Decision time for folic acid fortification: Intentionally inadequate vs fully effective

Dr Jonathan Sher – Instead of my regular Column, I have the privilege of devoting this space within IJBPE to an article co-authored by nine of my most knowledgeable and respected colleagues. I hope you will share it widely in order to influence key policymakers to make wiser decisions.

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magine you have a wound requiring five stitches to prevent infection or further harm. And yet, you are informed that only one stitch will be administered. While admitting that it will close only 20% of the wound, you are told to be content with one stitch because it is 'better than nothing' and 'a good start'. Now, imagine your reaction to this situation.

This odd and unacceptable partial solution is analogous to what the UK Government is pursuing on the fortification of some foods with folic acid to prevent Neural Tube Defects (NTDs). The neural tube, which develops into the baby's brain, spinal cord and nervous system, is fully formed (or malformed) by the end of the 4th week of pregnancy - a point when most women don't yet know they are pregnant (Wald, 2022).

Neural Tube Defects are major congenital malformations that cause fetal deaths or serious lifelong, life-limiting disabilities. They can, however, largely be prevented by the simple measure of ensuring that women of child-bearing potential have a sufficient intake of folic acid *prior* to pregnancy (Kanchera et al., 2022).

Once pregnancy is confirmed (usually at 6-8

weeks), GPs, midwives and obstetricians are often asked by prospective parents whether *starting* to take folic acid now is a good idea. They ask because many people have heard that folic acid (Vitamin B9) is beneficial during pregnancy. Sadly, medical professionals must answer that the time when sufficient folic acid matters most (in order to prevent NTDs) has already passed.

NTDs are a major cause of the loss of a baby - through miscarriage, therapeutic termination, stillbirth or neonatal death (Allen et al., 2021). They also cause significant suffering for many hundreds of children annually in the UK who survive pregnancy with an NTD - only to face lifelong challenges (as do their parents) because of such conditions as Spina Bifida and Hydrocephalus. The human, financial and societal costs are high when failing to prevent as many NTDs as possible (Rodrigues et al., 2021).

It has been understood internationally for over 30 years - since Professor Sir Nicholas Wald's landmark study for the UK Medical Research Council (MRC) - that a sufficient intake of folic acid before, and during the first month of pregnancy can prevent the vast majority (more than 80%) of NTDs (MRC Vitamin Study Research Group, 1991). This was achieved with a daily intake of 4mg of folic acid before and after conception.

Government advice in the UK and beyond has long been for women of childbearing potential to take folic acid supplements regularly when planning (or likely) to become pregnant. This advice did help women who heeded it by taking enough folic acid early and regularly enough to secure the NTD-prevention benefits.

Unfortunately, this was a small proportion of women – and most commonly those of higher socioeconomic status. After more than a decade of promoting individual supplementation, the reality is that the uptake has been too limited to significantly reduce the overall incidence of NTDs. It also inadvertently widened inequalities, with less well-off prospective parents losing out (Morris et al., 2021; Sher et al., 2021).

The recently published 'National Diet and Nutrition Survey' revealed a startlingly low folate (folic acid) status across the UK population between 2008 and 2019 (Jones et al., 2023). Almost 90% of women of child-bearing age were below the level necessary to prevent NTDs. This reinforces the reality that individual supplementation has not proven popular or effective. And, it has long been understood that it is not plausible to consume enough folaterich foods to safeguard fetuses and babies.

Therefore, the sensible public health answer is to fortify a wide enough range of appropriate foods with a sufficient level of folic acid in order to safeguard ALL women of child-bearing potential from unwelcome Neural Tube Defects (Crider et al., 2022).

Fortification is already a tried-and-tested policy to equitably enhance public health. Since World War 2, the UK has routinely added healthpromoting ingredients (including two other B vitamins) to a variety of foods. Folic acid (Vitamin B9) was not included simply because its role in preventing NTDs was not known back then. However, since Professor Wald's research in 1991, it is incredible that such harm and suffering has been allowed to continue for over three decades when it was, and still is, largely preventable.

Through an upcoming, but long-promised, revision of food regulations, the UK Government has the opportunity to prevent the vast majority of NTDs (UK Dept. of Environment, Food and Rural Affairs, 2022). Yet, despite criticisms, it continues proposing an inadequate approach.

While the Government has finally accepted the case for fortification with folic acid, its 'halfbaked' proposal is to add Vitamin B9 only to non-wholemeal flour and only at a very low level (UK Dept of Environment, Food & Rural Affairs and UK Dept of Health and Social Care, 2024).

By its own admission, the UK Government estimates its fortification plan would prevent only 18-22% of NTDs (Haggarty, 2021). This intentionally inadequate, 'one stitch' approach to fortification will not benefit those who consume other types of flour, such as gluten-free, nor those whose diet is based on other grains, such as rice or maize (Mitchell et al., 2019). A wider approach is important in a multicultural society, as in the UK - and has already been implemented by other countries with diverse populations, such as the United States (Looi 2023).

Fortification with folic acid has proven to be safe and is already happening in more than 90 countries around the world. No country has ever documented adverse effects after evaluations - and no country has ever discontinued fortification (Food Fortification Initiative, 2023).

The UK is not alone in taking a suboptimal approach, with many countries limiting the range of flours and grains which are fortified and settling for fortification levels well below that already proven to be both safe and efficacious in preventing NTDs. Fully Effective Fortification can be achieved and measured in two ways, according to Professor Sir Nicholas Wald (2022):

- 4mg of folic acid daily for the months before, and the month after, pregnancy; or,
- A fortification level of 1mg/100g of flour and grains.

The main reason for timidity in setting the level appears to derive from outdated and disproven speculation regarding 'too much' folic acid exacerbating sequelae related to Vitamin B12 deficiency. However, in a review of the evidence prior to the UK Government's proposed policy, distinguished researchers concluded there is 'no evidence of harm arising from folic acid fortification at the higher levels needed to achieve fully effective fortification' (Wald et al., 2018).

The example of failing to properly fortify staple foods with folic acid (Vitamin B9) reveals an international reluctance to act fully and effectively upon the scientific evidence. The primary benefit of Fully Effective Fortification would be to prevent 80% of all NTDs (Morris & Wald, 2023).

Why accept a 20% solution to a longstanding health problem that is the cause of many fetal deaths, as well as major birth defects when a safe and more effective 80% solution is within the UK's grasp? It is tantamount to choosing governmental action that limits medications to a quarter dose (e.g., half of one paracetamol) when a full dose (e.g., two paracetamol) has been proven by robust research and longstanding clinical experience to be both safe and more effective.

Experiencing any of those unwelcome, far-from-trivial, pregnancy outcomes is personally painful, professionally unwelcome and economically counterproductive. Settling for preventing only 20% of NTDs through suboptimal fortification means these tragic consequences will predictably occur *four times more often* than would be the case if implementing the 80% solution offered by Fully Effective Fortification with folic acid.

As Decision Time rapidly approaches in the UK, the time has arrived to advocate for, and insist upon, Fully Effective Fortification. It is not yet too late for the Government to change direction, choose to do the right thing and do it right! Thousands of lives and life chances each and every year hang in the balance.

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