was paucity of data on Vitamin D status in elderly Indian population. According to a recent study conducted in elderly population of more than 50 years of age in North India, Vitamin D deficiency (VDD) was noted in more than 97 % of the North Indian population (Marwaha etal). Older people are more prone to develop VDD because of various risk factors like decreased dietary intake, diminished sunlight exposure, reduced skin thickness, impaired intestinal absorption, and impaired hydroxylation in the liver and kidneys.

Section 3: IMPACT OF VITAMIN D DEFICIENCY

Vitamin D is essential for optimal human health. Its main function, is to maintain healthy bones. Classical role of Vitamin D is to improve bone mineral density through calcium absorption and deposition, which is necessary to prevent rickets and osteomalacia. Recently, many extra-skeletal benefits of vitamin D have been recognized but these benefits still remain to be determined through randomized control trials.

Vitamin D has been shown to maintain muscle mass and strength and reduce the risk of falling particularly in elderly and prevent fractures. It has also been reported to strengthen the immune system by immune-modulation and impart resistance to infection, reduce risk of multiple sclerosis, diabetes mellitus, and tuberculosis. It is believed to inhibit uncontrolled cell proliferation and stimulate cell differentiation thereby preventing common cancers such as prostate, colon and breast cancers. Since Vitamin D is related to calcium homeostasis, which is an essential factor in cardiovascular functions, it's deficiency is associated with hypertension and increased prevalence of heart diseases. Recently, Vitamin D deficiency has been reported to be associated with increased mortality in population based studies.

It has been estimated that Vitamin D sufficiency alone can decrease bone fractures by 20%, cardiovascular disease by 20%, diabetes and cancer by 25% each and multiple sclerosis by 50%. The economic burden of these diseases is also very high.

Vitamin D sufficiency achieved through natural sources, supplementation or food fortification will have a tremendous impact on the health and longevity of Indian people. What is required is a concerted national effort to screen for Vitamin D status, and implement policies/ guidelines for dietary intake, sun exposure, supplementation and Vitamin D fortification to improve the health status of the people.

Section 4: HOW TO ADDRESS VITAMIN D DEFICIENCY IN INDIA?

There is an urgent need to address the problem of Vitamin D deficiency. Increasing sun exposure and improving nutrition status either by nutritional supplementation or mass food fortification are all low cost measures which will improve public health and save huge medical expenses by the society.

I. Sun Exposure

In the olden days, Indians synthesized most of their Vitamin D through adequate sun exposure. However inadequate sun exposure due to increased working hours indoors, atmospheric pollution, traditional clothing concealing most of the body parts, dark skin and UV creams have resulted in limited formation of Vitamin D in the skin.

Ultraviolet rays of wavelength (290-315nm) which are responsible for formation of Vitamin D are maximum during mid-day (1000-1500h) and depend on latitude and angle of rays with skin (zenith angle). As zenith angle increases, efficiency of skin to synthesize Vitamin D decreases. Zenith angle is the narrowest near equator and increases as latitude increases. India is situated between 8.4° N and 37.6° N latitude, which also explains seasonal variation and different serum levels of Vitamin D in various parts of India .

Though, It is amply clear from the studies carried out in India that just exposure to sunlight may not bring the serum Vitamin D levels to within normal range, one should not discourage people from exposing themselves to adequate sunlight.

II. Food

There are very few naturally occurring food sources of Vitamin D. Fatty fish, fish liver oil, and egg yolk etc. are some of natural foods which are rich in Vitamin D. Their Vitamin D content is listed below:

Table 2: Sources of Vitamin D: Food

Items	Vitamin D (IU)
Fatty Fish (100gms)	
- Salmon	
Fresh, wild	600–1000
Fresh, farmed	100–250
Canned	300–600
-Sardines, canned	**300**
-Mackerel, canned	**250**
-Tuna, canned	**230**
Cod liver oil (1 tsp)	**400–1000**
Shiitake mushrooms (100gms)	
-Fresh	100
-Sun-dried	1600
Egg yolk	**20**
Whole Milk- Cow (100ml)*	**2**
Whole Milk Buffalo (100 ml)*	**Negligible**

IU = 25 ng

Source: Holick et al , Endocrine Society Guidelines 2011, p 9.

