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Food fortification: A Review

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Abstract

Nowadays, consumers prefer nutritious and safe food products having natural taste and freshness. The nutritional status of the population is one of the important factors determining the quality and productivity of the population, which in turn affects national productivity. Food fortification is the process whereby nutrients are added to foods (in relatively small quantities) to maintain or improve the quality of the diet of a group, a community or a population. Fortification is the addition of one or more essential nutrients to a food, whether or not normally contained in food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrient in the population or specific population groups. Food fortification is regarded as one of the safest and most cost-effective strategies to combat micronutrient deficiencies worldwide, which account for 7.3 % of the global burden of disease, with iron and vitamin A deficiencies included in the 15 leading causes of global disease burden. Fortification is often more cost effective than other strategies. Certain types of fortification are more accurately called enrichment in which micronutrients added to food are those that are lost during processing. Micronutrient malnutrition is frequent and severe in the developing world; nevertheless, it can also represent a public health problem in more industrialized countries. Food fortification has the advantage of delivering essential nutrients to large segments of the population without requiring radical changes in food consumption patterns. Foods used as fortification vehicles vary from country to country, but they generally include cereals and cereal-based products, milk and dairy products, fats and oils, tea and other beverages, and various condiments such as salt, soy sauce and sugar. In practice, the choice of any combination of food vehicle and fortificant is mainly governed by both technological. Fortification of food has been responsible for eradicating most of the vitamin and mineral deficiencies in developed countries.

Keywords: Fortification, value-addition, malnutrition

Introduction

Malnutrition has become one of the major health problems facing by the developing countries which contributes to infant mortality, poor physical and intellectual development of children which lowers the resistance to diseases. Throughout the developing world, malnutrition affects about 800 million people which approximately accounts for 20 percent of the world population. For instance, Sri Lanka Demographic and Health Survey (2006/07) highlighted that 18 % of Sri Lankan children are stunt, 15 % are wasted, 22 % are underweight and 4% are severely underweight. High price of commercially available fortified foods, vegetables, animal proteins and the non-availability of low priced nutritious foods, and late introduction of supplementary foods, are mostly responsible for the observed malnourishment among children in Asia. Fortification is the process whereby nutrients are added to foods (in relatively small quantities) to maintain or improve the quality of the diet of a group, a community or a population. Fortification helps in making weaning foods that are generally introduced between the ages of six months to three years where the breast feeding itself no longer meets the increasing nutritional requirements of the child. Therefore, there is a high possibility of occurring Protein Energy Malnutrition (PEM) during this transitional phase when children are weaned from liquid to semi-solid or fully adult foods where the growing body of children needs a nutritionally balanced and calorie dense supplementary foods such as weaning foods in addition to mother's milk (Amankwah *et al.*, 2009) [2]. This can be more severe if abrupt weaning is practiced where the family menu is directly introduced to the infant that leads to malnutrition, growth retardation and higher rates of mortality. In developing countries, most of the complementary foods are based on local staple foods mainly produced from cereals and given in liquid gruel form for infants. To be suitable for the feeding of young children, these cereal-based weaning foods are prepared in liquid form by dilution with a large quantity of water, thereby resulting in more volume but with a low energy and low nutrient

dense food. These cereal-based gruel forms are poor in nutritional value as they are lack in essential amino acids such as threonine, lysine and tryptophan. Moreover, the poor quality of protein and high viscosity of such gruel makes it difficult for the child to consume enough to meet both energy and protein requirements which leads to occurrence of protein energy malnutrition. Food based approaches used in combination with nutritional education programs can be used as a strategy to overcome the nutrient deficiencies. One such strategy is blending of legumes with cereals or in other words, fortification of legumes into solely cereal-based diets. Therefore, locally available legumes: mung bean (*Vigna radiata*) and soybean (*Glycine max*) can be used due to their high protein and iron content (Clarke *et al.*, 2011)^[4]. As these grain legumes are relatively low cost source of iron and protein, they can be used to prepare supplementary foods for children in low income families. Legumes are high in lysine but lack in sulfur-containing amino acids. On the other hand,

cereals are lack in lysine but high in sulfur-containing amino acids. Soybean is often used to improve the protein quality of cereal blends, due to its high levels of protein (40%) and fat (20%) content. Moreover, soybean is rich in lysine which is deficient in most cereals however, lack in sulfur containing amino acids as common in legumes. Therefore, fortification of legumes with cereals may overcome the nutritional deficiencies while improving the nutritional quality of the cereal-based weaning foods (Banureka and Mahendran, 2009)^[3]. Processing methods such as malting and extrusion has been reported to improve nutritional value of the food blends. Common food vehicles that can be fortified include wheat and wheat products, corn, rice, milk and milk products, cooking oils, salt, sugar, breakfast cereals, and condiments. As processed foods gain popularity and market reach in the developing world, they offer new channels for micronutrient delivery. Potential food vehicles can be presented in Figure 1.

