Review Article

Large-scale Staple Food Fortification as a Complementary Strategy to Address Vitamin and Mineral Vulnerabilities in India: A Critical Review

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Summary

The slow improvement in micronutrient malnutrition globally and in India warrants a need for scaling-up scientifically proven, cost-effective public health interventions. The present review discusses the potential of staple food fortification as a complementary strategy to tackle micronutrient deficiencies, while addressing the current concerns raised regarding its implementation. The review indicates the below par status of current strategies like dietary diversity and supplementation to address multiple micronutrients deficiencies in India and the need for complementary strategies to tackle this problem. Based on systematic reviews and meta-analysis, global and national evidence has identified staple food fortification as a proven and recognized cost-effective solution to address micronutrient deficiencies. The Government of India has shown a strong leadership to promote this proven intervention. Further, the paper addresses the concern that large-scale staple food fortification (LSFF) may lead to excessive nutrient intakes when delivered together with other interventions, e.g., supplementation, dietary diversity, among the same populations. A key message that emerges from this review is that LSFF is safe with current dietary intake and deficiencies and low coverage of other interventions. Given the current situation of food and nutrition insecurity which the COVID-19 pandemic has further exacerbated, and the critical role that nutrition plays in building immunity, it is even more important that health and nutrition of the population, especially vulnerable age groups, is not only safeguarded but also strengthened. LSFF should be implemented without any further delay to reach the most vulnerable segments of the population to reduce the dietary nutrient gap and prevent micronutrient deficiencies. Effective monitoring and regular dietary surveys will help ensure these interventions are being deployed correctly.

Key words: Anemia, dietary requirements, fortified food, India, micronutrient deficiency

Introduction

Although "micronutrients" are required in small quantities, the lack of sufficient intake is associated with major adverse consequences, particularly for children and women. These consequences include poor physical and cognitive development, serious congenital disabilities, reduced productivity, as well as increased severity of infections due to decreased immune function, which leads to an increased risk of child and maternal mortality.[1] Reviews such as the Copenhagen Consensus have consistently ranked micronutrient interventions as the most cost-effective development interventions that provide significant returns for a low cost.[2]

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The most recent data from National family health survey (NFHS-5) indicate limited improvement in nutrition outcomes since 2015–2016 (NFHS-4) and an actual increase in the prevalence of anemia across all age and gender groups through the income quintiles, most notable women of

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reproductive age (WRA), and preschool children.[3,4] The main cause of anemia remains iron deficiency and the deficiencies of other micronutrients such as folic acid, vitamin B6, and vitamin B12, which are also widely prevalent in India, especially in children, as indicated by the comprehensive national nutrition survey (CNNS) 2016–2018 report. 50%–70% of anemia is caused by iron, folate, or vitamin B12 deficiency or a combination of these micronutrients.[5] A recent systematic review highlights the high burden of micronutrient deficiencies in India particularly that of folic acid (37%), iron (54%), vitamin B12 (53%), and vitamin D (61%).[6] Micronutrient malnutrition is particularly a concern in the current COVID-19 pandemic context as the pandemic has impacted all four aspects, namely "availability, access, stability, and utilization" of food.

Current Status of Approaches for Addressing Nutrient Inadequacy in India

It is important to acknowledge the fact that micronutrient malnutrition is multifactorial, and as such, comprehensive and complementary approaches are required to address it. The most sustainable intervention to prevent micronutrient malnutrition is to increase the consumption of diverse diets. However, monitoring data collected over the past three decades and recent national surveys reveal that the levels of nutrient intake, including tribal communities and those living in rural areas and urban populations, are consistently deficient in multiple vitamins and minerals (NNMB 1984; 1993; 2002; 2012; 2017).[7-11] Achievement of nutrient adequacy is a challenge in India for several reasons. First, the high cost of healthy, nutritious diets is beyond the means of many households. Second, Indian population consume predominantly vegetarian diet which may have antinutrients that can interfere with iron absorption. Third, the intake of animal sources food is low in India, which has higher bioavailability of iron.[3] Fourth, the high burden of disease, especially gastroenteric infection, impairs the absorption and bioavailability of those nutrients which are consumed. The cost of the diet in accordance with EAT-Lancet dietary recommendations for rural India was found to be $3.00–5.00/person/day, whereas the actual dietary intake was estimated to be around $1.00/person/day.[12] Bridging the wide gap for consumption of healthy and diverse diets in the vulnerable population will be resource-intensive and challenging for India especially in the midst of the COVID-19 pandemic. A recent study from Bihar conducted among rural households clearly indicates that affordability remains a major barrier in improving quality food intake among the study population besides poor market accessibility.[13]

