

PERSPECTIVE

Mandatory policy: Most successful way to maximize fortification's effect on vitamin and mineral deficiency

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Abstract

Background: Damaging effects of vitamin and mineral deficiencies contribute to health and development problems throughout the world. Food fortification has substantially improved nutrition-related health conditions in many countries, but opportunities for fortification are not fully utilized. Where food fortification is considered, leaders have to determine whether fortification should be mandatory or voluntary. **Objective:** This article explores experiences with mandatory wheat flour fortification as compared to voluntary fortification to offer insight for policies related to any type of food fortification. Mandatory fortification means the country requires the addition of specific nutrients at predetermined levels to specified foods or food products. Voluntary policies allow food manufacturers to enrich their products but do not require them to do so. **Results:** Mandatory fortification is more likely than voluntary fortification to reach a high proportion of the population and hence achieve the desired health impact. Mandatory fortification does not require consumers to change food purchasing preferences, it distributes the health benefits more equitably than voluntary fortification across a population, it establishes safe levels of included nutrients, and it is not subject to the food manufacturers' marketing investments or discretion. **Conclusion:** The health benefits of mandatory fortification are most likely to be achieved and sustained if national, multi-sector leaders develop a cooperative approach for appropriate food fortification policies that can be feasibly implemented and effectively monitored. Mandatory fortification, however, requires high-level commitment through the political process. Policy makers must contend with possible criticism that it interferes with personal choices or may cause unintended health problems.

Key Words

Mandatory; wheat flour fortification; salt iodization; public-private partnerships; nutrition; vitamin and mineral deficiency; Food Fortification Initiative

Introduction

While global health is improving by many measures [1], poor nutrition remains a threat, particularly to women and children [2]. One aspect of poor

nutrition is vitamin and mineral deficiency. Iron deficiency, for example, remains among the most widespread, serious nutritional deficiencies in the world [3]. Iron deficiency impairs cognitive development of children, reduces work capacity

among men and women by as much as 30%, and is associated with pregnancy complications such as hemorrhage, sepsis, and low birth weight[3].

One strategy used for more than 100 years to overcome vitamin and mineral deficiency among the general population is fortifying staple foods and condiments such as bread, milk, margarine, and salt[4]. These efforts often improve specific health conditions, for instance fortifying wheat flour with niacin in the United States to eliminate pellagra[5]. Likewise, fortifying wheat flour with folic acid reduces the risk of neural tube defects (NTDs)[6] and leads to significant healthcare savings when paralyzing birth defects such as spina bifida are prevented[7,8,9].

Despite these achievements, vitamin and mineral deficiencies are pervasive in many countries, and opportunities to improve a population's nutrition by increasing the amount of fortified foods are under-utilized. For example, although the proportion of the world's industrially milled wheat flour fortified with at least iron or folic acid has increased from 18% in 2004[10] to 31% in 2013[11], the remaining 69% of unfortified wheat flour represents a great potential for improving nutrition. Likewise, rice is rarely fortified though it is consumed regularly by billions of people [12].

While this article primarily uses examples of wheat flour fortification to illustrate the advantages of mandatory fortification policies, the principles could be applied to the fortification of maize products, whole grain rice, and other commonly consumed items such as vegetable oil, salt, and soya/fish sauce. Equitably Reaching National Scale Fortification: For fortification to have the desired health outcome, fortified products must be consumed by a high proportion of the targeted population. Most countries allow manufacturers to voluntarily fortify food; in other words, the countries have no ban to prohibit adding vitamins and minerals to food. But even with extensive consumer education, voluntary efforts generally do not result in high levels of coverage that can be expected to have population-wide health benefits. The most effective means of reaching national-scale consumption of fortified foods, and the resulting health benefits, is to require fortification. This was demonstrated with salt iodization as countries with mandatory legislation for salt iodization had a greater increase in household coverage (from 49% to 72%) in one decade compared with the increases in countries

with voluntary iodization (40% to 49%)[13]. In the 76 countries with legislation that requires fortification of at least one commonly consumed type of wheat flour[11], 90% of the industrially milled wheat flour is fortified with at least iron or folic acid[14] (Table 1).