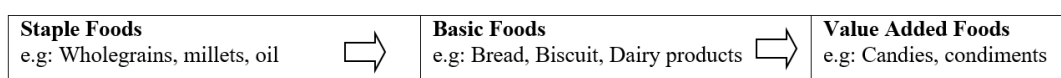


Fig 1: Food Fortification Flow

Food fortification

For the purpose of these guidelines, food fortification is defined as the practice of deliberately increasing the content of essential micronutrients viz vitamins and minerals (including trace elements) in a food so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health. Nutrients used for food shortages are often referred to as "vehicles" for fortification, as shown in the Fig. 2. The public health benefits of fortification may either be demonstrable or indicated as potential or plausible by generally accepted scientific research, and include:

- Prevention or minimization of the risk of occurrence of

micronutrient deficiency in a population or specific population groups.

- Contribution to the correction of a demonstrated micronutrient deficiency in a population or specific population groups.
- A potential for an improvement in nutritional status and dietary intakes that may be, or may become, suboptimal as a result of changes in dietary habits/lifestyles.
- Plausible beneficial effects of micronutrients consistent with maintaining or improving health (e.g. there is some evidence to suggest that a diet rich in selected antioxidants might help to prevent cancer and other diseases).

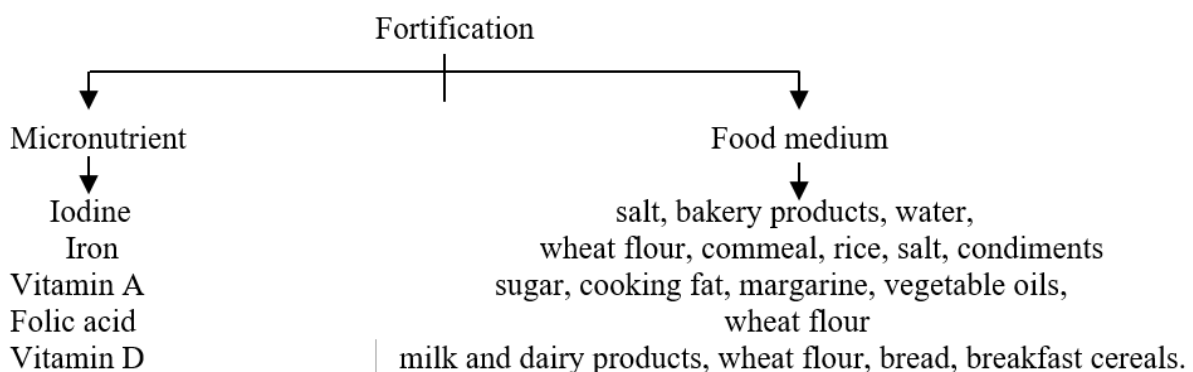


Fig 2: Micronutrients and various food medium for fortification.

The Codex General Principles for the Addition of Essential Nutrients to Foods defines “fortification”, or synonymously “enrichment”, as “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”. The Codex General Principles go on to state that the first-mentioned condition for the fulfilment of any fortification programme “should be a demonstrated need for increasing the intake of an essential

nutrient in one or more population groups (Gifford, 1986)^[5]. This may be in the form of actual 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”.

Figure 3 illustrates how supplementation with high doses of micronutrients is a short-term measure to address a severe deficiency, and its use is envisaged to come down as the longer-term measures are established.

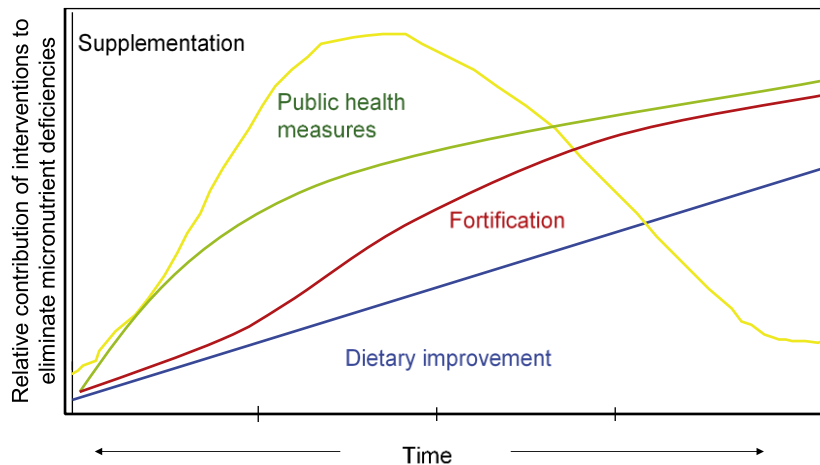


Fig 3: Complementary micronutrient interventions.

