

Consultation on the proposal to add folic acid to flour A response to the UK Government August 2019

Spina bifida • Hydrocephalus • Information • Networking • Equality – **Shine** is the only charity that works across England, Wales and Northern Ireland to represent and support over 12,000 individuals and their families whose lives have been affected by Spina Bifida, Hydrocephalus, Anencephaly and Encephalocele.

For many, many years we have been campaigning on the need for mandatory fortification of flour with folic acid to reduce the risk of having a pregnancy affected by a neural tube defect, such as Spina Bifida or Anencephaly.

We therefore welcome this opportunity to respond to the UK Government's consultation on this issue:

<https://www.gov.uk/government/consultations/adding-folic-acid-to-flour/proposal-to-add-folic-acid-to-flour-consultation-document>

This response was submitted on-line on Friday 23 August 2019.

Do you agree or disagree with the proposal for mandatory fortification of non-wholemeal wheat flour in the UK with folic acid to help prevent neural tube defects?

Shine **strongly agrees** with the proposal for mandatory fortification of all flours in the UK with folic acid to help prevent NTDs.

Shine welcomes the detailed information and evidence set out in the Government's proposal to add folic acid to flour, and in the impact assessment. The documents describe so well the worsening picture in the UK, which is likely to deteriorate further if there is no mandate for folic acid to be added to flour. The folate levels of women of childbearing age are so low as to leave around 75% at risk of having a pregnancy affected by neural tube defects (NTDs). Thirteen per cent of young girls are clinically deficient. Obesity and diabetes, both significant risk factors for NTDs, are increasing.

As a charity, we have been asking for this measure to be implemented, in line with Scientific Advisory Committee on Nutrition's recommendations, for many years. We have watched helplessly as other nations across the world began to benefit from fortification, lowering the numbers of families going through the trauma of pregnancies affected by NTDs, while the UK procrastinated.

As a charity, we have listened, over and over, while women expecting a baby with spina bifida have told us they started to take folic acid ‘as soon as I knew I was pregnant’, when we knew this was just too late.

We have sent cards and attended funerals of wonderful people taken far too soon by spina bifida, and comforted parents who knew their baby would die of anencephaly.

Since the Medical Research Council trial published its findings in 1991 showing the preventative effects of periconceptional folic acid, we have been trying to promote folic acid supplementation with limited success. In the UK, we now have the second generation of women bearing children since the publication of this study, and fewer of them take the correct dose of folic acid at the correct time than in times past.

We know mandatory fortification will not prevent all NTDs, but it will prevent a significant number and will do so safely, as evidence from other countries already shows. The USA and Canada now have over 20 years’ experience of fortification, and more than 80 countries now fortify. It is time for the UK to join them.

Which products should be included

Which of the following do you think mandatory fortification with folic acid should apply to? Please choose one.

All flour including wholemeal and gluten-free.

It is important that fortification reaches as much of the population as possible to reduce health inequality, and to do this, as many different grains as possible should be included. People in the UK are being encouraged to eat more whole grains. By fortifying white flour but not wholemeal flour, people choosing wholemeal products would be denied an important health benefit. Gluten-free products should be included to benefit those who must avoid gluten, and those who are choosing to omit gluten from their diet for other reasons.

Alternative approaches

Are there any alternative ways of helping reduce the number of neural tube defects that you may prefer, other than our proposal for mandatory fortification of flour with folic acid?

No, there are no alternative ways that Shine prefers of helping reduce the number of NTDs other than mandatory fortification of flour with folic acid.

The need to increase the red blood cell folate in women prior to conception when so many pregnancies in the UK are unplanned makes fortification the most reliable way of achieving this.

There are many difficulties in getting health messages to healthy young women, who often do not see the need to prepare for pregnancy, even those who are actively trying to conceive.

Folic acid supplementation will always be an important part of NTD prevention but any efforts to ensure women take sufficient folic acid supplements at the correct time have always had very limited success, and that success has not been sustained, in the UK and elsewhere.