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**Estmation provided by Col (Dr) M K Garg, Senior Adviser (Medicine & Endocrinology), Command Hospital (Southern Command)*

The majority of population in India being vegetarian does not consume foods that are rich in Vitamin D content as substantiated by dietary evaluation of North Indian children from upper socio-economic strata. Their maximum intake of Vitamin D through diet is only 80-100IU/day as against daily requirement of 600-800 IU/day (Seema & Marwaha et al).

Vitamin D is available in two forms for supplementation:

- **Firstly Vitamin D2** is manufactured in plant through the ultraviolet irradiation of ergosterol from yeast, and
- **Secondly Vitamin D3** through the ultraviolet irradiation of 7-dehydrocholesterol from lanolin. Both are used in over-the-counter Vitamin D supplements.

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Vitamin D is available in many nutritional supplements in India like multivitamin tablets and combination with calcium tablets. However, these are used for medicinal purpose rather than food supplements.

III: Food Fortification

The evidence presented above clearly shows high prevalence of Vitamin D deficiency, Further, Indian foods and limited sun exposure, do not provide adequate Vitamin D. In view of the critical role of calcium and Vitamin D in the prevention of serious chronic diseases beyond rickets, osteomalacia, osteoporosis and fractures, industrialized countries have made fortification of milk and other food products with Vitamin D a routine practice.

In the United States, milk is voluntarily fortified with 400 IU per quart (385 IU/L) of Vitamin D (though US regulations do not specify the form). In Canada, under Food and Drug Regulations, fortification of milk and margarine with Vitamin D is mandatory. Milk must contain 35-45 IU Vitamin D per 100 ml and margarine, 530 IU per 100 gms. In addition, fortified plant-based beverage must contain Vitamin D in an amount equivalent to milk.

Based on data from US FDA survey that provides information on the labels of processed packaged food products, one study reported that almost all milks, almost 75% ready to eat breakfast cereals, slightly more than half of all milk substitutes, approximately one quarter of yogurts, and about 8%-14% of cheese, juices, and spreads are fortified with Vitamin D. In human milk Vitamin D content is about 4-5 IU/100 Kcal, which is lower than daily requirement for the new-born. This level is also dependent on maternal Vitamin D status. In view of this, US FDA has established that infant formula must contain 40-100 IU of Vitamin D per 100 Kcal.

In contrast, fortification of food with Vitamin D has not been considered in India due to, the widely held view that adequate sunshine is available. However, most studies show evidence to the contrary. Since advocacy regarding dietary measures, lifestyle modifications as well as supplementation of Vitamin D have not born fruits, fortification of common food articles with Vitamin D appears to be the most effective public health measure for India.

Section 5: ILSI-INDIA EFFICACY STUDY ON MILK FORTIFICATION

Before recommending Vitamin D fortification program in India, ILSI-India considered it imperative to carry out a randomized control trial to evaluate the impact and safety of fortifying food products. Since, milk is the most commonly consumed food item in different age groups and maximum experience in fortification worldwide has been with milk or milk products, ILSI-India undertook the milk fortification project to evaluate efficacy and safety of fortified milk with Vitamin D in school children.

The Study

This study enrolled 776 apparently healthy children aged 10-14 years (boys-332; girls-464) from three private schools, located in the National Capital Region of Delhi. The study subjects were enrolled with the consent of the school authorities, parents/ guardians and verbal assent from children themselves. Ethics permission was obtained from the ethics committee of the Institute. All were given 200 ml of unfortified milk every day for 12 weeks and, then randomized into three groups. .

This study was double blinded, in which neither the investigators knew which group was getting unfortified or fortified milk nor school children till the end of study. Subjects in group A continued to receive unfortified milk whereas group B and C received 200 ml of milk fortified with 600 and 1000 IU of Vitamin D per day respectively, for 12 weeks. Blood and urine samples were collected at the start of study and at the end of study.

