

Is it time that Europe makes folic acid fortification mandatory?

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How does Neural Tube Defect relate to the milling and grain industry? 2017 marks the 26th anniversary of a ground-breaking international study that changed the future for the global prevention of some of the world's most common congenital birth defects, Neural Tube Defects (NTDs). The 1991 study conducted by the Medical Research Council (MRC), led by Professor Sir Nicholas Wald, confirmed the protective benefits of folic acid in the prevention of NTDs, with this B vitamin reducing the risk to unborn babies by up to 72 percent.

The positive correlation was so overwhelmingly that the trial was ended ahead of schedule, as it was deemed unethical to continue withholding folic acid from women in the control group. A quarter of a century later and the milling and grain industry has become a vital player in the worldwide strategy to prevent these serious conditions. Having said that, there is still much more to be done.

What is folic acid?

Folic acid (vitamin B9) is the manmade version of folate, which is found naturally in green leafy vegetables, some fruits and pulses, the kinds of food that we're all encouraged to eat more of. However, whilst a healthy balanced diet is always beneficial, food folates are very unstable, and they can lose much of their nutritional content as a result of cooking and poor or prolonged storage.

Folate/folic acid plays an essential role in cell growth and development and the formation of DNA, consequently its role becomes even more vital in the early stages of pregnancy, when cell growth and reproduction is at its most rapid. Most of us will get enough of this essential vitamin through a healthy balanced diet, but it's impossible for women to obtain the daily additional folate they need to support a healthy pregnancy through diet alone.

Folate insufficiency at the time of conception is known to increase the risk of serious birth defects, NTDs, which occur in the very early stages of pregnancy when the brain and spine fail to form properly, with around 70 percent of babies affected also developing the commonly associated condition hydrocephalus (often termed, water on the brain). The instability of natural folates makes it very difficult to accurately gauge how much of the original vitamin content has been preserved to benefit the consumer, yet its manmade counterpart is considerably more stable. Both forms are water soluble, so our bodies can't retain them very effectively, making daily consumption essential.

As a result, since 1992, most countries around the world have advised all women that could become pregnant to take a daily supplement containing 400mcg of folic acid to help reduce the risk of their pregnancy being affected by NTDs. Despite this measure, NTDs still affect around ½ million pregnancies every year, resulting in thousands of late terminations every year (most NTDs are first diagnosed during a 20-week ultrasound), and many babies being born with a wide spectrum of both physical and learning disabilities. Many of these cases could have been prevented with daily additional, timely folic acid.

Breaking the myths

Whilst the solution may appear simple, there are a number of barriers to successful prevention through supplementation alone, and to date, strategies have been relatively unsuccessful due to a complex combination of social, personal and economic factors. 'Timeliness', is one of the key barriers to prevention, as to provide effective protection against NTDs, folate levels need to be raised to protective levels before conception occurs.

In addition to this, successful supplementation is dependent upon a variety of factors such as pregnancies being planned (over 50 percent of the world's pregnancies are unplanned); essential human behaviour change within the target group; availability and access to supplements (lacking in many developing countries). Further to this, it depends upon correcting the many common misconceptions about folic acid i.e. that folic acid 'is something that you can choose to take when you're pregnant because it's good for the baby', rather than something that's essential preconception to prevent some very serious consequences; or that you can get all the additional folic acid you need through a healthy diet; and even that folic acid prevents pregnancy (a misconception held by many men in the developing world). So, despite 26 years of scientific knowledge to enable prevention, we are still presented with a considerable global public health issue.

The milling and grain industry has been instrumental in helping overcome many complex global barriers to NTD prevention through both voluntary and mandatory fortification of staple grains and flour with folic acid. All over the world, people commonly consume wheat flour, maize flour, or rice as a staple part of their diets. Fortifying one or more of these grains is a cost-effective way to improve the population's nutrient intake.

Food fortification with folic acid

In 1996, Oman became the first country to introduce national scale mandatory fortification of wheat flour with folic acid. The USA followed in 1998, introducing fortification (in addition to supplementation), as part of a national strategy to maximise prevention of NTDs. Through this action, the milling and grain industry has contributed towards an estimated 35 percent decrease in the birth prevalence of NTDs across the USA, which in real terms equates to 1,300 fewer babies being born with these conditions. A major public health success story!

But, not only does fortification with folic acid reduce the risk of NTDs, it also reduces the risk of folate deficiency and folate deficiency anaemia across the wider population. Today, over 80 countries now have a mandate to fortify at least one staple grain with folic acid, with the notable exclusion of Europe, where we have yet to secure a single mandate. Whilst Europe remains reliant on supplementation (with its associated shortcomings) and voluntary fortification (which has a positive, but limited impact), mandatory fortification is proven to be considerably more effective in producing positive equitable public health outcomes. For example, when voluntary fortification began in Australia in 1995, two in 1,000 babies born to aboriginal mothers were affected by an NTD (double the rate born to non-indigenous mothers). The introduction of mandatory fortification in 2009, resulted in a staggering reduction, to 0.5 in 1,000 of these pregnancies being affected. This also serves to demonstrate the unique ability of mandatory fortification with folic acid to reduce the significant impact of socioeconomic inequality in the aetiology and prevention of these complex conditions.

