

FORTIFICATION POLICY . . . STILL WAITING



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The quality of the evidence of folic acid as the best method of risk reduction of NTD development is excellent and has never been seriously challenged, but the translation into a fortification policy has stalled. In the light of a proposed Scottish initiative to add folic acid to flour, Ursula Arens makes the point that evidence is not enough; politics, public opinion and power games all contribute to decisions on nutrition policy.

Dietitians and doctors are now taught that you should evidence-base your professional advice. Was there ever another way? But what is meant by the shorthand phrase is that you should consider the tiers and quality of data available and from this, base the firmness and enthusiasm of your guidance to patients. If there is stronger evidence: shout. If there is weaker evidence: mumble. And if there is no good evidence: say so.

Always easier said than done, and especially as in today's information-overloaded environments, there is often high quality data supporting seemingly opposite conclusions. A less considered aspect of evidence-based-medicine (EBM) is not the making of judgments and giving advice where evidence is weak, but rather the not making of judgments and not giving advice where evidence is strong. And the latter sadly captures the meandering trail of policy in the UK in relation to the subject of the fortification of foods with folic acid.

So, it is wonderful that in October 2015, the UK's top nutrition experts, members of the Scientific Advisory Committee on Nutrition (SACN), have written to the Health Ministers in England, Scotland, Wales and Northern Ireland, saying, paraphrased, "why are we waiting?"...because it is coming up to the 25-year anniversary of the publication of the results of the UK Medical Research Council (MRC) randomised double blind study, showing that additional folic acid

in early pregnancy* reduced the risk of congenital neural tube defects (NTD) by more than 70%.

There have been previous features on folic acid fortification practices in *NHD Magazine* (Arens, 2005, 2007) and I have my own reasons for particular interest in the subject, having had the great privilege of discussing the subject with Professor Sir Nickolas Wald, who is the UK's most dedicated folic-acid champion. Nick Wald developed blood tests to identify spina bifida during pregnancy in 1974 and then led the Medical Research Council folic acid supplement trial 1983-1990 (MRC, 1991). Because the protective actions of folic acid occur so early in pregnancy and because of the much-quoted guess that about 50% of pregnancies in the UK are unplanned and unexpected, the fortification of foods was immediately under consideration as the best way to enhance the population status of mothers-to-be.

In 1993 we discussed the possible effects that changes to food labelling regulations might have, to intakes of folic acid from fortified foods. The outgoing rules (UK Food Labelling Regulations of 1984) required for a labelling claim on a folic acid fortified food, at least one sixth of the reference amount, of 300ug, per serving. The incoming rules (EC directive on nutrition labelling of foodstuffs of 1990) required at least 15% of the reference amount of 200ug per 100g of food. As voluntary fortification decisions are

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very strongly driven by labelling regulations, the changes could be predicted to strongly reduce actual intakes of folic acid from fortified foods. For example, intakes from a serving of breakfast cereal, where a serving size was 30g, would need to contain at least 50µg of folic acid under UK 84 regulations, versus only a measly 9.0µg of folic acid under EC 90 regulations. This was an unintended outcome of changes to the provision of nutrition information to consumers, but was likely to result in a dilution of folic acid fortification practices. The rather low hurdles needed to allow micronutrient claims on some foods (those whose portion size was much lower than 100g), has since been described as 'pixie-dust' dosing. Nick Wald was concerned over any developments that would reduce possible intakes of folic acid in the national diet, and was hugely keen to reach beyond academe, to involve food industry advisers in discussions on folic acid policies.

A UK report from the Expert Advisory Group published by the Department of Health in 1992 recommended some modest support for voluntary fortification: this should be restricted to the food categories of breads and breakfast cereals, at levels not exceeding those in current (1992) products. Fortified foods should be labelled to indicate this, and there should continue to be a choice of unfortified breads and cereals available: in practice this was likely to be products that were wholemeal or organic. In the meantime, 83 countries have now introduced mandatory statutory fortification of foods (A-Y: Argentina to Yemen), including most notably the USA, with data demonstrating subsequent significant reductions in the incidence of NTDs in their populations.

SACN have now (October 2015) written to Health Ministers requesting a decision be made

on measures to improve the folate status of the population. They had already presented risk assessments for a fortification policy in 2006 and 2009, and in both reports recommended the mandatory fortification of flour as a national policy. They reassured Ministers that no adverse effects on cardiovascular disease or on any site specific cancers had been observed from meta-analysis of data assessing the effects of increased intakes of folic acid. They cited calculations from the USA that the prevalence of NTDs had fallen from 10.8 to 6.5 per 10,000 live births, with an estimated healthcare cost saving US\$508 million.

Data on the number of NTD affected pregnancies in the UK suggested a possible increase. The recent UK survey of blood folate levels from more than 750 women (NDNS, 2015), showed levels lower than levels measured in US women prior to their national fortification policy, with 85% of UK women having levels below the targets set by the World Health Organisation for women of reproductive age. The final note of concern communicated by SACN to Health Ministers was that there had been a reduction in voluntary folic acid fortification of foods in the UK in recent years, in compliance with SACN recommendations prior to the instruments of mandatory fortification. This outcome was not intended or foreseen, but may have unintentionally reduced folic acid intakes in the UK population since 2006.

So, with all the talk of decisions based on quality evidence, the work of Professor Sir Nicholas Wald, whose gold-level research was published in 1991, still sits on the pending pile. Hopefully, the SACN letter to Health Ministers will prompt some action, so that the UK population can finally benefit from enhanced folate status. And dietitians will be the essential profession needed to support and communicate the policy when it is announced - hopefully soon.

* Early pregnancy actually means very early pregnancy: the neural tube closure of the foetus occurs before about day 30 post conception, which is about two weeks after a missed period. Enhanced levels of folate status after this time will make no difference to the risk of NTD. So, in fact, only folic acid supplementation taken prior to conception, or immediately upon a missed period (usually prior to a positive pregnancy confirmation) can be protective. This does not fully match the impression conveyed by the advice to take folic acid supplements in the first trimester of pregnancy.