Types of fortification

Food fortification can take several forms. It is possible to fortify foods that are widely consumed by the general population (mass fortification), to fortify foods designed for specific population subgroups, such as complementary foods for young children or rations for displaced populations (targeted fortification) and/or to allow food manufacturers to voluntarily fortify foods available in the market place (market-driven fortification) as shown in Fig. 4. 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, and market-driven fortification is always voluntary, but governed by regulatory limits (Guilbert, 2002) [6]. The choice between mandatory or voluntary food fortification usually depends on national circumstances. For example, in countries where a large proportion of maize flour is produced by small mills, enforcement of mandatory fortification might be impractical. Under such circumstances, one option would be, if feasible, to allow small mills to fortify their product on a voluntary basis but following specified regulations.

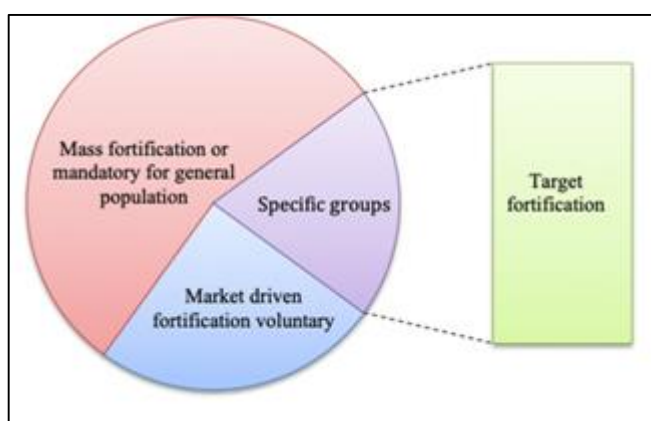


Fig 4: Various Types of Fortification. The pie chart presented is based on data collected from papers published earlier.

Mass fortification

As indicated above, mass fortification is the term used to describe the addition of one or more micronutrients to foods commonly consumed by the general public, such as cereals, condiments and milk. It is usually instigated, mandated and regulated by the government sector. Mass 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. In some situations, deficiency may be demonstrable, as evidenced by unacceptably low intakes and/or biochemical signs of deficiency (Patki and Arya, 1994) [12]. In others, the population may not actually be deficient according to usual biochemical or dietary criteria, but are likely to benefit from fortification. The mandatory addition of folic acid to wheat flour with a view to lowering the risk of birth defects, a practice which has been introduced in Canada and the United States, and also in many Latin American countries, is one example of the latter scenario.

Targeted fortification

In targeted food fortification programmes, foods aimed at specific subgroups of the population are fortified, thereby increasing the intake of that particular group rather than that of the population as a whole. Examples include complementary foods for infants and young children, foods developed for school feeding programmes, special biscuits for children and pregnant women, and rations (blended foods) for emergency feeding and displaced persons. In some cases, such foods may be required to provide a substantial proportion of daily micronutrient requirements of the target group (Tontisirin *et al.*, 2002) [16]. The majority of blended foods for feeding refugees and displaced persons are managed by the World Food Programme (WFP) and guidelines covering their fortification (including wheat soy blends and corn soy blends) are already available. Although blended foods usually supply all or nearly all of the energy and protein intake of refugees and displaced individuals, especially in the earlier stages of dislocation, for historical reasons such foods may not always provide adequate amounts of all micronutrients. Therefore, other sources of micronutrients may need to be provided. In particular, it may be necessary to add iodized salt to foods, provide iron supplements to pregnant women or supply high-dose vitamin A supplements to young children and postpartum women. Whenever possible, fresh fruits and vegetables should be added to the diets of displaced persons relying on blended foods. Fortified foods for displaced persons are often targeted at children and pregnant or lactating women.

Market-driven fortification

The term “market-driven fortification” is applied to situations whereby a food manufacturer takes a business-oriented initiative to add specific amounts of one or more

micronutrients to processed foods. Although voluntary, this type of food fortification usually takes place within government-set regulatory limits. Market-driven fortification can play a positive role in public health by contributing to meeting nutrient requirements and thereby reducing the risk of micronutrient deficiency. In the European Union, fortified processed foods have been shown to be a substantial source of micronutrients such as iron, and vitamins A and D. Market-driven fortification can also improve the supply of micronutrients that are otherwise difficult to add in sufficient amounts through the mass fortification of staple foods and condiments because of safety, technological or cost constraints. Examples include certain minerals (*e.g.* iron, calcium) and sometimes selected vitamins (*e.g.* vitamin C, vitamin B₂). Market-driven fortification is more widespread in industrialized countries, whereas in most developing countries the public health impact of market-driven food interventions is still rather limited. However, their importance is likely to be greater in the future, because of increasing urbanization and wider availability of such foods. The predicted increase in the availability of fortified processed foods in developing countries has given rise to a number of concerns. Firstly, these fortified foods especially those that are attractive to consumers could divert consumers from their usual dietary pattern and result in, for example, an increased consumption of sugar, or a lower consumption of fibre. Secondly, because in most developing countries foods fortified through market-driven fortification currently receive scant regulatory attention even though such foods are intended for wide-scale consumption, there is a potential risk that unnecessarily high levels of micronutrients may be delivered to children if the same serving size of the fortified food (such as breakfast cereals, beverages and nutrition bars) is intended for all members of a household. Regulation is thus necessary to ensure that the consumption of these foods will not result in an excessive intake of micronutrients. Furthermore, manufacturers of processed fortified foods should be encouraged to follow the same quality control and assurance procedures as those that are prescribed for mandatory mass-fortified products.