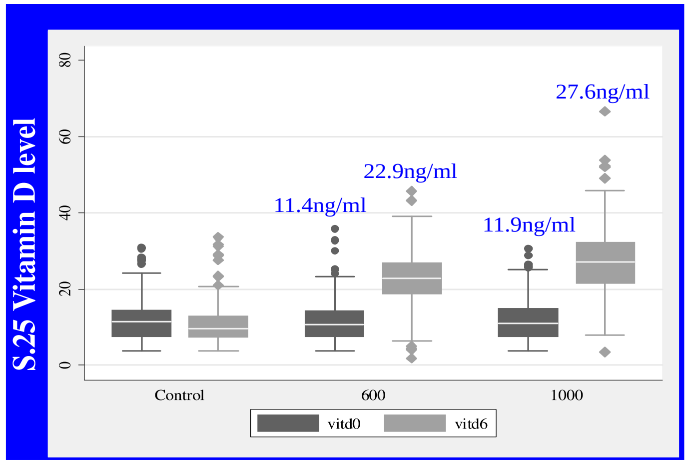
Method of Fortification

Fortification of milk was carried out using Vitamin D3 100SD/S, spray dried and water soluble form of Vitamin D3. The calculated quantity of Vitamin D3 was added to two liters of processed milk along with a small quantity of sugar and stirred at slow speed to mix the ingredients. These two liters of milk were then added to the batch tank containing processed milk and continuously stirred for 15-20 minutes to ensure homogenous mixing. This fortified milk was packed into 200 ml of tetra packs. Samples of fortified milk were collected at different time intervals during production and sent for Vitamin D estimation by HPLC. Stability of fortification was also checked during and after completion of study in random samples and compared with the samples before starting fortification which did not show more than 10% variation.

Estimation of Vitamin D

Serum Vitamin D (25OHD) levels significantly improved in both the groups (Group B from 11.4ng/ml to 22.9ng/ml and Group C from 11.9ng/ml to 27.6ng/ml) following supplementation of milk fortified with Vitamin D. While the percentage increase in number of subjects who achieved Vitamin D levels more than 20 ng/ml in group B rose from 4.93% to 69.95% and group C from 12% to 81.11%, no significant change was noted in the group A (6.32% to 5.9%) after fortification. Similarly, prevalence of Vitamin D sufficiency (>30 ng/ml) improved from 1.23% to 12.34% in group B and from 0.42% to 36.05% in group C following supplementation with no notable change in group A. No adverse events were documented in the study.

Graph 1: The Mean Improvement In Serum Vitamin D Level After Fortification



Conclusion

This study concluded that milk fortification is an effective strategy to improve Vitamin D status in school children. There is no reason to believe that this strategy will not be effective in other age-groups.

Section 6: FORTIFICATION OF MILK WITH VITAMIN D AS PUBLIC HEALTH STRATEGY

Food fortification is the process of adding micronutrients (essential trace elements and Vitamins) to food. It can be purely a commercial choice to provide extra nutrients in a food, or sometimes it is a public health policy which aims to reduce numbers of people with dietary deficiencies in a population. Diets that lack variety can be deficient in certain nutrients. Sometimes the staple foods of a region can lack particular nutrients, due to the soil of a region, or because of the inherent inadequacy of the normal diet. Addition of micronutrients to staples and condiments can prevent large-scale deficiency diseases in these cases. The best example of this is iodized salt, which has substantially reduced Iodine Deficiency Disorders in India.

Concept of food fortification is not new. In 1833, the French chemist, Boussingault, recommended the addition of Iodine to salt to prevent thyroid goiter in South America. In 1918, Vitamin A began to be added to margarine. In 1923, United Kingdom and in 1931, United States, started adding Vitamin D to milk as a measure to help prevent rickets in children. Scandinavian countries and North America have mandatory provision for the addition of Vitamin D in toned, double toned and skimmed milk and are adding in the range of 400-900IU. Some developing countries, mainly in Central America and few in Africa have decades of experience in food fortification for reduction of Vitamin D deficiency. Milk fortification programs also exist in Chile, Argentina, and Ireland.