Supplementation is another proven short-term intervention to increase the intake of critical nutrients. In India, a national iron and folic acid supplementation program targeted to pregnant and lactating women has been in place to combat iron-deficiency anemia since 1970 and is currently implemented under the *POSHAN Abhiyaan.*[14] The coverage of the program continues to be relatively low, due to both issues of supply and compliance. In addition, there is a universal Vitamin A supplementation program for 6–59 months of children, but coverage with the biannual massive dose Vitamin A solution should be strengthened to prevent and control Vitamin A deficiency among vulnerable children.

A third critical intervention to increase nutrient intake is through large-scale staple food fortification (LSFF); a great body of evidence exists, including a recent systematic review and meta-analysis of LSFF programs, which affirms its contribution toward improved nutritional outcomes.[15] The present review focuses on the potential of LSFF as a complementary intervention to tackle micronutrient deficiencies in India. This review summarizes the results of a literature search from empirical reports, scientific publications, and reports from government organizations which was carried out using the key terms "Fortified Foods," "Micronutrient deficiency," "India" "anemia," and "dietary diversity" from various research handles like Refseek, PubMed, and Google Scholar.

Scope of Food Fortification as a Complementary Strategy to Combat Malnutrition

A meta-analysis by the WHO indicates that fortified rice may reduce the risk of iron deficiency by 35% and increased the average concentration of hemoglobin by almost 2 g/L.[16] In addition, reviews of LSFF programs have confirmed its impact on critical functional outcomes and 34% reduction in anemia from improved iron intake, with greater benefits realized by those most at risk of deficiency; 74% reduction in the risk of goiter; and a 41% reduction in the odds of neural tube defects (NTDs).[15] In another systematic review on the impact of iron-fortified foods on Hb concentration in children (10 years), it was seen that out of total 24 studies, 22 studies showed the improved mean hemoglobin after intervention of iron fortification as compared to their respective controls.[17] A major meta-analysis of 14 studies showed a positive impact of iodine fortification on many important outcomes.[18] Universal salt iodization (USI) has been globally recognized as the major LSFF success story and is responsible for the virtual elimination of 720 million cases of clinical iodine deficiency disorders (IDDs) over the past 25 years (a reduction of 75.9%), prevention of 20.5 million newborns affected by IDDs/year, with the resulting improvement in cognitive development and future earnings suggesting a potential global economic benefit of nearly $33 billion.[19]

The experience with fortification varies for different age groups and sub-groups in the population due to variations in baseline nutrient adequacy (or inadequacy), per capita consumption of different food vehicles and physiological needs. As shown in Figure 1, the potential benefits of fortification are consistent across the life cycle, with the exception of preschool children. Pregnant and lactating women with high micronutrient needs have a high potential to benefit from staple fortification like rice and wheat, because they consume a substantial amount of these.[20]

	Pregnancy	Lactating mother	6–23 mo	2–5 years	5–18 years	WRA (15–49 years)	Adult men	Elderly
Micro-nutrient need	very high	very high	very high	high	moderate to high	moderate to high	low to moderate	moderate to high
Amount of food eaten	moderate	moderate	low	low, increasing with age	increases with age	moderate	high	moderate
Potential to benefit	high	high	low	low, increasing with age	increases with age	high	high	high
Potential to fully meet need	low	low	no	low, increasing with age	increases with age	high	high	high

Figure 1: Potential benefits of food fortification across lifecycle.[20] WRA: Women of reproductive age.