Household and community fortification

Efforts are under way in a number of countries to develop and test practical ways of adding micronutrients to foods at the household level, in particular, to complementary foods for young children. In effect, this approach is a combination of supplementation and fortification, and has been referred to by some as “complementary food supplementation”. The efficacy and effectiveness of several different types of products, including soluble or crushable tablets, micronutrient-based powder (“sprinkles”) and micronutrient-rich spreads are currently being evaluated. Crushable tablets and especially micronutrient-based powder, are relatively expensive ways of increasing micronutrient intakes, certainly more costly than mass fortification, but may be especially useful for improving local foods fed to infants and young children, or where universal fortification is not. The micronutrient-dense fortified spreads have been found to be very popular with children. Fortification of foods at the community level is also still at the experimental stage. One such approach involves the addition of a commercial micronutrient premix, available in sachets, to small batches of flour during the milling process. Although feasible in theory, major challenges to local-scale fortification programmes include the initial cost of the mixing equipment,

the price of the premix (which would need to be imported in most cases), achieving and maintaining an adequate standard of quality control (*e.g.* in uniformity of mixing), and sustaining monitoring and distribution systems.

Biofortification of staple food

The biofortification of staple foods, *i.e.* the breeding and genetic modification of plants so as to improve their nutrient content and/or absorption is another novel approach that is currently being considered. The potential for plant breeding to increase the micronutrient content of various cereals, legumes and tubers certainly exists; for instance, it is possible to select certain cereals (such as rice) and legumes for their high iron content, various varieties of carrots and sweet potatoes for their favourable β -carotene levels, and maize for their low phytate content (which improves the absorption of iron and zinc). However, much more work still needs to be done before the efficacy and effectiveness of these foods are proven, and current concerns about their safety, cost and impact on the environment are alleviated.

Food fortification in India

With a population of over 1.3 billion, India is the second most populated country in the world. Although the country has fostered one of the fastest-growing major economies in recent decades, India continues to face the challenges of poverty, malnutrition and inadequate public healthcare. Micronutrient deficiencies and the effects of malnutrition affect large segments of India’s population, making efforts to curtail this issue a major focus. An ongoing process, India’s food fortification campaign has been in motion for some time (WHO, 2009). However, the 2016 publication of the Draft Food Safety & Standards (Fortification) Regulation marked a turning point. Since then, several Government-funded initiatives have been launched to try to combat micronutrient deficiencies and the effects of malnutrition within the most affected population groups. Although micronutrient deficiencies can affect all age groups, young children and women of reproductive age tend to be most at risk of developing them. For example, more than half of all women in the 15-49 age group, approximately a quarter of all men in the same age group and seven out of ten children between 6-59 months of age, are anaemic (Lopez *et al.*, 2010) ^[10]. Micronutrient malnutrition is a serious health risk in India, mostly for those who are economically, disadvantaged and do not have access to safe, nutritious food. Either they do not consume a balanced diet or they lack variety which results in inadequate micronutrients being consumed. For these reasons, state-wide fortification initiatives have been implemented for various food commodities such as wheat flour, rice, oil and milk under different Government Schemes.

Fortification of wheat flour with folic acid

Folate (vitamin B₉) has a key role in the synthesis and methylation of nucleotides that intervene in cell multiplication and tissue growth. Its role in protein synthesis is interrelated with that of vitamin B₁₂, and the combination of severe folate deficiency with vitamin B₁₂ deficiency can result in Megaloblastic anaemia. Folate deficiency defined as <7 nmol/l (~3 μ g/l) of serum folate or <315 nmol/l (~140 μ g/l) of erythrocytes (red blood cell) folate (the latter serves as a long-term indicator of folate deficiency has shown to be associated with an increased risk of giving birth to infants with neural tube defects and possibly other birth defects and with a higher

risk of cardiovascular disease and impaired cognitive function through its effect on plasma homo cysteine levels. Folate deficiency is more prevalent in populations with high intake of refined cereals (which are low in folate) and low intake of leafy greens, legumes, fruits, yeast and liver (which are high in folate). Because of this, it is possible that populations in certain developing countries have higher folate levels than

those in industrialized countries (Williams *et al.*, 2012) [12]. The recommended dietary allowance (RDA) for all males and non pregnant females 14 years of age and older is 400 µg DFE/day, while for pregnant and lactating women, the RDA increases to 600 and 500 µgDFE/day, respectively. Figure 5 depicts a simplified framework of how fortification of cereal flour takes place.