Of the 14 countries where at least some flour is fortified through voluntary efforts, only 5% of the industrially milled flour is fortified[14]. The Food Fortification Initiative (FFI), which conducts an annual survey of flour fortification practices, has found no indication that any wheat flour is fortified in the remaining countries[14]. The effects of mandatory fortification are seen in nutritional indicators. For example, Australia began allowing voluntary wheat flour fortification with folic acid in 1995[15]. An analysis of 20,592 blood samples from a public hospital showed a 9.3% prevalence of low serum folate in April 2009, representing the voluntary fortification period[15]. Mandatory wheat flour fortification with folic acid began in September that year, and seven months later the prevalence of low serum folate was 2.1%[15].

With voluntary practices, fortified products may not be distributed throughout the target population due to the manufacturers' market share. In Ireland, a 2007 survey of major grocery stores showed that 211 food products were voluntarily fortified with folic acid[16]. However, the percentage of market held by fortified products ranged widely, from 1% for yogurt to 60% for breakfast cereals[16]. Ireland's voluntary fortification contributed to a 30% increase in folic acid in the Irish diet. Although children and older adults had high circulating levels of folate, the target population - women of childbearing age - had lower folate status compared with other groups[16]. Another study from Ireland recommended making wheat flour fortification mandatory to make the benefits available to all women of reproductive age[17], but Ireland has yet to follow this recommendation. Well-designed fortification programs identify a food commonly consumed by the deficient population and set levels of nutrients to be added as needed by the target population[18,19]. The fortification levels become part of the mandatory food requirements, leading to distribution of fortified foods throughout the target population without regard to the manufacturers' market share.

Mandatory programs are also more likely to ensure that fortified products are available across all socio-

economic levels. One reason is that mandatory programs create equitable costs for food producers. With mandatory fortification, millers are all required to purchase the same type and quantity of vitamins and minerals to add to flour. If this cost is passed to consumers, all foods made with the fortified product will likely have similar price increases – generally less than US\$0.02 per 5 kilogram bag of flour[20]. With voluntary fortification, millers need to market their fortified products, and they will most likely pass the marketing as well as the fortification costs to consumers. Also, the fortified product may be sold at premium pricing because it includes the added health benefits. A voluntary approach led to disparity in the Philippines which created a “Sangkap Pinoy” seal for foods that met certain requirements so consumers could easily identify voluntarily fortified foods[21]. Ultimately these products were unaffordable to the majority of Filipino families[21]. The Strategic Alliance for the Fortification of Oil and Other Staple Foods (SAFO) found that mandatory regulation is usually the most effective way to reach the poorest consumers who are probably more concerned about pricing than branding[22].

Sustaining Safe Practices

Appropriately implemented and monitored mandatory fortification programs are safer than voluntary efforts, in part because mandatory programs specify the concentrations of all vitamins and minerals to include so that the population is not in danger of consuming an excess of some nutrients. Well implemented mandatory fortification programs are monitored to ensure that the country’s standards are met. In some voluntary situations, levels of nutrients permissible in fortification are controlled, but in many cases, the manufacturer decides the levels and types of nutrients to include. This can lead to a broad range of vitamin and mineral content in some brands and no additional nutrients in other brands. In the United States, national legislation requires certain nutrients at specific levels in enriched flour, but ready-to-eat breakfast cereals can be voluntarily fortified [23]. As a result, the range of nutrients claimed on breakfast cereal labels varies from 8 to 100% of the daily recommended intake of iron and from 4 to 100% of the daily recommended intake of folic acid [23].

