

# Examination of selected national policies towards mandatory folic acid fortification

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*The purpose of this paper is to present an examination of the contrasting policies towards mandatory folic acid fortification in six countries from different regions of the world. Three questions are addressed: 1) What is the policy of the country? 2) Why was the policy adopted? 3) What lessons have been learned? Policy contrasts among countries were assessed as reflecting different interpretations of the potential risks and benefits associated with folic acid fortification. Although commonalities were identified, it was considered unlikely that there could be a standard policy response for all countries. Instead, a country-by-country policy response based on national circumstances is indicated.*

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## INTRODUCTION

Since the early 1990s, many national authorities have been interested in the potential for mandatory folic acid fortification as a policy response to epidemiological evidence of the relationship between folic acid and reduced risk of neural tube defects (NTDs). However, mandatory folic acid fortification also raises scientific, ethical, and technical challenges.<sup>1</sup>

At a workshop at the First World Congress of Public Health Nutrition in Barcelona, Spain, the mandatory folic acid fortification policies of six countries selected from different regions around the world were examined. The six countries represented a range of policy responses. The United States had adopted mandatory folic acid fortification; Australia, China, Ireland, and the United Kingdom were reviewing their policy position; and Finland had not adopted a policy response. The workshop objective was to examine the national policies and experiences that select countries have had with mandatory folic acid fortification. An expert in folic acid/food regulation from each of the selected countries was invited to address three questions: 1) What is the policy of the country? 2) Why was the

policy adopted? 3) What lessons have been learned? The presentations and the panel discussion that followed are summarized in this paper.

## SUMMARY OF PRESENTATIONS

The folic acid intake recommendations and policy towards mandatory folic acid fortification, the reasons for the policy, and the lessons associated with policy-making and implementation for each of the six countries whose experiences were presented and then discussed at the workshop are summarized here and in Table 1.

### Australia

*What is the rationale for the folic acid fortification policy?* There is a divergence of views towards mandatory folic acid fortification in Australia. Food Standards Australia New Zealand (FSANZ) included the following reasons for its policy recommendation:<sup>2</sup>

- 1) Experience in the United States, which has an incidence of NTDs comparable to that in Australia

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*Key words:* folic acid, mandatory fortification, policy

doi:10.1111/j.1753-4887.2009.00164.x

*Nutrition Reviews*® Vol. 67(Suppl. 1):S73–S78

**Table 1 Folic acid intake recommendations and folic acid fortification policy for six selected countries.**

Country	Recommendation for folic acid intake	Folic acid fortification policy
Australia	The National Health and Medical Research Council recommendation is that women capable of, or planning, a pregnancy consume 400 µg additional folic acid per day for at least 1 month before and 3 months after conception, in addition to consuming naturally occurring folate in foods. <sup>2</sup>	Since 1995, folic acid has been permitted to be voluntarily added to a range of staple foods. As of June 2007, the Australian New Zealand Food Regulation Ministerial Council accepted an amended draft standard requiring the mandatory addition of folic acid to wheat flour for bread-making within the prescribed range of 200–300 µg per 100 g of flour for inclusion in the <i>Australia New Zealand Food Standards Code</i> . <sup>3</sup>
China	The Ministry of Health recommends that all women of child-bearing age obtain folic acid and health information as well as advice on folic acid supplementation (400 µg/day 3 months before and 3 months after conception) at their premarital, periconceptional check-up conducted through the maternal and infant healthcare system. <sup>4</sup>	In 2001, the State Grain Bureau and the Ministry of Health agreed jointly to initiate a flour fortification pilot program (includes 2 mg folic acid/kg of flour). The pilot trial of fortified flour consumption was conducted during 2003–2006. In 2004, fortified flour was introduced into the marketplace. In 2006, the State Grain Bureau drafted a national standard for fortified flour that was still awaiting government authorization at the time of writing.
Finland	A balanced diet rich in folate is recommended for all women planning a pregnancy or in early pregnancy in order to obtain at least 400 µg folate daily. <sup>5</sup> In addition, a daily supplement of 400 µg folic acid is recommended for all women planning a pregnancy or in the early stages of pregnancy.	Mandatory fortification of staple foods with folic acid is not permitted. There are no policy discussions on the topic at the moment in Finland. Instead, voluntary fortification of certain food products is allowed subject to permission of the Food Safety Authority. Currently, there are several folic-acid-fortified breakfast cereals, yoghurts, juices, sweets, and mineral waters on the market.
Ireland	In 1993, the Department of Health and Children issued a recommendation that women likely to become pregnant should take an extra 400 µg folic acid prior to conception and during the first 12 weeks of pregnancy. <sup>6</sup>	The Irish Government formed a fortification implementation committee in 1995 under the auspices of the Food Safety Authority of Ireland. In 2006, this committee decided that mandatory fortification should be introduced. <sup>7</sup> Subject to feasibility, it was agreed that addition of folic acid to bread at the bakery stage would be preferable. If this was not feasible, it was agreed to add folic acid to flour that was destined for bread-making. On average, the level of supplementation chosen was an additional 110 µg of folic acid per day.
United Kingdom	All women planning a pregnancy are advised to take a 400 µg/day folic acid supplement until week 12 of pregnancy <sup>8</sup> and to eat more foods that are naturally rich in folate or fortified with folic acid. <sup>9</sup>	In 2002, the Food Standards Agency (FSA) advised health ministers not to introduce folic acid fortification of flour due to concerns about risks to the elderly. In 2006, the Scientific Advisory Committee on Nutrition recommended mandatory fortification of flour to reduce the numbers of NTD-affected pregnancies, <sup>10</sup> but only if accompanied by controls on voluntary fortification. In 2007, the FSA recommended mandatory fortification as well as controls on voluntary fortification to health ministers.
United States	In 1992, the Public Health Service published the recommendation that all women of childbearing age consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a child affected with spina bifida or other NTDs. <sup>11</sup>	A directive by the US Food and Drug Administration (FDA) released in March 1996 <sup>12</sup> mandated that, by January 1998, all flour and grain products labeled as “enriched” would contain folic acid. The policy, based on the FDA projections and models of the use of 140 µg per 100 g of flour, prescribed a roughly twofold restoration of the amount of folate lost after milling and, on average, would supply about 100 µg of folic acid per day to the American population.