There are several advantages in making up nutrient deficiencies among populations via food fortification as opposed to other methods. Fortification does not call for specific dietary interventions or change in dietary patterns, ensures continuous delivery of the nutrient with potential to maintain nutrient stores more efficiently. Food fortification strategy can lead to relatively rapid improvements in the micronutrient status of a population, at a very reasonable cost, especially if advantage can be taken of existing technology and local distribution networks. Since the benefits are potentially large, food fortification can be a very cost-effective public health strategy. However, an obvious requirement is that the fortified food should be consumed in adequate amounts by a large proportion of the target population. It is also necessary to have access to, and to use, fortificants that are bioavailable and do not affect the sensory properties of foods. In most cases, it is preferable to use food vehicles that are centrally processed.

It is possible to fortify foods that are widely consumed by the general population (mass fortification), to fortify foods designed for specific population subgroups. The latter include complementary foods for infants and young children, or rations for displaced populations (targeted fortification).

Generally speaking, mass fortification is nearly always mandatory. Targeted fortification can be either mandatory or voluntary depending on the public health significance of the problem it is seeking to address. Market-driven fortification is always voluntary, but governed by regulatory limits. The choice between mandatory or voluntary food fortifications usually depends on national circumstances and regulations.

I Mass Scale Milk Fortification

Mass scale fortification is generally the best option when the majority of the population has an unacceptable risk, in terms of public health, of being or becoming deficient in specific micronutrients. With the expanding range of fortificant compounds available and the need to use various vehicles according to the designated target groups, there is need to consider the technologies best suited to achieve a fortified product with the desired properties. Ideally, a fortified food should:

- Be commonly consumed by the target population;
- Have a constant consumption pattern with a low risk of excess consumption;
- Have good stability during storage;
- Be relatively low in cost;
- Be centrally processed with minimal stratification of the fortificant;
- Have no interaction between the fortificant and the carrier food;
- Be contained in most meals with availability unrelated to socio-economic status; and
- Be linked to energy intake.
- Be locally available.

II Vehicles For Fortification

1. Milk and Milk Products

To eliminate/reduce Vitamin D deficiency in India, the best vehicle is milk and milk products. India is the world's largest producer of dairy products by volume, accounting for more than 13% of world's total milk production. The per capita consumption of drinking milk is approximately 250 ml/day and 35 % of the total dairy produce is handled by the organized sector. In 2010, the Government and National Dairy Development Board had drawn up a national Dairy Plan (NDP) that proposes to nearly double India's milk production by 2020 and increase distribution through organized sector. In view of this, fortification of milk with Vitamin D, if undertaken through organized sector, could benefit a large section of the Indian population.

Technology: Technology for fortification of milk is simple. All the vitamins and minerals that can be added to milk are available in dry powder form. The fat-soluble vitamins like Vitamin D are also available in an oily form. These are added preferably as a premix, which is a homogenous mixture of the desired amount of Vitamin D concentrated in a small amount of milk. Premixes ensure the addition of correct amounts and uniform homogenization of the micronutrients in the final product. These premixes can then be added to the final product in a suitable ratio as was done in ILSI-India milk fortification study *(page 6)*.

Micronutrient Stability: Nutrients naturally present in or added to liquid milk are fairly stable during processing. Most vitamins and minerals show retention of 70% to 100% after a single common industrial heat treatment. The stability of most nutrients in liquid milk during storage is also good.

Fortification Limits: With currently available data, average serum Vitamin D levels in Indians vary in different parts of the country from 10 ng/ml -18.5 ng/ml approximately depending on the latitude. Each 100 IU of added Vitamin D will improve serum Vitamin D by 1 ng/ml. This means 1000 IU added to each liter of milk can improve Vitamin D status if milk is consumed in sufficient quantity (500-700ml), without causing any harmful effect as safety limit of Vitamin D levels are 100 ng/ml.

Cost of Fortification: The cost of fortifying 1000 IU/liter. is less than 5 paise with Vitamin D3.

2. Edible Oils

Vegetable oils and fats are consumed by everyone. It has 99% penetration into the household in India and it is possible to improve people's access to fat soluble Vitamin D through the fortification of edible oils.