Fortification is safe and is the best way of reducing inequality in this area across all levels of the UK's social structure. Women from black and minority ethnic communities, young women and those in poverty are all less likely to take supplements and fortification would do much to address this health inequality. Other women from all walks of life may decline supplements on unfounded health grounds.

The Department of Health and Social Care's impact assessment document, which accompanies the consultation, sets out several alternative approaches, including improving surgical outcomes in the womb.

Whilst Shine welcomes any advances in treatment that can improve outcomes for an unborn baby with spina bifida, pre-natal or post-natal surgery is not a cure for spina bifida. A baby diagnosed with spina bifida will always have spina bifida, even after surgical intervention. Health and social challenges for babies who undergo surgery may be lessened through surgery, but current evidence suggests that these babies will still face a lifetime of on-going issues. There are numerous exclusion criteria to this surgery, such as twin pregnancy and placenta previa and, given the significant risks and maternal morbidity associated with this surgery, it will not be an option offered to or acceptable to everyone. As much as Shine welcomes this advance, it is no substitute for primary prevention measures, such as fortification.

Access to surgery cannot alter a diagnosis of anencephaly. Nor will it change the outcome as the baby will not live.

How individuals and businesses are affected

Are there any particular groups or individuals that might be negatively affected by mandatory fortification of flour with folic acid, or miss out on the benefits?

We do not believe any groups will be negatively affected by mandatory fortification of flour with folic acid.

The potential risk to people with B12 deficiency has been looked at in detail and the Guidance Level (GL) of 1mg per day has been reviewed recently by the Committee for Toxicity, following publication of Professor Sir Nicholas Wald's 2018 paper. The Committee noted that scientific evidence on adverse effects from folic acid in people with B12 deficiency was of a poor standard, mainly single cases and small, uncontrolled studies performed prior to the identification of B12, but opted to keep the GL at 1mg per day, only because there was no scientific evidence supporting any alternative dose.

It is widely accepted that the GL is a very conservative limit, at 20% of the lowest dose which might 'mask' B12 deficiency. However, 5mg per day is prescribed to women before conception to prevent recurrence of NTD, with no monitoring of their B12 levels.

B12 deficiency is common in older people, many of whom have insufficient folate levels, so they too would benefit from an increased intake.

In addition, many of the population who are close to or exceeding the Guidance Level, do so by taking supplements or eating fortified foods, and much of this also contains free B12, reducing the risk of deficiency.

We have been approached by individuals who believe having certain (commonly occurring) gene variants for MTHFR means they should avoid folic acid in favour of methyl folate. Shine has taken advice from Prof Anne Molloy, of Trinity College Dublin (who has advised the World Health Organisation on folic acid). She has confirmed that their fears are unfounded; because these gene variants can lead to a lower blood folate through difficulty processing natural dietary folate, there is potentially an even greater need for folic acid.

How could we make sure these groups or individuals are supported or not affected negatively?

An education campaign, with good quality, scientifically sound advice could be launched ahead of fortification

Are there any businesses that might be negatively affected by mandatory fortification of flour with folic acid, or miss out on the benefits?

Shine has no comment to make

How could we make sure these businesses are supported or not affected negatively?

Shine has no comment to make

Voluntary fortification

If the fortification of flour with folic acid is made mandatory, do you agree or disagree that there should be limits on voluntary fortification of other food products and/or supplements with folic acid?

Shine disagrees that there should be limits on voluntary fortification of other food products. Reducing voluntary fortification from foods such as breakfast cereals could disadvantage women who eat them in preference to bread, by lowering their folate intake, instead of increasing it. The NDNS will probably be able to ascertain how many people currently consume voluntarily fortified foods to the extent that they are close to the GL, and additionally large quantities of bread, which if also fortified, might cause the GL to be exceeded, but we expect most people would choose bread or cereal at mealtimes, not both.