(1.32 per 1,000 births), has demonstrated a significant reduction in NTDs and no apparent risks.

- 2) The NTD incidence among the indigenous population in one state of Australia was reported to be almost twice that of the nonindigenous population.
- 3) Bread is consumed regularly by the target population of women aged 16–44 years, and at the recommended level of fortification, only a small proportion of the population would exceed the upper level of safety for folic acid. It was estimated, however, that at this fortification level, just 8% of NTD cases would be prevented.

*Lessons learned.* During the policy-making process, there was limited available information about the folate intake and folate status of the target group and the population in general. Rather than delay its policy decision until comprehensive nutrition information was available, FSANZ recommended proceeding with mandatory fortification and encouraged future monitoring of this policy. The process also identified a lack of investment in alternatives to fortification, such as promoting the use of folic acid supplements. In the future, such alternatives will be important, as at the recommended level of fortification, the target group will need to consume supplements to achieve the recommended intake of folic acid.

## China

*What is the rationale for the folic acid fortification policy?* China launched its folic acid education and supplementation program through the maternal and infant healthcare system and commenced the pilot trial of flour fortification for the following reasons:

- 1) Each year in China there are 80,000–100,000 babies born with NTDs.<sup>13</sup>
- 2) The incidence of birth defects is 3–4 times higher in rural areas than in urban areas and 2.7–3.8 times higher in northern China than in southern China.
- 3) A folic acid supplementation trial among Chinese women reported a decrease in NTD incidence of 85% in the northern regions and 40% in the southern regions of China.<sup>14</sup>
- 4) The pilot trial of the effectiveness of fortified flour identified that the micronutrient intake of the study population was significantly below the Chinese Dietary Reference Intakes and that flour fortification increased the dietary micronutrient intake and the level of nutritional health of the study population.

*Lessons learned.* Certain local government regions encourage implementation of folic acid fortification of flour. However, a national regulatory framework for

introducing mandatorily fortified flour into the marketplace needs to be established. Mandatory flour fortification has elicited much concern and discussion. China has a diverse consumption pattern of food staples. The best candidate food vehicle for folic acid fortification is still being assessed. The NTD incidence is highest in remote and less developed regions of China. Generally, in these regions, people consume homemade flour rather than commercial flour that has been fortified with folic acid.