Globally, over 140 countries currently have guidance or regulations in place for fortification of different food vehicles, the majority of which are mandatory: one hundred twenty-three countries have mandatory fortification for salt, 91 countries mandate at least one kind of cereal grain (maize, rice, or wheat) to be fortified with iron and folic acid, while 33 countries mandate the fortification of oils with Vitamin A and/or vitamin D.[21]

In India, fortification of Vanaspati was first introduced in 1953. India was one of the first countries in the world to initiate a USI program in 1962.[22] The CNNS survey demonstrated optimal iodine status among children confirming the success of the USI program, while the deficiencies are other micronutrients is still high. The National Nutrition Policy, 9th, 11th and 12th 5-year Plan as well as the National Nutrition Strategy on "Kuposhan Mukt Bharat" all recommend fortification of staples with micronutrients as one of the key strategies for tackling malnutrition.

The progress in India on staple food fortification has been driven by strong government leadership. Food fortification standards and a logo by food safety standards authority of India (FSSAI) were issued by for five staples in 2016. Directives for inclusion of fortified staples in social safety net programs (SSNP) programs like public distribution system (PDS), integrated child development scheme (ICDS), and mid-day meal (MDM) also exists. The fortified stables include rice and wheat (fortified with iron, folic acid and vitamin B12), oil and milk (fortified with vitamin A and D) and double fortified salt (DFS) with iron and iodine. Integration of fortified rice in the government social safety net program is currently being pursued by the Government of India. The directive for its scale up through the ICDS and MDM to reduce the prevalence of nutritional deficiency anemia was issued in 2021 and recently cabinet gave approval for scale-up in PDS in pan India by 2024.[23]

A literature review of 47 studies highlights improvements in hemoglobin or iron markers when fortifying foods with either iron alone or iron combined with other nutrients. The study concluded that fortification with multiple nutrients had better health impacts than using a single fortificant.[24] A recent case–control study from Gujarat showed increased mean hemoglobin by 0.4 g/dL, an 11.3-point improvement in cognitive scores and a reduced anemia prevalence of 10% among school-aged children after receiving fortified rice over a period of 8 months through the MDM program.[25] Similarly, in a few other Indian studies conducted among pregnant women and school children, a positive impact of providing DFS was observed on hemoglobin and urinary iodine levels as well as the status of other micronutrients.[26,27]

Unfolding Illusion on Potential Risk of Excessive Nutrient Intake in Case of Layering of Interventions

Even though food fortification has been widely recognized as an efficacious and cost-effective solution to address vitamin and mineral deficiencies, some important concerns have been raised. One such issue is of the potential risk of excessive intake of nutrients if multiple interventions are implemented simultaneously and targeting the same population. Although LSFF programs aim to address the lower intake levels of the most disadvantaged population groups, ensuring safe intakes of population groups who are at the higher end of their intake distribution curves remains important.[28]

FSSAI has followed a rigorous process to define the standards for fortification in India considering the dietary habits and consumption patterns of the Indian population. These standards have been reviewed as part of a recent analysis undertaken by food fortification resource centre (FFRC) to model the potential contribution of fortified foods toward nutrient needs at different stages of the lifecycle as compared with the reference diet of an individual not consuming fortified foods. It focused on the levels provided for several key nutrients added to fortified foods in comparison with the most recently recommended estimated average requirements, recommended dietary allowances (RDA) and tolerable upper limit (TUL). The analysis revealed that the current standards will only provide 30%–50% of RDA given average per capita consumption levels, to fill the missing nutrient gap with no risk of overload.[29]

There have also been concerns about excessive intake specifically for iron with multiple vehicles fortification. It is noteworthy to acknowledge that iron metabolism is strictly regulated by the body and levels are balanced by alterations in absorption with the help of the hepcidin/ferroportin axis.[30] Therefore, the body will downregulate absorption if it is iron replete or upregulate absorption if it is iron deficient. Under normal circumstances, approximately 0.8 mg to 2 mg of iron is absorbed daily by the body and is tightly controlled.