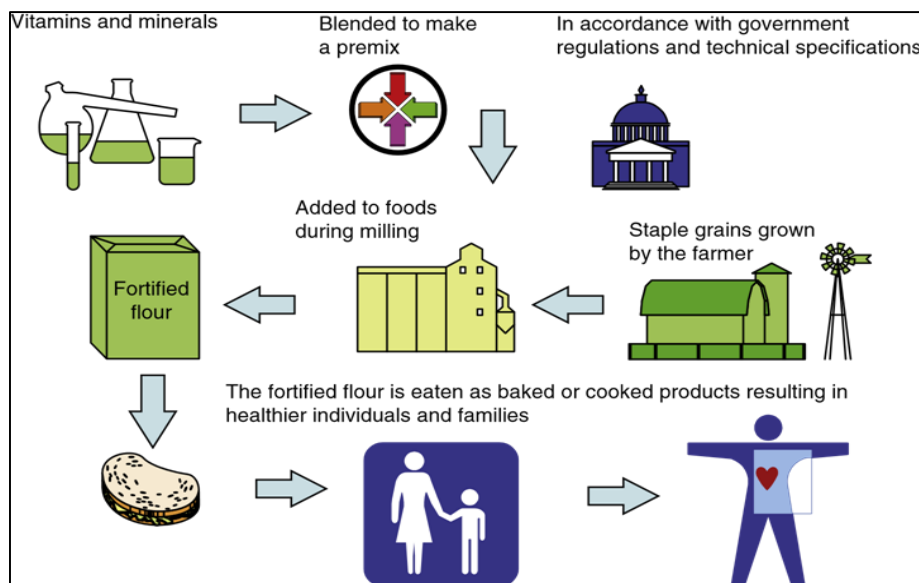


Fig 5: Schematic diagram of cereal flour fortification.

Evidence of the effectiveness of folic acid supplementation and fortification programs Neural tube defects (NTDs)

Recommendations for pregnant women to take a daily periconceptional supplement that contains 400 µg folic acid beginning at least 1 month before conception through early pregnancy is a well-established practice to prevent NTDs in many developed countries, guided by solid evidence of its protective effects. Nevertheless, evidence from 18 European countries with peri-conceptional folic acid supplementation policies, however without mandatory folic acid fortification programs demonstrates that reliance on supplementation recommendations alone is insufficient to translate the known protective effects of folic acid into population-wide reductions in the prevalence of NTDs. Specifically, data from the European network of population-based registries for congenital anomalies (EUROCAT; excluding UK and Ireland) showed that in countries that by 1999 had endorsed a policy for supplementation of folic acid or dietary intake of folate to increase folate status among pregnant women, there was no decline in the rates of NTDs from 1980 to 2002 (2% reduction; 95% CI: from 28% reduction to 32% increase) compared to countries with no such policy in place (8% reduction; 95% CI: from 26% reduction to 16% increase). A decline of 30% in the prevalence of NTDs was calculated in the UK and Ireland for this period, however, authors were not able to distinguish this from the strong decline observed prior to the policy endorsement (Thomas *et al.*, 2010) [15]. Although this study did not directly assess the levels of uptake of folic acid supplements by pregnant women, one of the potential factors that might account for the failure of these interventions is the high rate of unplanned pregnancies in these countries. Therefore, the authors draw on folic acid fortification strategies as more effective alternatives. Flour fortification with folic acid was mandated in the United States and Canada in the late 1990s, followed by a number of