## Finland

*What is the rationale for the folic acid fortification policy?* Mandatory fortification is not allowed, but voluntary fortification of specific food products authorized by the Food Safety Authority is permitted. The following factors influence this policy:

- 1) The incidence of NTDs in Finland is relatively low, at 0.74 per 1,000 births and selective terminations. The incidence has been stable during 1993–2005. Increasing folic acid intake does not necessarily have any further impact on the incidence.
- 2) The reported intake of food folate is modest (approximately 220 µg/day in 24- to 44-year-old women in 2002)<sup>15</sup> but is considered to be adequate because of the inherent underestimation of food consumption data in national dietary surveys and the use of supplements. In addition, plasma levels of folate have been found to be normal in 99% and optimal in 90% of the population.<sup>16</sup>
- 3) According to the national nutrition recommendations, a balanced low-fat and low-sugar diet with abundant fresh vegetables, berries, and fruit as well as whole-grain products usually guarantees an adequate folate supply.

*Lessons learned.* Between 37% and 86% of pregnancies are planned (depending on the interpretation of “planned”). The average time for the first prenatal visit is 9 weeks, a period that is too late for planning NTD prevention. Current data on folate intake and status among fertile women and other population groups, as well as risk evaluation and mechanisms to monitor fortification, are needed before any general decisions on fortification can be made.

## Ireland

*What is the rationale for the folic acid fortification policy?* As in other countries, surveys have shown that less than 20% of pregnant women take either supplements or fortified foods at the optimal time for NTD prevention.

Ireland traditionally has had one of the highest prevalences of NTDs in the world. This fell, prior to folic acid intervention, perhaps due to better preservation and distribution of folate in food. However, while the levels have decreased from >6 to <1 per 1,000 births, NTDs remain the most common birth defect in Ireland. This high risk, coupled with the prohibition of pregnancy termination in Ireland (it is a criminal offense), puts an extra onus on the Irish government to take every reasonable measure to prevent NTDs.

*Lessons learned.* It is recommended not to get caught up in endless rounds of discussions about the specific amount of folic acid to be added. It is advisable to choose a level of fortification with a low risk of overexposure in the elderly and others, with the rationale being that although it would be less than optimal, it would be achievable. Thus, a measure would be put in place that would be of benefit (albeit not optimal) in NTD prevention. This would be of greater benefit to women of lower socioeconomic backgrounds, who are likely to have the lowest intake of dietary folate. These women are also the least likely to be aware of the benefits of taking folic acid supplements periconceptionally.

### United Kingdom

*What is the rationale for the folic acid fortification policy?* A number of countries, including the United Kingdom, have actively campaigned to improve awareness among women about the benefits of folic acid. These campaigns have had little impact on reducing NTDs. Only about one-quarter of women take folic acid supplements. This low rate is partly because only half of all pregnancies are planned.<sup>9</sup>

The Scientific Advisory Council on Nutrition (SACN) has estimated that there are about 700–900 NTD-affected pregnancies per year in the United Kingdom;<sup>10</sup> this estimate does not take into account the NTD-related miscarriages.

*Lessons learned.* The SACN assessed the folate and folic acid intakes of the UK population; some people, particularly young women and the elderly, had low intakes, while others had high intakes close to or exceeding the guidance values for safe intake of folic acid (1 mg/day for adults). These high intake levels are due to the consumption of voluntarily fortified food (primarily breakfast cereals and low-fat spreads) and/or supplements. Modelling of dietary data by SACN shows that mandatory fortification of flour, in the absence of voluntary fortification, would improve the folic acid intake of low-level consumers and reduce the intake of high-level consumers. The SACN noted, however, that in the United States,

mandatory fortification resulted in substantially higher intakes than recommended due to the practice of “overage,” so they have also recommended tight regulation and monitoring.

### United States

*What is the rationale for the folic acid fortification policy?* The Food Policy Committee and Subcommittee on Folic Acid of the Food and Drug Administration (FDA) concluded that while an increase in the intake of folate-containing foods would be beneficial in the periconceptional period, the success of achieving that increased intake in large segments of the population was uncertain. It was also determined that the use of supplementation as the main intervention would not have sufficient penetration, especially in populations less likely to use supplements, which included subpopulations with a higher incidence of NTDs. Therefore, folic acid fortification was mandated. Flour was chosen as the vehicle because it is widely consumed by the population, along with other cereal grain products. The mechanism for mandating fortification left open the possibility that consumers could choose flour that was not fortified, should they want to avoid vitamin-enriched flour, and this was one means of addressing the concern that mandated fortification would be coercive to some. Still, the vast majority of flour and cereal products in the United States are enriched; therefore, by this standard of identity, the bulk of flour and cereal grain products will have additional folic acid. An elaborate process of intake modeling by the FDA led to the appropriate dose. The FDA was able to arrive at dose models that would maintain a safe intake in almost the entire population, even in those that also took an additional vitamin supplement of 400 µg of folic acid per day. “Safe” in this case refers to the assumption and amounts promulgated in the Dietary Reference Intakes report of the National Academy of Sciences.<sup>17</sup>