If some measure was required to ensure the numbers of people exceeding the GL did not increase, our preference would be to cap supplements containing folic acid to 200mcg (RDA), **unless they are formulated for or targeted at women who might become pregnant.**

However, the main purpose of the Guidance Level is to protect people with B12 deficiency; many 'general use' vitamin preparations also contain free B12, thus reducing the chance of B12 deficiency at the same time as boosting folic acid intake.

Impact assessment

Do you agree or disagree with the provisional cost/benefit analysis outlined in the impact assessment?

Shine agrees with the provisional cost/benefit analysis outlined in the impact assessment.

Can you provide any additional evidence to inform the impact assessment?

Yes.

The annual figures for NTD have remained fairly stable for years. The live birth rate for spina bifida is now around 36% (EUROCAT¹), up from less than 10% in 1994 (ONS). This equates to approximately 90 more babies per year with significant disability.

In our own cost/benefit analysis paper 'Lifetime costs associated with living with spina bifida (2018)' **Shine** considered some of the key areas where we know costs are incurred in addition to the multitude of health and social care services required to support an individual and their families throughout their lifetime

1. Most of the papers that consider the economic burden of NTDs published in the past do not consider new methods for treatment, care and support have been introduced.

For example:

a. Bowel management.

Trans anal irrigation has become the treatment of choice for many children over three years of age. A baby born now, started on the market leader, Peristeen at age 3 and used until 64 years of age would cost **£107,484.44** just in product, without cost of support

b. Welfare support and benefits

A baby born today with mobility difficulties, needing bladder, bowel management and physio from a caregiver/parent or other support to live independently, would be entitled to

- £47,670 DLA Middle Rate of Care (16 years (less 3 months))
- £40,391 DLA Higher Rate Mobility (13 years)
- £143,020 PIP Standard Rate care (48 years)
- £149,136 PIP Enhanced Rate mobility (48 years)

=£ 380,217 in 64 years on Non-Means Tested Benefits

(Hunt and Oakeshott (2003) found only 26% of adult survivors aged 26-33 in their cohort were in open employment and 30% needed daily care).

¹ European network of population-based registries for the epidemiological surveillance of congenital anomalies

An adult aged 25 on ESA would receive **£186,258** until age 65

c. Other costs that could be considered

- Education- additional support in schools for personal care and education @c.£6000 pa =**£90,000** per child in school from 3 to 18.
- Housing adaptations-Disabled Facilities Grants for disabled children do not take parents income into account
- Additional Tax Credits
- Reduction in working hours of parents or other carers, paying less tax/receiving more in benefits
- Personal/social care

Do you think there are any other benefits, costs or wider impacts of this policy proposal that have not been mentioned yet?

Yes, we do.

1. The impact on the mental health and well-being of the parents-to-be and on the family must be considered.

To a certain extent, neural tube defects have been 'managed' by termination of pregnancy.

For parents with a diagnosis of spina bifida in their unborn baby, making a decision to continue or end a pregnancy more than halfway through is a tremendous, life changing burden. Many tell us they feel guilt, fear or anxiety for many years after termination. The impact affects family relationships and increases the strain on siblings, work and finances. Some parents experience such poor mental health they are unable to return to work. Fortification would reduce the number of families facing this awful situation, every year.

2. Possible reduction in deaths from stroke - the decline in deaths from stroke in USA and Canada accelerated significantly after fortification with folic acid, but remained constant in UK, which had no mandatory fortification.

(Improvement in Stroke Mortality in Canada and the United States, 1990 to 2002

Quanhe Yang, PhD; Lorenzo D. Botto, MD; J. David Erickson, DDS, PhD; Robert J. Berry, MD; Christie Sambell, PhD; Helen Johansen, PhD; J.M. Friedman, MD, PhD)

Practicalities for businesses

What are the practical issues that need to be thought about for mandatory fortification with folic acid?

Shine has no comment to make

Are there any further trade implications for industry that need to be considered?

Shine has no comment to make

Are there any effects on small businesses and medium businesses that need to be considered? (Small and medium sized businesses are businesses with fewer than 250 employees.)

Shine has no comment to make.

Kate Steele, CEO
Gill Yaz, Health Development Manager
23 August 2019