The only documented examples of voluntary wheat flour fortification reaching national scale and being sustainable occur in countries with four or fewer

mills or where all the flour is imported. Only seven countries fortify at least half their industrially milled wheat flour through voluntary efforts[11]. In these examples, usually one company owns the mill(s), and the company leadership is committed to fortification to improve the health of the population. The experience of Doruk Flour Mills in Turkey is a more common example of voluntary fortification. The company voluntarily fortified flour before 2008 and conducted extensive and expensive marketing campaigns[24]. Yet this did not increase the company’s market share, and eventually the voluntary fortification was discontinued except for a few products (Küçüktezcan E, Doruk Group, personal correspondence). Because mandatory fortification does not depend on the food manufacturer’s preference regarding fortification, it creates a higher level of certainty that adequately fortified food will be consumed by the relevant population and lead to the desired health benefits[25].

Achieving Health and Economic Impact

As mandatory fortification is more prone to result in widespread consumption of fortified foods, it is more likely than voluntary fortification to achieve the desired health outcome. One reason that mandatory fortification is effective is that it does not require consumers to change their consumption habits. This is particularly important regarding folic acid which is needed in adequate quantities before conception to protect against neural tube defects (NTDs). Despite campaigns to encourage all women who may become pregnant to consume at least 400 micrograms of folic acid daily, many countries indicate that less than 55% of reproductive-age women report taking folic acid supplements periconceptionally [26]. This was true in the Sultanate of Oman which conducted an education campaign to encourage women of child-bearing age to take folic acid [27]. The campaign had little effect on the birth prevalence of NTDs [27]. In contrast, the birth prevalence of spina bifida, the most common NTD, dropped from an average of 3.17 per 1000 births before mandatory wheat flour fortification to an average of 0.96 per 1000 births after Oman fortified wheat flour with folic acid and other nutrients [27].

Once the health impact is realized, countries begin to experience the economic benefit of fortification. A number of countries have reported dramatic savings by averting healthcare expenditures when they

fortify flour with folic acid to prevent NTDs. Children born with spina bifida have varying levels of paralysis and loss of bowel and bladder control. They undergo a lifetime of surgeries and often have many complications as a result of the birth defect. Chile compared the costs of surgical treatment and rehabilitative services for a sample of children with spina bifida in one year with the cost of adding folic acid to flour. The findings represent an average of nearly 12 healthcare dollars averted for every dollar spent on fortification[7]. South Africa found that it saved 30 rand for every one rand spent on fortification when it calculated the cost of treating a child with spina bifida during the first three years of life[8]. In the United States, fortification is credited with preventing 1000 neural tube defects a year. Annual fortification costs are approximately US\$ 3 million, and direct medical costs averted are US\$ 145 million per year; consequently US\$ 48 is saved for every dollar spent on fortification[9]. Similar savings could be expected for every year of the person's life, compounding the healthcare savings for years to come.

Iron is also commonly used in wheat flour fortification. Among other consequences, iron deficiency hinders physical activity and productivity in adults[3]. The median value of annual physical productivity losses due to iron deficiency is US\$ 2.32 per capita, based on illustrative calculations for 10 developing countries[28].

Addressing Challenges

Despite evidence for the public health and economic benefits of mandatory fortification, such policies are often resisted. One common complaint is that mandating fortification removes people's freedom of choice. This freedom can be protected without undermining the national scale of the fortified products by making some unfortified flour available. Using this approach, commonly consumed flours are fortified to achieve high coverage of the population, and specialized flours such as organic or whole-wheat flour remain unfortified for people who want that choice.

One purpose of legislation is to protect and promote the well being of a population[29]. Examples include mandates for motorcyclists to wear helmets and for food to meet safety requirements. While such measures are generally supported, about half of 18,500 adults surveyed in 24 countries feared this type of legislation would lead to a "nanny state"

whereby the government's actions limit their choices about how to behave[30]. If voters with that view are outspoken, politicians are unlikely to pass mandatory fortification legislation, even if it would lead to health benefits[31].