Table 1 shows the cumulative iron intake if multiple interventions are implemented in India at 100% coverage including fortification of rice/wheat provided through PDS, provision of DFS, and supplementation. Daily consumption of fortified cereal (167 g allocated under PDS scheme) and DFS with 10 g salt[31] will provide about 4.7–7.1 mg and 4.3–11 mg of incremental iron intake respectively, that too is embedded in the food matrix. The coverage of all these interventions is currently very low with DFS present in 4–5 states and that too not universally; supplementation coverage is low for most age groups for most age groups and fortified rice provision through SSNPs has just begun in last couple of years. The analysis indicates that when fortification of cereals and salt is done in accordance with current standards and consumed at expected levels, there is no risk of exceeding the TULs (40–45 mg/d) across all age groups. However, the amount of iron delivered through food fortification during pregnancy and lactation is substantially lower than the amount delivered through supplementation alone. The WHO recommends a daily dose of 60 mg elemental iron in settings where the prevalence of anemia is higher than 40% which can be safely increased to 120 mg/d for pregnant women diagnosed with anemia.[32] From 1990 till 2018, the Government of India has been providing 100 mg of elemental iron for pregnant and lactating women and no toxicity has been reported. Furthermore, as indicated by large surveys such as NFHS-5, the compliance with iron-folic acid supplementation remains low and challenging in India. Only 26% and 44.1% of pregnant women consume iron folic acid supplements for 180 days and 100 days respectively.[3] The coverage of supplementation programs for the other vulnerable groups like WRA, school children, and adolescent girls is still a miss (10%–20%).[33]

Iron overload is an uncommon condition and can probably be due to genetic defects such as hemochromatosis, or in diseases, such as the thalassemia in which the hemostatic control may be altered.[34] Moreover, only major and intermedia forms of thalassemia are associated with iron overload, prevalence of which is minimal in India.[35] The greatest contributor in these patients to iron overload is blood transfusions, not diet. On the other hand, for nontransfused thalassemic patients, a higher amount of dietary iron may be absorbed resulting in iron loading over time, but this may occur even in the absence of iron fortification.[36] Iron overload does not occur in genetic carriers with normal phenotypes.Therefore,withholding LSFF on the premise of preventing overloading can prevent reaching larger segment of vulnerable population who require critical nutrients and thus perpetuate the problem of micronutrient malnutrition. To conclude, the potential for iron fortification to cause iron overload is low given both the homeostatic controls preventing excess iron accumulation in the normal population and the current low exposure from multiple interventions.

A similar modeling, with respect to Vitamin A [Table 2], comparing intake from multiple interventions (dietary intake, fortification of foods, and supplementation) revealed that even if fortification of milk and oil is done at the maximum permitted level, there is no risk of exceeding the TULs at any age, even for children aged 1–3 years who are being given Vitamin A supplements (VAS). Evidence indicates that in children who received high-dose VAS, the serum retinol concentrations measured later in a few countries had returned toward baseline status in 2–3 months.[37] A recent study has suggested that Vitamin A supplementation alone is not sufficient to provide all Vitamin A needs for preschool children, who are the main target for VAS programs.[38] To address Vitamin A deficiency, dietary intake alone is not sufficient as it is contributing to only 16%–34% of the requirements for Vitamin A across age groups. Furthermore, vitamin A supplementation programs is in place only for preschool children and not for any other age group, neither there is a supplementation program for other nutrients like Vitamin D.

The role of Vitamin A and D in building immunity is well known and stressed during the COVID-19 pandemic. Given the critical role that nutrition plays in building immunity, it is even more important that the health and nutrition of the population, especially vulnerable age groups, is safeguarded and strengthened. Fortification of oils and milk through the organized sector could play a central role in overcoming deficiencies of these nutrients. The total oil consumption of oil in India is 24 million metric tons (MMT) annually, split between the organized sector, producing 19 MMT and the unorganized sector producing 5 MMT. At present, of the total fortifiable oil (11.25–11.75 MMT), 65.2% (7.5MMT/annum edible oil) is being fortified. Since a significant amount of oil is produced and marketed by leading oil brands, including small and medium industries, and reaches different parts of the country, fortification of oil to reach the masses is feasible strategy. Similarly, 416 lakh liters per day (LLPD) is produced by milk cooperatives and private sector of which about 150 LLPD gets fortified currently, reaching about 100 million people. If fortified, the total quality of milk can potentially benefit almost 275 million people.[39] Fortification of oil and milk with vitamins A and D, coupled with establishment of strong monitoring mechanism would help in reaching the unreached and reduce the dietary nutrient gap and prevent deficiencies of these two fat-soluble vitamins.