countries in South America in the early 2000s. A recent systematic review that aimed to study the impact of folic acid fortification of wheat flour (*i.e.* national folic acid fortification programs) on the prevalence of NTDs in different countries found that fortification of flour with folic acid has significantly reduced the prevalence rates of NTDs in all countries that reported these data. This review included 27 studies from 9 countries of changes in the prevalence rates of NTDs between pre-fortification and post-fortification periods. The included countries were: the USA, Canada, Argentina, Chile, Costa Rica, South Africa, Brazil, Jordan and Iran. The largest drops in the NTD prevalence were observed in Costa Rica (58%), Argentina (49.7%), and Canada (49%), while the largest drops in spina bifida – in Costa Rica (61%), Canada (55%) and Chile (55%). For anencephaly, the greatest reductions were observed for Costa Rica (68%), the province of Ontario in Canada (58%), Argentine (57%) and Chile (50%). The authors also conducted dose-response analysis for Chile, and found that the highest prevalence of NTDs was observed when wheat flour folic acid content was at its lowest (median = 1.1 mg/kg), and the lowest prevalence was observed when the median folic acid reached 1.5 mg/kg. It is however worth noting, that the uncontrolled design of the included studies, as well as the large variability of the data sources and failure to account for the stability of wheat flour-based food consumption patterns in these countries limit conclusions for causal relationships. These results are confirmed by another recent systematic review that aimed to assess the effectiveness of food fortification with single and multiple micronutrients compared with no fortification on the health and nutrition of women and children. With regards to folate fortification, a total of 31 before-after mass fortification studies were identified with flour as the food vehicle and fortification levels varying from 40 µg/100g to 500 µg/100g. Results showed that folate fortification had a significant

impact in reducing NTDs (RR: 0.57; 95% CI: 0.45 to 0.73), spina bifida (RR: 0.64; 95% CI: 0.57 to 0.71) and anencephaly (RR: 0.80; 95% CI: 0.73 to 0.87). However, no significant effect was observed on red blood cell folate levels or serum folate concentrations. Subgroup analysis revealed that use of different folate concentrations (40 µg/100g or more than 100 µg/100g) had consistent significant effect in reducing NTDs and spina bifida, while only 40 µg/100g folate fortification was effective in reducing the incidence of anencephaly.

Cardiovascular disease (CVD)

Because of folate's potential effects on plasma homocysteine levels, and evidence suggesting that elevated plasma homocysteine levels are in turn associated with higher risks of CVD, there have been scientific debates whether folic acid supplementation (as homocysteine lowering interventions) or fortification strategies are effective in reducing CVD risks. This question was brought to the front by a quasi experimental study demonstrating improvements in stroke mortality after folic acid fortification in the US and Canada but not in England and Wales, where folic acid fortification is not required. Specifically, the authors found that decline in stroke mortality observed in the US between 1990 and 1997 (pre-fortification period) accelerated in 1998 to 2002 (post-fortification period) with an overall change from -0.03% to -2.9% per year. The fall in stroke mortality in Canada averaged to -1.0% and accelerated to -5.4% per year in 1998 to 2002 (post-fortification period). In contrast, the decline in stroke mortality did not demonstrate significant changes between 1990 and 2002 in England and Wales (Lips, 2000) [9]. In addition, authors conducted sensitivity analysis for 4 main risk factors of stroke mortality (current cigarette smoking, hypertension, diabetes, and total serum cholesterol concentration of more than 239 mg/dL) and found that changes in these factors were not likely to account for the reduced number of stroke-related deaths. The major drawback of this evaluation, however, was that the authors did not account for the changes in the stroke incidence in the US and Canada during this period, and it might be that the decline in stroke mortality was a result of a reduced case-fatality rate instead. Three meta-analyses were conducted after the abovementioned study that studied the effects of lowering homocysteine levels with B vitamins (including folic acid) on CVD outcomes. Two of these meta-analyses did not find any significant effect of folic acid supplementation on CVD outcomes or cancer risk, while the third study found a significant effect only when the supplementation was given in regions without folate fortification. The first meta-analysis included 8 randomized, placebo-controlled studies of folic acid supplementation involving 37,485 individuals at increased risk of CVD. Even though, folic acid allocation yielded 25% reduction in homocysteine levels, during a median five year follow-up period, folic acid supplementation had no significant effect on any of the cardiovascular outcomes. Authors neither found any significant effect for overall cancer incidence, cancer mortality or all-cause mortality within 5 years. The second meta-analysis is a recent Cochrane review that aimed to determine whether homocysteine-lowering interventions in the form of vitamins B₆, B₉, and B₁₂ supplements were effective in preventing cardiovascular events, as well as all-cause mortality when delivered to patients with and without pre-existing CVDs. his

review included 12 randomized controlled trials (RCTs; involving 47,429 individuals) from countries with and without mandatory fortification of foods. Authors found that homocysteine-lowering interventions had no significant effect on non-fatal or fatal myocardial infarction, stroke, and death from any cause or risk of cancer in comparison with placebo (the follow-up period for cancer incidence ranged from 3.4 to 7 years). Evidence for all these outcomes were given "high" quality scores. Finally, the third meta-analysis aimed to investigate the potential effect of folate fortification on folic acid-based homocysteine-lowering intervention and stroke risk by stratifying previous RCTs according to the folate fortification status of the country or the region. The review included 14 RCTs involving 39,420 patients, which were stratified into subgroups with folate fortification, without folate fortification and partial folate fortification. Authors found significant difference in the risk of stroke between the subgroups with folate fortification and without folate fortification ($p < 0.05$). The RR for stroke was 0.88 (95% CI: 0.77 to 1.00) in the subgroup without folate fortification, 0.91 (95% CI: 0.82 to 1.01) in the subgroup with partial folate fortification and 0.94 (95% CI: 0.58 to 1.54) in the subgroup with folate fortification. These findings imply that stroke reduction as a result of folic acid supplementation might be effective in the regions without folate fortification, where the maximum benefit from folate supply to the risk of stroke is not yet achieved by folic acid supplementation interventions.