Another challenge to making fortification mandatory is that nutrition may not be a priority for policy makers. Dealing with other issues such as economic turmoil may keep them from taking action to prevent future health conditions and protect public health over the long-term[32]. Consistent advocacy is required to focus attention on fortification to prevent vitamin and mineral deficiencies and their consequences.

Additionally, some people fear that mandatory fortification will harm a subset of the general population by leading to an over-abundance of vitamins or minerals. As fortification is designed to reach entire populations, recommended levels of individual nutrients are deliberately low to avoid excessive intake. Exceeding tolerable levels is more likely to be associated with taking high-dose supplements than consuming fortified foods[33].

Country leaders seeking to establish mandatory fortification guidelines can refer to the World Health Organization (WHO). A Nutrition Guidance Expert Advisory Group works specifically to review evidence in the development of guidelines for nutrition interventions, including fortification[34]. As new guidelines become available and as existing guidelines are updated, they can be used to establish new fortification standards or update existing standards.

Partnering for Success

Food fortification laws meet their public health objectives when they are clearly expressed and appropriately enforced[25]. Establishing such programs, however, is a time-consuming process that includes raising awareness of nutritional deficiencies, establishing country standards, training food manufacturers and regulators, moving legislation and regulations through government systems, and developing, implementing and maintaining a monitoring system. Since any person can raise concerns that thwart the process, multi-sector cooperation in countries is essential to keeping the fortification process on track.

The movement toward universal salt iodization illustrates the value of multi-sector partnerships. By 1990, only Switzerland, some of the Scandinavian

countries, Australia, the United States, and Canada were completely iodine sufficient[35]. Little progress was made as the public sector promoted elimination of iodine deficiency without engaging the private sector which produced and sold salt (Haxon D, retired executive director of the international council for the control of iodine deficiency disorders and retired UNICEF country office representative, personal correspondence). Eventually the private sector was included, and by 1994, the late James P. Grant, UNICEF Executive Director, had become a champion of public-private partnerships[36]. In 1999, WHO leaders also called for cooperation with the private sector to support efficient and effective iodization of salt[37]. The civic sector joined the movement as Kiwanis International made eliminating iodine deficiency its first worldwide service project. Kiwanis members raised more than US\$ 80 million and supported testing, monitoring, and community outreach and education[38]. With these collaborative efforts, 105 countries had adequate iodine intake in 2011[34].

Learning from the salt iodization experiences, members of the Food Fortification Initiative have stressed since the partnership's creation in 2002 that public, private, and civic sector leaders in each country should be involved in fortification programs from their inception. Through the involvement of multi-sector individuals and organizations, the number of countries with mandates to fortify wheat flour grew from 33 in 2004[10] to 76 in 2013[11].

Conclusion

Fortifying staple foods has been used for decades to improve vitamin and mineral deficiencies among a population. Global experiences demonstrate that when mandatory fortification programs are well-designed, implemented, and monitored, they are more effective than voluntary programs at leading to the desired public health impact. Mandatory food fortification is more likely than voluntary fortification to reach people of all socio-economic strata and to lead to national scale distribution of fortified products without depending on consumers' behavior or the manufacturers' decisions. Mandatory fortification can be difficult to achieve, however, without a high-level of commitment and leadership from the public, private, and civic sectors as they work together to provide additional vitamins and minerals in foods commonly consumed by the target population.

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Tables

TABLE 1 PERCENT OF FORTIFIED WHEAT FLOUR COMPARED TO COUNTRY’S LEGISLATIVE STATUS, 2013

	Number of countries	Percent of industrially milled wheat flour fortified in these countries
Countries with legislative mandates to fortify wheat flour with at least iron or folic acid	76	90
Countries where at least some wheat flour is fortified through voluntary efforts	14	5
a Legislation is considered mandatory if it has the effect of mandating fortification of one or more types of commonly consumed wheat flour with at least iron or folic acid.		
Source: Food Fortification Initiative database [14]		