Conclusion

As a cost-effective strategy with demonstrated health,

Table 1: Calculations of iron intake based on dietary intake, fortification of foods (based on allocation of food grain under public distribution scheme) and supplementation

Age groups	Iron requirements, RDA and TUL			Consumption of foods fortified with iron		Amount contributed by various sources to daily intake of iron (mg)					
	TUL mg/d	RDA (2020) (mg/d)	EAR (2020) (mg/d)	Allocation of cereals under PDS scheme*	Average salt consumption of Indians (g)**	Daily diet (nonfortified foods) (NNMB - median intake)	Fortified cereals (low level) (mg/d)	Fortified cereals (high level value) (mg/d)	Double fortified salt (low level) (mg/d)	Double fortified Salt (high level) (mg/d)	IFA supplements (mg/d)
1-3 years	40	8	6	167	5	4.7	4.7	7.1	4.3	5.5	5.7
4-6 years	40	11	8	167	5	7.2	4.7	7.1	4.3	5.5	6.4
10-12 years (girls)	40	28	16	167	5	9.3	4.7	7.1	4.3	5.5	8.6
10-12 year (boys)	40	16	12	167	5	9.8	4.7	7.1	4.3	5.5	8.6
13-15 years (girls)	45	30	17	167	10	10.1	4.7	7.1	8.5	11	8.6
13-15 year (boys)	45	22	15	167	10	11.2	4.7	7.1	8.5	11	8.6
Men (S)	45	19	11	167	10	13.0	4.7	7.1	8.5	11	0.0
Women (S)	45	29	15	167	10	11.5	4.7	7.1	8.5	11	8.6
Pregnant women	45	27	21	167	10	11.3	4.7	7.1	8.5	11	60.0
Lactating women	45	23	16	167	10	12.9	4.7	7.1	8.5	11	60.0

Age groups	Total minimum intake of iron (mg/d)	Total maximum Intake of iron (mg/d)	Total minimum intake exceeding (%)			Total maximum intake exceeding (%)		
			TUL	RDA	EAR	TUL	RDA	EAR
1-3 years	19.3	23.0	−51.6	141.8	222.3	−42.5	187.6	283.5
4-6 years	22.6	26.2	−43.6	105.0	181.9	−34.4	138.4	227.8
10-12 years (girls)	26.8	30.5	−33.0	−4.3	67.5	−23.8	8.8	90.4
10-12 year (boys)	27.3	31.0	−31.8	70.6	127.5	−22.6	93.6	158.1
13-15 years (girls)	31.8	36.8	−29.2	6.2	87.3	−18.3	22.6	116.3
13-15 year (boys)	32.9	37.9	−26.8	49.8	119.6	−15.8	72.1	152.5
Men (S)	26.2	31.1	−41.8	37.8	138.0	−30.9	63.7	182.7
Women (S)	33.2	38.2	−26.1	14.6	121.6	−15.2	31.6	154.5
Pregnant women	84.5	89.4	87.7	212.9	302.3	98.7	231.1	325.7
Lactating women	86.1	91.0	91.3	274.2	438.0	102.2	295.6	468.7

*Daily intake of fortified rice computed for all age groups based on PDS allocation of 5 kg max per person. This implies a daily intake of 167 g (5000 g/30 days), **For adults salt consumption is estimated to be 10 mg[2] There is no data on salt consumption among children therefore, recommended amount of salt intake has been considered. EAR: Estimated average requirements, RDA: Recommended daily allowance, TUL: Tolerable upper limit, PDS: Public distribution system, IFA: Iron folic acid; NNMB: National nutrition monitoring bureau

Table 2: Calculations of Vitamin A intake based on dietary intake, fortification of foods (based on national nutrition monitoring bureau survey) and supplementation