Scientific data shows that the addition of Vitamin D to all cooking oil sold for human consumption is an inexpensive and well-established method for eliminating Vitamin D Deficiency. Rickets was eliminated in many European countries and in North America by double fortifying margarine with Vitamin A and D.

Table below gives example of countries which started with mandatory fortification of Vitamin D in oil.

Table 3: Countries With Mandatory Fortification Provision

Nutrient	Countries
Vitamin D	Denmark 1918, Singapore 1973, *Philippines 1975, Honduras 1976, Ecuador 1978, Peru 1984, Indonesia 1996, Nigeria 2004, New Zealand 2007, Canada Mexico, Columbia, Turkey, New Zealand, Malaysia, Indonesia, Australia, South Africa

** Philippines started with Margarine fortification in 1975 and refined cooking oil in 2000*

III Social Marketing For Creating Awareness

All food fortification programs share two objectives:

(i) To create an enabling environment; and

(ii) To help people adopt healthful behaviors.

To increase the chances of success, a fortification program needs to be supported by a range of well-coordinated communication activities that promote individual, community, corporate and political change. In this respect it is important to note that messages about the benefits of fortification can be communicated in a number of different ways, using a variety of techniques, depending on the intended audience.

IV Regulations On Fortified Milk

National Nutrition Policy recommends fortification of staple foods to address wide-spread micronutrient malnutrition amongst general population. The 11th Five Year plan (2007-2012) also recommends food fortification/ enrichment as one of the strategies for combating micronutrient malnutrition in the country. DBT- NIN (Department of Biotechnology, GOI and National Institute of Nutrition) meeting in 2007 on food fortification recommended Vitamin A and D suitable for milk fortification. Some Members of Parliament had also initiated a Private Members Bill on mandatory replenishment of toned and double toned milk in Lower House and Upper House respectively in the year 2007. An expert group consultation convened by National Institute of Nutrition in 2011 gave recommendation on regulation for Vitamin A and D fortification in milk. But progress has been extremely limited.

1: Global Regulatory Landscape

Several countries have established mandatory fortification of milk since early in this century. Table below illustrates the current status of milk fortification with Vitamins A and D in different countries.

Table 4: Mandatory Fortification Of Liquid And Dried Milk In Different Countries

Country	Product	Vitamin D (IU)
Argentina	Fluid and dry milk (whole and Skim)	400/L
Brazil	Dry skim milk for complimentary food programs	2000-2400/Kg
Guatemala	Skim Milk	400-600/L
Honduras	Milk	400/L
Malaysia	Evaporated/unsweetened Condensed Milk	—
Malaysia	Sweetened Condensed Milk	—
Malaysia	Filled evaporated/filled condensed milk	—-
Mexico	Sterilized Low-fat Milk	400/L
Mexico	Pasteurized low-fat milk	400/L
Mexico	Evaporated whole and low-fat milk	400/L
Philippines	Filled Evaporated/Filled Condensed Milk	(973/Kg)
USA	Fortified Nonfat dry milk(Reconstituted)	425/L
USA	Evaporated Milk	845/L
USA	Evaporated skim Milk	845/L
Venezuela	Dry Milk Powder	400/L

Figures in parentheses indicate that addition is optional

Source: Adapted from: Raunhardt .O. and Bowley. A Mandatory Food Enrichment. Nutriview Supplement to 1/1996 Issue.

The UK mandatorily fortifies margarine with a fat content of 80% or above, while in the USA, only milks labeled as 'fortified', have to be fortified with Vitamin D; however. More products are fortified in both the USA and the UK, such as breakfast cereals. Both Canada and Finland have introduced mandatory fortification of milk and margarine.

2: RDAs For Vitamin D

Recently recommendations have been made for increasing DRIs and RDAs for Vitamin D keeping in view its impact on bone health. For example:

- Review of latest data on bone health by IOM has resulted in new in US. The DRI for general population aged 1-70 years is 600 IU/day and for elderly (greater than 70 years of age) 800 IU.
- The European nutrition societies from D-A-CH (Germany, Austria and Switzerland) raised Vitamin D intake to 600 IU/day for the general population aged 1-65 years and 800 IU/day for elderly (over age 65 years).
- China has raised Vitamin D RNI for population aged 1-65 years to 15ug/day (600IU) and for elderly (above 65 years) to 20ug/day (800 IU).

