

Clinicians and managers should remain vigilant in balancing carefully the wishes of patients and politicians against clinical need.¹¹ Schemes for intermediate care

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Delaying folic acid fortification of flour

Governments that do not ensure fortification are committing public health malpractice

The failure of European governments to mandate universal fortification of flour with folic acid has allowed a continuing epidemic of preventable human illness. It is ironic that the United Kingdom has not required fortification, as it was a ran-

domised controlled trial from the United Kingdom that conclusively proved that supplementation with synthetic folic acid prevents about 75% of spina bifida and anencephaly—common and serious birth defects.¹ This study provided the primary scientific basis for the

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United States, Canada, Chile, and other countries to require fortification.

In Europe fortification has been delayed because it has erroneously been portrayed as having definitive benefits for embryos and children and no benefits for adults, especially elderly people. Speculation of possible harm from fortification for elderly people, though hypothetical and not data driven, has resulted in unnecessary delay. Strong evidence exists that universal fortification benefits adults, including elderly people, and that it is safe.^{2,3} Policy discussions should compare the definite and probable benefits for adults with the hypothetical risks.

Most adults do not have sufficient serum folate. Plasma concentration of homocysteine is a good biomarker for folate deficiency.⁴ A large American study conducted before fortification found that at least 50% of people aged over 60 had homocysteine concentrations that implied insufficient serum concentrations of folate.⁵ A recent Dutch study showed that even people in the upper fifth of folate consumption had a mean homocysteine concentration of 11 $\mu\text{mol/l}$, higher than the 8 $\mu\text{mol/l}$ usually found when serum folates are sufficient.⁶ Folate deficiency is very common.

In the United States fortification of all enriched grain products such as flour has resulted in a population-wide increase in the concentration of serum folate and a reduction in the concentration of plasma homocysteine^{7,8}: for people with homocysteine concentrations above 13 $\mu\text{mol/l}$, the mean plasma homocysteine concentration dropped from 18.7 $\mu\text{mol/l}$ to 9.8 $\mu\text{mol/l}$.

Recent evidence indicates that fortification improved the lives of adults. The distribution of serum folate in the United States has shifted upwards sufficiently to eradicate folate deficiency anaemia among adults.⁷ In 1998, the year in which fortification was made mandatory, 4753 fewer deaths from stroke and 21 943 fewer deaths from heart attack occurred than in 1997—a 3.4% reduction in mortality for each condition.⁹

Two randomised controlled trials—one showing that a multivitamin with folic acid reduced deaths due to stroke in Chinese men and the other showing that folic acid reduces the need for revascularisation after angioplasty—provide additional evidence that increasing the consumption of folic acid prevents cardiovascular disease.^{10,11} No adverse effects have been reported after fortification.

Some people argue that results from more randomised controlled trials are necessary before acknowledging the possibility that fortification is beneficial to adults. This position is not defensible from a scientific or a public health policy perspective. It ignores the prevention of folate deficiency anaemia and the probable prevention of cardiovascular disease. Sir Bradford Hill noted that there are times when it is prudent to assume operative causality in the absence of multiple randomised controlled trials in order to take necessary public health actions.¹² Major public health actions were taken for cigarette smoking and “mad cow” disease in the absence of randomised controlled trials proving causality. The probable reduction in deaths from cardiovascular disease after fortification

justifies operative causality, as fortification could save as many lives as are lost each year in vehicle crashes.

The United Kingdom’s Food Standards Agency has been influenced by two weak arguments against fortification. One is technical: fortification was easily accomplished in the United States, Canada, and Chile; surely the millers in the United Kingdom can do likewise. The other is that consumers should have the choice to buy flour that is not fortified. Choice is easily preserved by not requiring fortification of whole wheat flour.

Although fortification of flour is long overdue in the United Kingdom and the remainder of Europe, on 9 May 2002, the UK Board of the Food Standards Agency decided against mandatory folic acid fortification.¹³ The ministers of health of England and Wales, Scotland, and Northern Ireland should not accept the board’s recommendation. Rather, the ministers should follow the advice of the UK Department of Health committee on medical aspects of food and nutrition policy and require universal fortification of flour with folic acid at a concentration of 240 mg per 100 g of flour. This prudent action would improve the health of children and adults.

Rare is the opportunity to implement a sustainable, inexpensive, and effective intervention to prevent major human diseases. Folic acid fortification of flour is one of those rare opportunities. The available evidence argues that governments that do not ensure that flour is fortified with sufficient folic acid are committing public health malpractice.

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