**The Importance of getting the right UK Folic Acid Fortification Policy**

Joan Morris1and Nicholas Wald1, 2

1 Population Health Research Institute, St George’s, University of London. [jmorris@sgul.ac.uk](mailto:jmorris@sgul.ac.uk)

2 Institute of Health Informatics, University College London. [n.wald@ucl.ac.uk](mailto:n.wald@ucl.ac.uk)

**Key words:** folic acid fortification

**Word count**: 1160

Neural tube defects (NTDs) are a global problem that result in many distressing adverse outcomes including miscarriage, stillbirth, neonatal death and termination of pregnancy following screening. Children born with spina bifida typically have multiple surgical operations and many are paraplegic and incontinent for all their life. In 1991 a randomised double-blind study provided robust evidence that the risk of an NTD could be reduced by an estimated 83% among women who took a daily 4 mg supplement of folic acid (1). However, relying on supplement use to reduce NTDs has not been effective as only a small percentage of women take supplements before becoming pregnant (2, 3) There is substantial evidence in support of the efficacy and safety of increasing folic acid intake through fortification. About 80 countries in the world have introduced folic acid fortification. Although the UK government has decided to fortify flour, this has not yet been implemented and there remains an important issue over the level of fortification that would achieve a meaningful reduction in the risk of NTDs.

**The UK decision to fortify**

In June 2019, the UK Government issued an open public consultation on the proposal to introduce mandatory fortification of UK flour with folic acid (vitamin B9) to help prevent NTDs in fetuses. The consultation received responses from 1,438 participants. In September 2021 the UK Government and the devolved administrations provided a summary of these responses and announced their decision to proceed with the mandatory fortification of non-wholemeal wheat flour such that folic acid intake is increased on average by 60-100 micrograms per day. (<https://www.gov.uk/government/consultations/adding-folic-acid-to-Flour>).

**The public response to the consultation**

53% of respondents agreed with the mandatory fortification of non-wholemeal flour in the UK with folic acid (39% disagreed and 8% did not know or did not answer). Of those who agreed, 64% thought that all flour in the UK and other non-wheat products such as ‘gluten free’ should be fortified. The statement in the Government response to the public consultation that there was no single option which commanded majority support of the respondents’ preferences is incorrect. A clear majority were in favour of fortifying all flour and non-wheat products. To decide to fortify non-wholemeal flour only is not justified from the responses to the survey.

The Government response also states: “By opting to undertake the baseline option of fortifying non-wholemeal wheat flour with folic acid, the UK Government and devolved administration’s note that not all will explicitly benefit from this policy. The burdens upon business were considered and it was agreed not to fortify wider than the flour that is presently fortified. However, we intend on engaging with industry in relation to the voluntary fortification of gluten-free products.” This statement indicates that the Government intends to rely on the voluntary actions of “industry” instead of the Government determining policy from qualified experts.

Whilst public health education and public engagement in health interventions is desirable, public health polic needs to be based on the advice of trusted experts in the field. It is important for professional medical bodies to lend their support in achieving this objective.

**The decision to increase daily folic acid intake by 60-100 micrograms**

There was no question in the consultation specifically addressing the level of folic acid fortification and the document stated that the proposed level of fortification of folic acid in flour in this policy was under consideration. The consultation states “The modelling undertaken as part of the impact assessment shows that an increase in daily folic acid intake of 60-100 micrograms (0.06-0.1mg) of folate is required to see significant benefits in a reduction of NTDs, and this minimum can be achieved by fortifying by approximately 200 micrograms (0.2mg) of folic acid per 100 grams of flour.” The `significant benefit’ referred to is quantified in the impact assessment as only an 8-12% reduction in risk of an NTD pregnancy as stated on p.15 in the Government’s folic acid fortification Impact Assessment (<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/808698/folic-acid-impact-assessment.pdf>). It would be a major policy error to adopt such a low level of fortification. It is “token” fortification that will mislead the public on the true expected preventive effect.

An argument given against having a higher level of fortification is concern that a significant proportion of the population would have a folic acid level intake about 1mg/day and that this would be harmful. A paper published in 2018 demonstrated that limiting folic acid intakes to ≤1 mg/day is without scientific or medical justification (4). However, the paper was not acknowledged in the Government response document.

The statement “Further details on the full policy will be finalised at a later date including the assessment of the need to limit voluntary fortification of other products.” is of concern because there is no scientific need to set an upper intake level and the proposed level of fortification is so low, limiting voluntary fortification of other product may result in some women consuming less folic acid than they do at present.

**The decision to continue to recommend that women who could become pregnant take a daily supplement (tablet) of 400 micrograms of folic acid before conception and do so until the 12th week of pregnancy**

If the level of fortification being considered by the Government were adopted a daily folic acid supplementation would still be needed, which should be a dose of 4 or 5mg available without the need for a medical prescription. However, reliance on supplement use has been a failure (2). Public health policy needs to be based on fully effective folic acid fortification to achieve the level of neural tube defect prevention observed in the MRC trial and eliminate the need to take folic acid supplements.

**Fully effective fortification**

It has been estimated that fully effective fortification would require a daily intake of folic acid from fortification of about 1.6mg (5). This is substantially higher than the Government is currently considering. There is no evidence or indication that fortification at this level will pose a risk to health (6). Policy-makers need to be bold in making the right public health decision; a timid response will not achieve the expected health benefits. It is a tragedy that 30 years after the evidence on folic acid and neural tube defect prevention was published, the UK has not introduced mandatory folic acid fortification. has been

I Now we have the opportunity to avoid another potential tragedy by adopting fully effective fortification rather than token fortification.

**Conclusion**

The proposed folic acid fortification policy is inadequate and falls well short of full effectiveness. The exclusion of potential mothers with a diet that is not covered by the fortification policy is socially divisive and should not be acceptable. All flour and grains, such as rice, should be fortified at a sufficient level to achieve fully effective fortification across the whole population.

It is not too late to adopt this policy.

References

1. Wald NJ et al. Prevention of neural tube defects: Results of the Medical Research Council vitamin study. *Lancet.* 338:132-137, 1991. A407/512

2. Bestwick JP, Huttly WJ, Morris JK, Wald NJ. Prevention of neural tube defects: a cross-sectional study of the uptake of folic acid supplementation in nearly half a million women. *PLoS One*. 2014;9(2):e89354.

3. Khoshnood, B et al. Long term trends in prevalence of neural tube defects in Europe: population based study. *BMJ*. 351:h5949, 2015.

4. Wald NJ, Morris JK, Blakemore C. Public health failure in the prevention of neural tube defects: time to abandon the tolerable upper intake level of folate. *Public Health* Reviews, 39(2) 2018

5. Wald NJ. Postscript to ‘Folic acid and neural tube defects: Discovery, debate and the need for policy change’. In press.

6. Wald NJ. Folic acid and neural tube defects: Discovery, debate and the need for policy change. *Journal of Medical Screening.* June 2022.