- The International Osteoporosis Foundation recommends higher intakes of Vitamin D of 800-1000 IU/day for those at risk of osteoporosis and generally everyone aged 60 years and above. It also suggests that the intakes may need to be adjusted upward to as much as 2000 IU/day for individuals who are obese, have limited sun exposure (institutionalized, home bound), are suffering from mal-absorption and for population known to be at high risk for Vitamin D deficiency.

In India the Indian Council of Medical Research (ICMR) has prescribed specific recommendation of 400 IU/day for the population under situation of minimal exposure to sunlight. This may need to be revised upwards considering the fact that there is wide scale Vitamin D deficiency encompassing the entire population.

Section 7: THE WAY FORWARD

Considering the significant wide spread Vitamin D deficiency in India it is vital that active steps are taken in public health interest, to fortify milk with Vitamin D, which is the most accepted and prevalent strategy internationally. The research project undertaken by ILSI-India confirms that milk fortification is effective and sustainable. It is suggested that an action plan needs to be designed and implemented based on the following concrete measures:

- Lay down clear definition of fortified milk just as in case of fortified atta. This will eliminate the need to take another license / NOC and encourage fortification of milk. Food Safety and Standards Authority of India (FSSAI) can initiate action.
- Lay down guidelines for fortification with Vitamin D. It could be $1/3^{rd}$ of RDA (which is most countries is now at 600 IU), allowing for regional differences. Food Safety and Standards Authority of India (FSSAI) can initiate action.
- Evaluate UVB rays of 290-320nm wavelength in different parts of the country to enable framing of guidelines for daily sun exposure. Such studies can be easily sponsored by meteorological department.
- All partners involved in fortification programs should actively participate in the respective areas. These should include; relevant governmental organizations, food industry, trade organizations, consumer organizations, academic and research facilities, marketing specialists and interested international organizations and agencies.
- Use Mid-day meal (MDM) program of Ministry of Human Resource Development, GOI to distribute fortified milk with low cost packaging, maintenance of cold chain, and proper storage facility. The technical feasibility of polypack packaging should be explored to reduce the cost of packaging.
- Distribute fortified milk to pregnant and lactating mothers through Integrated Child Development Services (ICDS) Program of Ministry of Women and Child Development, GOI.

REFERENCES:

1. Munger KL, Levin LI, Hollis BW, Howard NS, Ascherio A. Serum 25-hydroxyvitamin D levels and risk of multiple sclerosis. JAMA 2006;296:2832-8. [PubMed abstract]
2. Wahl DA, Cooper C, Ebeling PR et al. A global representation of Vitamin D status in healthy populations. Arch Osteoporosis. 2012;7:155-72.
3. Babu US, Calvo MS. Modern India and the vitamin D dilemma: evidence for the need of a national food fortification program. Mol Nutr Food Res. 2010;54:1134-47.
4. Calvo MS, Whiting SJ, Barton CN. Vitamin D fortification in the United States and Canada: current status and data needs. Am J Clin Nutr 2004;80:1710S-6S. [PubMed abstract]
5. Davis CD. Vitamin D and cancer: current dilemmas and future research needs. Am J Clin Nutr 2008;88:565S-9S. [PubMed abstract]
6. Harinarayan CV, Joshi SR. Vitamin D status in India – Its implications and remedial measures. J Assoc Physicians India 2009; 57: 40-48.
7. Grant WB, Cross HS, Garland CF et al. Estimated benefit of increased Vitamin D status in reducing the economic burden of disease in western Europe. Prog Biophys Mol Biol. 2009;99:104-13.
8. Pittas AG, Dawson-Hughes B, Li T, Van Dam RM, Willett WC, Manson JE, et al. Vitamin D and calcium intake in relation to type 2 diabetes in women. Diabetes Care 2006;29:650-6. [PubMed abstract]
9. Wagner CL, Greer FR; American Academy of Pediatrics Section on Breastfeeding; American Academy of Pediatrics Committee on Nutrition. Prevention of rickets and vitamin D deficiency in infants, children, and adolescents. Pediatrics 2008;122:1142-1152. [PubMed abstract]
10. Norman AW, Henry HH. Vitamin D. In: Bowman BA, Russell RM, eds. Present Knowledge in Nutrition, 9th ed. Washington DC: ILSI Press, 2006.
11. Ovesen L, Brot C, Jakobsen J. Food contents and biological activity of 25-hydroxyvitamin D: a vitamin D metabolite to be reckoned with? Ann Nutr Metab 2003;47:107-13. [PubMed abstract]
12. Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes for Calcium and Vitamin D. Washington, DC: National Academy Press, 2010.
13. International Agency for Research on Cancer Working Group on ultraviolet (UV) light and skin cancer. The association of use of sunbeds with cutaneous malignant melanoma and other skin cancers: a systematic review. Int J Cancer 2006;120:1116-22. [PubMed abstract]
14. International Osteoporosis Foundation: Vitamin D Status around the world - http://www.iofbonehealth.org/facts-and-statistics/vitamin-d-studies-map
15. Holick MF. Vitamin D deficiency. N Engl J Med 2007;357:266-81. [PubMed abstract]
16. Holick MF. Vitamin D: the underappreciated D-lightful hormone that is important for skeletal and cellular health. Curr Opin Endocrinol Diabetes 2002;9:87-98.
17. Marwaha RK, Tandon N, Garg MK et al. Vitamin D status in healthy Indians aged 50 years and above. J Assoc Physicians India. 2011;59:706 9
18. Marwaha RK, Puri S, Tandon N et al. Effects of sports training & nutrition on bone mineral density in young Indian healthy females. Indian J Med Res. 2011;134:307-13
19. Marwaha RK, Tandon N, Chopra S et al. Vitamin D status in pregnant Indian women across trimesters and different seasons and its correlation with neonatal serum 25-Hydroxyvitamin D levels. Br J Nutr. 2011;106:1383-9.