Advocacy efforts

The International Federation for Spina Bifida and Hydrocephalus (IF) has maintained a high profile presence throughout ongoing global fortification activity. When the Regulation (EC) 1925/2006 on the addition of vitamins and minerals to foods was introduced in the EU, IF strongly advocated for the mandatory fortification of flour with folic acid within Europe, and submitted a statement to the United Nations, calling on them to ratify a policy urging all Member States to fortify a staple food with folic acid. To make greater progress, IF joined the Flour Fortification Initiative, (now the Food Fortification Initiative - FFI), an international public, private and civic partnership, working to improve health through fortification of industrially milled grain products.

As IF's President Margo Whiteford recalls, "The primary prevention of neural tube defects became a recurring topic during IF's annual international conferences, starting in 2007 in Kampala, Uganda, where Prof. Dr. Glen Maberley, then coordinator of FFI, gave an overview of mandatory food fortification worldwide. That same year, IF and FFI organised a meeting in Europe, with the aim to develop a strategy to influence European authorities to support the mandatory fortification of flour with folic acid.

The event brought together interested partners from the scientific world, international organisations, industry, and the disability movement. In 2008, IF took part in the 1st Central and Eastern European Summit on Preconception Health and Prevention of Birth Defects in Budapest, Hungary. Speakers from both the US and South America emphasised the effectiveness, sustainability and cost-effectiveness of folic acid fortification as a public health intervention, tackling both folate insufficiency and effecting an average reduction in NTD incidence of 46 percent in countries where fortification had been implemented.

The preventative benefits of this intervention were notably magnified in countries with greatest incidence (i.e. Brazil, Peru, Chile). The recent addition of corn masa flour (a food staple in Latin America) to the US fortification programme aims to further address the distinctly higher risk of NTD among Hispanic women.”

Global partnerships and activities

Through a partnership including AkzoNobel, Helen Keller International, FFI, and IF, the project Smarter Futures was launched in 2009 with funding from the Dutch government to improve health in Africa through the enrichment of wheat and maize flour with essential vitamins and minerals. Smarter Futures provides technical support and training for flour millers as well as government food control staff, vitamin and mineral suppliers, international organizations, and academic institutions in Africa.

Whilst the emotional, psychological, personal and health consequences of these largely preventable conditions remains the primary motivation for maximising their primary prevention, the cost benefits of doing so (particularly at a time when healthcare budgets and resources are at breaking point) are also undeniable. IF presented the case of flour fortification with folic acid as a cost-effective way to prevent birth defects at the 4th International Mühlenchemie Symposium “Future of Flour” in 2011, and in 2012 IF and FFI organised a workshop to highlight opportunities for flour fortification to improve nutrition and prevent birth defects at the 15th European Health Forum Gastein in Austria.

In 2013, IF also cooperated on a review article with FFI, the Emory Centre for Spina Bifida Research, Prevention and Policy, and UNICEF, “Folic acid fortification of wheat flour: A cost-effective public health intervention to prevent birth defects in Europe”, published in the June issue of the Nutrition Bulletin.

At the Future Fortified Global Summit on Food Fortification in Tanzania, organised by GAIN in 2015, IF participated in the panel “Protecting life before it begins: The impact of Spina Bifida” and emphasised how difficult the optimal folate levels in the preconception period is to be achieved with supplements. With FFI, Boston Children’s Hospital and CURE Hydrocephalus, the Hydrocephalus Association, the U.S. Spina Bifida Association, and the University of Toronto, Sunnybrook Health Sciences Centre, IF initiated the PUSH! Global Alliance, with advisory support of the U.S. Centres for

Disease Control and Prevention, National Centre on Birth Defects and Developmental Disabilities. This was in order to accelerate spina bifida and hydrocephalus prevention, and to realise optimal care and a better quality of life for those affected.

The way forward

NTDs remain an important cause of perinatal mortality and disability worldwide, with the mandatory fortification of flour with folic acid proving to be the most successful public health intervention to date towards reducing the global prevalence of NTD-affected pregnancies. Whilst we have yet to achieve a mandate for folic acid fortification in Europe, IF maintains its commitment to achieve this goal, and will consequently be issuing a renewed call to action to governments to commit to this vital public health action.

IF President Margo Whiteford commented, “IF calls on the EU to implement forthright policy propositions that will contribute to the effective reduction of NTD through increasing awareness, and folic acid food fortification and supplementation plans. IF proposes the creation of an international policy for mandatory food fortification to actively encourage all countries to adopt this measure”.

In a bid to consolidate the global effort towards maximising NTD prevention, IF launched its Global Prevention Initiative (GPI) at its international conference in 2016. Its first action was declaring the first World Folic Acid Awareness Week in January 2017. The GPI is the first initiative of its kind, aiming to maximise the risk reduction of NTDs (and the often associated condition, hydrocephalus) as a united global community, through the engagement of its members, academics, health professionals, governments, educators, commercial and NGO partners.

With a world renowned panel of global experts (in both NTDs, hydrocephalus and prevention), board membership of the Food Fortification Initiative, history of global engagement in supplementation recommendation, and unprecedented understanding of the lifelong impact of these conditions (as a long serving international patient organisation) IF is ideally positioned to lead on this drive, at the heart of which remains a global mandate for folic acid fortification.

Importantly, while IF actively supports primary prevention measures to reduce the prevalence of NTDs, it also emphasises that prevention campaigns should safeguard the dignity of people with disabilities and must not be seen to carry messages that may increase stigma and discrimination.

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Figure 1: Reductions in NTDs after flour fortification with folic acid was initiated