*Lessons learned.* After fortification, the first evidence of the major effects of fortification on folate intake came from the Framingham Heart Study cohort, and this was followed by findings of other studies from the West Coast of the United States, from Canada, and from analysis of post-fortification blood data collected through the National Health and Nutrition Examination Survey. All these studies showed a substantial increase in folic acid intake and blood levels, and a variable decrease in the incidence of NTD births ranging from about 19% to more than 50%. None of these were national population surveys because of the absence of a planned surveillance system. The variability in the percent decrease in the incidence of NTD births could be related not only to factors

including ascertainment but also to the prevalence of NTD births prior to intervention. The Chinese study,<sup>14</sup> which used supplementation rather than fortification in northern versus southern populations, clearly demonstrated not only the benefit of preconceptional supplementation but also showed unmistakably that the percent reduction was based strongly on the level of prevalence or incidence before supplementation. Thus, increasing attention is given to the actual incidence of NTD births after fortification, rather than the percent reduction. This needs to be discussed, as consideration is given to the effect of the intervention to date and whether the amount of exposure has approached the maximum protective effects, i.e., a nadir of incident NTDs, usually under 0.8/1,000 births.

Other observations that have emerged since the initiation of fortification include one study in which circulating levels of free folic acid in the blood of elderly persons in Washington state were associated with some suppression of natural killer cell activity,<sup>18</sup> and other studies indicating that excessive folic acid intake in the elderly may be associated with lower cognitive performance.<sup>19</sup> These observations have added to the call for a more comprehensive surveillance system to measure both the effectiveness and the safety of the intervention.<sup>20</sup>

## DISCUSSION

All of the countries selected for examination have identified the folic acid/NTD relationship as important and recommend the consumption of folic acid supplements (400 µg/day) and food folate for the target group (women of child-bearing age). However, despite having access to the same epidemiological evidence, the selected countries have diverse policy positions on mandatory folic acid fortification. This diversity is related to whether or not mandatory folic acid fortification is recommended, and if so, which food vehicles have been selected and what level of folic acid fortification has been implemented.

There are many explanations for the diverse decision-making processes in the six selected countries. Generally, different policy positions reflect different interpretations of the potential risks and benefits. Broad reasons for these differences are related to the contrast in NTD rates, e.g., the high rate in China relative to that in Finland. There is a lower limit of prevention beyond which the effectiveness of mandatory folic acid fortification may have a diminishing return.<sup>14</sup> In China, an additional compelling reason for mandatory folic acid fortification is the evidence of population-wide folate deficiency.

Further reasons for policy decisions relate to peculiar circumstances in certain countries. For example, at issue in Australia are the political and moral circumstances

associated with evidence of higher NTD rates among the indigenous population relative to the nonindigenous population in certain parts of the country. In Ireland, the broader social policy context (pregnancy termination being a criminal offense) results in a relatively substantial number of affected conceptions being carried to term and babies being born with birth defects.

The relationship between folic acid and health is a dynamic policy topic. As the evidence base continues to evolve, national authorities will need to continually review their policy towards mandatory folic acid fortification. There was strong encouragement for sufficient and timely monitoring and evaluation of policy decisions by national authorities. This monitoring should be inclusive of potential risks and benefits (inasmuch as these can be anticipated and detected) for the target group and population in general.

Folic acid fortification was noted as being just one policy approach to reducing the risk of NTDs. There is an identified need among the selected countries for nutrition education to promote folate-rich diets and folic acid supplements to the target group. During the panel session, it was advised that if national authorities do recommend mandatory fortification, then excessive fortification needs to be avoided, i.e., fortification at physiological levels (to result in an additional folic acid intake of up to 200 µg/day) was considered prudent.

## CONCLUSION

Mandatory folic acid fortification is a complex policy topic currently under review in many countries. Whereas the case for a national policy is relatively straightforward in those countries where there is evidence of inadequate folate reserves and folate deficiency among the population, the issue of responding to the folic acid/NTD relationship is more challenging. Rather than a case of one size (mandatory folic acid fortification policy) fits all (national circumstances), the policy should be determined on a country-by-country basis, taking into account the national circumstances and a national authority's assessment of potential risks and benefits.

## Acknowledgment

*Declaration of interest.* The authors have no relevant interests to declare.

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