20. Minutes of "Stakeholder Consultation On Regulation For Staple Food Fortification" Meeting Held On 15th April 2011, National Institute of Nutrition, Hyderabad
21. National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health. Osteoporosis Handout on Health. NIH Publication No. 11-5158; 2011.
22. National Institutes of Health Osteoporosis and Related Bone Diseases National Research Center. Osteoporosis overview. October 2010.
23. National Institutes of Health: Strengthening Knowledge and Understanding of Dietary Supplements
24. Garg MK, Marwaha RK, Khadgawat R et al. Efficacy of Vitamin D loading doses on serum 25-hydroxy Vitamin D levels in school going adolescents: an open label non-randomized prospective trial. J Pediatr Endocrinol Metab. 2013;26:515-23.
25. Khadgawat R, Marwaha RK, Garg MK et al. Impact of Vitamin D fortified milk supplementation on Vitamin D status of healthy school children aged 10-14 years. Osteoporosis Int. 2013;24:2335-43.
26. Aggarwal V, Seth A, Marwaha RK et al. Management of nutritional rickets in Indian children: a randomized controlled trial. J Trop Pediatr. 2013;59:127-33.
27. Mehrotra P, Marwaha RK, Aneja S et al. Hypovitaminosis d and hypocalcaemia seizures in infancy. Indian Pediatr. 2010;47:581-6
28. Seth A, Marwaha RK, Singla B et al. Vitamin D nutritional status of exclusively breast fed infants and their mothers. J Pediatr Endocrinol Metab. 2009;22:241-6.
29. Goswami R, Marwaha RK, Gupta N et al. Prevalence of Vitamin D deficiency and its relationship with thyroid autoimmunity in Asian Indians: a community-based survey. Br J Nutr. 2009;102:382-6
30. Marwaha RK, Sripathy G. Vitamin D & bone mineral density of healthy school children in northern India. Indian J Med Res. 2008;127:239-44
31. Puri S, Marwaha RK, Agarwal N et al. Vitamin D status of apparently healthy schoolgirls from two different socioeconomic strata in Delhi: relation to nutrition and lifestyle. Br J Nutr. 2008;99:876-82
32. Marwaha RK, Tandon N, Reddy DR et al. Vitamin D and bone mineral density status of healthy schoolchildren in northern India. Am J Clin Nutr. 2005;82:477-82.
33. Tandon N, Marwaha RK, Kalra S et al. Bone mineral parameters in healthy young Indian adults with optimal Vitamin D availability. Natl Med J India. 2003;16:298-302.
34. O'Sullivan K et al, 1988, Nutritional enhancement of cereals by fortification, Nutritional Aspects of Food Processing and Ingredients, (Ed Henry & Heppett).Aspen Publishers, quoted in Kellogg's Satellite Symposium (to the 8th European Nutrition Conference, Lillehammer, 17-19 June 1999) Addition of Nutrients to Foods: Accompanying papers.
35. Guidelines on food fortification with micronutrients, edited by Lindsay Allen, Bruno de Benoist, Omar Dary, Richer Hurell, World Health Organization and Food and Agriculture Organization of the United Nations 2006
36. Darnton-Hill I. Overview: rationale and elements of a successful food-fortification programme. Food and Nutrition Bulletin 1998;19:92–100.
37. Ian Darnton-Hill and Ritu Nalubola, Fortification strategies to meet micronutrient needs: successes and failures. Proceedings of the Nutrition Society 2002; 61:231–241
38. Alcalay R, Bell RA. Promoting nutrition and physical activity through social marketing: current practices and recommendations. Davis, CA, Center for Advanced Studies in Nutrition and Social Marketing, University of California, 2000.
39. David Borradale* and Michael Kimlin, Vitamin D in health and disease: an insight into traditional functions and new roles for the 'sunshine vitamin', Nutrition Research Reviews (2009), 22, 118–136
40. *Raunhardt .O. and Bowley. A Mandatory Food Enrichment. Nutriview Supplement to 1/1996 Issue.*
41 Agarwal KS[1], Mughal MZ, Upadhyay P, Berry JL, Mawer EB, Puliyel JM., Arch Dis Child. 2002 Aug;87(2):111-3., The impact of atmospheric pollution on vitamin D status of infants and toddlers in Delhi, India.

What is ILSI-India?

ILSI-India is a branch of International Life Sciences Institute (ILSI) with Head Quarters in Washington D.C. It works on issues relating to food safety, nutrition, toxicology, risk assessment, biotechnology and environment. It works very closely with industry, R&D organizations, and government departments, Ministry of Health, Department of Biotechnology, Ministry of Science and Technology, Ministry of Agriculture and Ministry of Food Processing Industries.

ILSI-India carries out its mission through sponsoring workshops, conferences, seminars, training programs and research. It also brings out publications and organizes educational programs. ILSI-India activities cover India and South Asian Region.

ILSI is a non-profit, worldwide organization whose mission is to provide science that improves human health and well-being and safeguards the environment. It achieves this mission by fostering collaboration among experts from public and private sectors of society on conducting, gathering, summarizing, and disseminating science.

ILSI strategy encourages global action on identifying and then resolving outstanding scientific questions in four thematic areas that capture the core of ILSI's work:

- food and water safety
- toxicology and risk science
- nutrition, health and well-being
- sustainable agriculture and nutrition security

ILSI branches include Argentina, Brazil, Europe, India, Japan, Korea, Mexico, North Africa and Gulf region, North America, North Andean, South Africa, South Andean, Southeast Asia Region, Taiwan, the Focal point in China, and the ILSI Health and Environmental science Institute. ILSI also accomplishes its work through the ILSI Research Foundation (composed of Center for Environmental Risk Assessment of Genetically Modified Crops (CERA), Center for Risk Science Innovation and Application (RSIA), Center for Nutrition and Health Promotion and Center for Integrated Modeling of Sustainable Agriculture & Nutrition Security (CIMSANS)

ILSI has a non-governmental status with World Health Organization and a special consultative status with Food and Agriculture Organization of the United Nation.

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