Food fortification in practice

Food fortification has a long history of use in industrialized countries for the successful control of deficiencies of vitamins A and D, several B vitamins (thiamine, riboflavin and niacin), iodine and iron as shown in Table 1. Salt iodization was introduced in the early 1920s in both Switzerland and the United States of America and has since expanded progressively all over the world to the extent that iodized salt is now used in most countries. From the early 1940s onwards, the fortification of cereal products with thiamine, riboflavin and niacin became common practice. Margarine was fortified with vitamin A in Denmark and milk with vitamin D in the United States. Foods for young children were fortified with iron, a practice which has substantially reduced the risk of iron-deficiency anaemia in this age group. In more recent years, folic acid fortification of wheat has become widespread in the Americas, a strategy adopted by Canada and the United States and about 20 Latin American countries. In the less industrialized countries, fortification has become an increasingly attractive option in recent years, so much so that planned programmes have moved forward to the implementation phase more rapidly than previously thought possible. Given the success of the relatively long-running programme to fortify sugar with vitamin A in Central America, where the prevalence of vitamin A deficiency has been reduced considerably, similar initiatives are being attempted in other world regions (Holick, 2001) [8]. Currently, the first sugar fortification experience in sub-Saharan Africa is taking place in Zambia, and if successful will be emulated elsewhere. Darnton-Hill and Nalubola have identified at least 27 developing countries that could benefit from programmes to fortify one or more foods. Despite apparent past successes, to date, very few fortification programmes have formally evaluated their impact on nutritional status.

Table 1: WHO recommendations for average micronutrient fortification levels Fortification level (ppm) according to flour consumption (g day⁻¹)

Micronutrient	Flour extraction rate	Compound	<75 g day ⁻¹	75–149 g day ⁻¹	150–300 g day ⁻¹	>300 g day ⁻¹
Iron	Low	NaFeEDTA	40	40	20	15
		Ferrous sulfate	60	60	30	20
		Ferrous fumarate	60	60	30	20
		Electrolytic iron	NR	NR	60	40
Folic acid	Low or high	NaFeEDTA	40	40	20	15
		Folic acid	5.0	2.6	1.3	1.0
Vitamin B12	Low or high	Cyanocobalamin	0.04	0.02	0.01	0.008
Vitamin A	Low or high	Vitamin A palmitate	5.9	3	1.5	1
Zinc	Low	Zinc oxide	95	55	40	30
	High	Zinc oxide	100	100	80	70

Source: Adapted from Hurrell *et al.*, 2010^[7]. Revised recommendations for iron fortification of wheat flour and an evaluation of the expected impact of current national wheat flour fortification programs.

However, without a specific evaluation component, once a fortification programme has been initiated, it is difficult to know whether subsequent improvements in the nutritional status of a population are due to the intervention or to other changes, such as, improvements in socioeconomic status or in public health provision that occurred over the same period of time. Evidence that food fortification programmes do indeed improve nutritional status has therefore tended to come from either efficacy trials and/or reports of programme effectiveness. Efficacy trials, *i.e.* trials conducted in controlled feeding situations, are relatively numerous and have usefully documented the impact of fortified foods on nutritional status and other outcomes. Evidence of programme effectiveness, which is obtained by assessing changes in nutritional status and other outcomes once a programme has been implemented, is less widely available. Of the few effectiveness studies that have been conducted, even fewer included a non-intervention control group, an omission that weakens the evidence that can be obtained from studies of this type.

Advantages of food fortification

If consumed on a regular and frequent basis, fortified foods will maintain body stores of nutrients more efficiently and more effectively than will intermittent supplements. Fortified foods are also better at lowering the risk of the multiple deficiencies that can result from seasonal deficits in the food supply or a poor quality diet. This is an important advantage to growing children who need a sustained supply of micronutrients for growth and development, and to women of fertile age who need to enter periods of pregnancy and lactation with adequate nutrient stores. Fortification can be an excellent way of increasing the content of vitamins in breast milk and thus reducing the need for supplementation in postpartum women and infants.

Fortification generally aims to supply micronutrients in amounts that approximate to those provided by a good, well-balanced diet. Consequently, fortified staple foods will contain “natural” or near natural levels of micronutrients, which may not necessarily be the case with supplements.