Age groups	Vitamin A requirements ICMR 2020 (ug/d)			Consumption of fortifiable foods with Vitamin A		Amount contributed by various sources to daily intake of Vitamin A (ug)					
	TUL	RDA	EAR	Daily intake of milk# (NNMB) (g)	Daily intake of oil# (NNMB) (g)	Daily diet (NNMB - median intake)	Fortified milk (low level) (ug/d)	Fortified milk (high level) (g/d)	Fortified oil (Low level) (ug/d)	Fortified oil (high level) (ug/d)	Vitamin A supplements (ug/d)*
1-3 years	600	390	180	86	6	61	23.2	38.7	36.0	59.4	333.3
4-6 years	900	510	240	67	9	74	18.1	30.2	54.0	89.1	333.3
10-12 years (girls)	1700	790	370	59	11	81	15.9	26.6	66.0	108.9	NA
10-12 year (boys)	1700	770	360	58	12	87	15.7	26.1	72.0	118.8	NA
13-15 years (girls)	2800	890	420	58	12	92	15.7	26.1	72.0	118.8	NA
13-15 year (boys)	2800	930	430	66	13	98	17.8	29.7	78.0	128.7	NA
Men (S)	3000	1000	460	91	17	132	24.6	41.0	102.0	168.3	NA
Women (S)	3000	840	390	82	15	119	22.1	36.9	90.0	148.5	NA
Pregnant women	3000	900	406	79	16	124	21.3	35.6	96.0	158.4	NA
Lactating women	3000	950	720	66	17	117	17.8	29.7	102.0	168.3	NA

Age groups	Total minimum intake of Vitamin A (ug/d)	Total maximum intake of vitamin A (ug/d)	Total minimum intake exceeding (%)			Total maximum intake exceeding (%)		
			TUL	RDA	EAR	TUL	RDA	EAR
1-3 years	453.6	492.4	−24.4	16.3	152.0	−17.9	26.3	173.6
4-6 years	479.4	526.6	−46.7	−6.0	99.8	−41.5	3.3	119.4
10-12 years (girls)	162.9	216.5	−90.4	−79.4	−56.0	−87.3	−72.6	−41.5
10-12 year (boys)	174.7	231.9	−89.7	−77.3	−51.5	−86.4	−69.9	−35.6
13-15 years (girls)	179.7	236.9	−93.6	−79.8	−57.2	−91.5	−73.4	−43.6
13-15 year (boys)	193.8	256.4	−93.1	−79.2	−54.9	−90.8	−72.4	−40.4
Men (S)	258.6	341.3	−91.4	−74.1	−43.8	−88.6	−65.9	−25.8
Women (S)	231.1	304.4	−92.3	−72.5	−40.7	−89.9	−63.8	−21.9
Pregnant women	241.3	318.0	−92.0	−73.2	−40.6	−89.4	−64.7	−21.7
Lactating women	236.8	315.0	−92.1	−75.1	−67.1	−89.5	−66.8	−56.3

EAR: Estimated average requirements, RDA: Recommended daily allowance, TUL: Tolerable upper limit, NNMB: National nutrition monitoring bureau, NA: Not available, * For computing the daily doses of Vitamin A supplementation for children who are administered a dose of 2,00,000IU biannually. The values were first converted into ug by multiplying with 0.3 and then dividing by 180 days to arrive at daily dose economic and social benefits, food fortification can be an important complementary intervention to increase the intake of critical nutrients and reduce the burden of micronutrient vulnerabilities in India. However, LSFF should not be implemented in isolation, but as part of a comprehensive program to address micronutrient malnutrition and deployed within the broader food systems agenda framework which ultimately aims to improve access and affordability of a nutritious and diverse diet. The FSSAI has set the level of fortification, which is safe and based on the population's food consumption pattern. There is a need to support the industry to fortify staples to ensure compliance with standards effectively. Sustained relevant coverage of staple fortified foods through safety net programs and open market can play substantial role in overcoming deficiencies of these nutrients. At the same time, rigorous monitoring is imperative to implement LSFF programs, and adjustments to the micronutrient level to be added to food should be reviewed as the programs mature.

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Conflicts of interest

There are no conflicts of interest.

Disclaimer

The manuscript has been read and approved by all the authors. Each author believes that the manuscript represents honest work. The views expressed in the journal is personal and does not represent any organization's views.

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