Fortification of widely distributed and widely consumed foods has the potential to improve the nutritional status of a large proportion of the population, both poor and wealthy. It requires neither changes in existing food patterns which are notoriously difficult to achieve, especially in the short-term nor individual compliance (Randall *et al.*, 2012)^[13].

Disadvantages of food fortification

While fortified foods contain increased amounts of selected micronutrients, they are not a substitute for a good quality diet that supplies adequate amounts of energy, protein, essential

fats and other food constituents required for optimal health.

A specific fortified foodstuff might not be consumed by all members of a target population. Conversely, everyone in the population is exposed to increased levels of micronutrients in food, irrespective of whether or not they will benefit from fortification. Infants and young children, who consume relatively small amounts of food, are less likely to be able to obtain their recommended intakes of all micronutrients from universally fortified staples or condiments alone; fortified complementary foods may be appropriate for these age groups. It is also likely that in many locations fortified foods will not supply adequate amounts of some micronutrients, such as iron for pregnant women, in which case supplements will still be needed to satisfy the requirements of selected population groups. Fortified foods often fail to reach the poorest segments of the general population who are at the greatest risk of micronutrient deficiency. This is because such groups often have restricted access to fortified foods due to low purchasing power and an underdeveloped distribution channel. Very low-income population groups are known to have co-existing multiple micronutrient deficiencies, as a result of inadequate intakes of the traditional diet. Although multiple micronutrient fortification is technically possible, the reality is that the poor will be unable to obtain recommended intakes of all micronutrients from fortified foods alone. Technological issues relating to food fortification have yet to be fully resolved, especially with regard to appropriate levels of nutrients, stability of fortificants, nutrient interactions, physical properties, as well as acceptability by consumers including cooking properties and taste (Rehman *et al.*, 2014)^[14].

Key features of successful fortification programs include the following

- Strong political commitment and enforcement of regulations
- Early private sector involvement and willingness to comply with regulations
- Public sector backing, with endorsement of medical organizations
- Financial support by donors
- Active consumer education to raise awareness and promote demand

Issues and Challenges

Notwithstanding the considerable progress in food fortification over the past decade, there are major challenges to ensure that undernourished people, especially in developing countries, receive meaningful amounts of micronutrients through improved access to fortified foods. For example,

although significant success has been achieved with salt iodization, in many countries, the groups without access to iodized salt are those most vulnerable and in greatest need for protection against iodine deficiency. While the relatively easier task of getting the large- and medium-scale units to comply has been achieved, compliance by small- and some medium-scale salt producers continues to pose challenges. Thus, the strategies used to achieve 70% coverage of iodized salt globally will not necessarily result in addressing the challenge for the remaining 30% of the population.

The sustainability of fortification programs is complicated by the fact that national programs consist of numerous components, including the preliminary assessment of micronutrient deficiencies, development of fortification standards and legislation, procurement of fortification equipment by food manufacturers, implementation of communication and social marketing activities, execution of quality assurance and control systems, and assessment of health impact. Each component requires input and consensus from the government ministries, standards bureaus, industry partners, civil society, and international agencies that provide funding and technical support.

Within a national fortification project, challenges related to legislation, quality assurance and control systems, social marketing and monitoring and evaluation can be addressed with modifications to project implementation (Mannar and Khan, 2016)^[11].

The time needed for a fortification intervention to become effective in developing countries is likely to be much longer than in developed countries. Such vehicles as salt and flour are often processed in a large number of widely dispersed cottage scale industries that are not professionally managed.

As food fortification policies evolve, the goal is to achieve a balance between addressing nutrient needs and preventing excessive nutrient intakes. The challenge is that food fortification levels are also influenced by pressures to harmonize national standards with other regulatory jurisdictions.

In addition to these programmatic challenges, there are differences in perceptions about fortification. While it is well established that food fortification has positive impacts on a population's health and well-being – easily outweighing any potential risk – historically, there has been public opposition (in some countries) to the addition of a foreign substance to food or water. It is important to understand different viewpoints but equally important to move forward, in a responsible way, with what is most beneficial to a large number of people whose lives would otherwise be compromised without essential vitamins and minerals in their diet.

Concluding Thoughts

A well-planned food fortification program can provide meaningful quantities of essential micronutrients to large populations on a permanent and self-sustaining basis. In most situations the enormous benefits of a carefully planned and implemented fortification program far outweigh any potential risks. Food fortification can thus be one of the most cost-effective means of overcoming micronutrient malnutrition. Food fortification efforts need to be integrated within the context of a country's public health and nutrition situation and a clearly defined component of an overall micronutrient strategy that uses a combination of interventions to address key deficiencies. Within the last decade, many large-scale

food fortification initiatives (iodized salt, sugar, flour, and oil fortification) have been implemented in a number of countries around the world, but many more people could still benefit from fortification programs.

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