

## EU DISEASE RISK REDUCTION HEALTH CLAIM FOR FOLIC ACID



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**Further to publication of the list of authorised EU health claims (3), a glaring omission has been a claim for the benefit of folic acid supplements prior to pregnancy and reduced risk of neural tube defects (NTD), such as spina bifida and anencephaly, in the foetus. This was despite conclusive evidence for this important health benefit, which is a global WHO health recommendation (4).**

Since publication of the conclusive MRC trial in 1991, which demonstrated that supplementary folic acid can help to reduce the risk of NTDs by up to 72 percent (5), women who might become pregnant have been recommended by the Department of Health to take a daily supplement of 400mcg folic acid, prior to conception and until the 12th week of pregnancy. Certain groups have a higher risk of an affected pregnancy and these include women or their partner who have spina bifida, women with a previously affected pregnancy or with a family history of NTD, women who are diabetic, take anti-epilepsy medication, have coeliac disease or have a BMI above 30 kg/m<sup>2</sup>. These groups are recommended to take 5.0mg folic acid a day, which requires a prescription.

Since this recommendation was introduced, women's awareness of this message has remained generally low. In 2011, Shine (1), the UK's spina bifida and hydrocephalus charity, initiated its 'Go Folic!' campaign to help raise awareness among women of the need to take folic acid before they become pregnant, and a commitment to the primary prevention of NTD.

### UPTAKE OF FOLIC ACID SUPPLEMENTS

A study exploring the rationale behind women's decision-making on folic acid supplement use (6), invited 292 women attending routine health visitor-led baby clinics to take part, of whom 211 women provided information on supplement use relating to their most recent preg-

nancy. Of these, only 67 (31 percent) reported having taken folic acid supplements as recommended, 118 (56 percent) took them only during pregnancy (22 or 18 percent only intermittently), and 26 (12 percent) had not taken folic acid at all. Discussion in focus groups revealed that though the rationale behind the current recommendation was generally known, folic acid use was often linked with morning sickness, and busy lives; competing priorities for concern and poor memory were given as reasons for intermittent use.

A more general survey in January 2012 of 10,000 consumers from the general UK population indicated that the uptake of folic acid supplements by women remains very low. Only 3.3% of the women respondents reported taking a folic acid supplement and, whilst this figure was slightly higher for women in the critical 18 to 34 age group, it is still worryingly low at four percent (7).

### EU HEALTH CLAIM FOR FOLATE

Under the initial round of EU health claim authorisations (3), up until now supplement manufacturers have only been able to claim on packaging and in other consumer communications that 'folate contributes to maternal tissue growth during pregnancy'. This was viewed as a missed opportunity to help educate and inform women about the vital role of folic acid taken preconceptionally and during the early stages of pregnancy, and it was recognised that a stronger health claim was needed.

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## DISEASE RISK REDUCTION CLAIM

During 2012, three dietary supplement trade associations in the UK (HFMA, PAGB and CRN-UK) (2) came together, in conjunction with Shine, with the support of the Department of Health, to prepare an application for an Article 14.1(a) disease risk reduction claim for folic acid, under the Nutrition and Health Claims Regulation (8).

The reason for Shine's commitment to this claim is the high incidence of NTD-affected pregnancies in Europe:

- A recent report *Act against Europe's Most Common Birth Defects: One Year On - Defining Neural Tube Defect prevention strategies in Europe* (9) has identified that there are 4,500 pregnancies affected by NTD each year in Europe, of which an estimated 72 percent are terminated following prenatal diagnosis. The condition is not usually diagnosed until the 20-week scan, causing much distress to the mother if it is decided to terminate the pregnancy as this is classed as 'late term'.
- Up to 70 percent of NTDs could be avoided by ensuring adequate folate status before conception in women of childbearing age.
- A European Commission report *Communication of Rare Diseases: Europe's Challenges* (10) recognises that NTDs are one of the few rare diseases for which the incidence could be reduced. Reduction of risk is very straightforward - the intake of folic acid supplements prior to pregnancy and hence all available means to communicate this crucial message should be utilised.
- In the UK, The Food Standards Agency has previously estimated that the economic cost associated with NTDs in the UK runs to almost £136 million per annum. Hence across Europe the costs are substantial.

A claim application was submitted in the early part of 2013 via the UK Competent Authority, the Department of Health. The application was awarded a positive EFSA opinion, which was published on 26th July 2013 (11). The claim was then subject to the ensuing authorisation procedures which included discussion by the Commission working group on claims (Member States, expert level) and by the Standing Com-

mittee, which awarded the claim a positive vote in April 2014. The claim was notified to the WTO, discussed by the European Council and was finally subject to a three-month scrutiny period by the European Parliament. The Regulation authorising the claim was published in the Official Journal on 24th October 2014 (12), and the claim came 'into force' on 18th November 2014.

The health claim is based on low maternal folate status as the risk factor for NTD in the foetus. EFSA commented that folate in serum or plasma is a sensitive marker of early changes in folate status, and that red blood cell folate is considered a reliable biomarker of long-term folate status as it reflects tissue folate stores, and decreases only weeks or months after the initial reduction of folate intake and the fall in serum folate concentrations (11).

The authorised wording of the claim is consistent with all the other authorised disease risk reduction claims to date and states that, 'Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of neural tube defects in the developing foetus.'

The conditions of use are restricted to folic acid supplements and state that the claim may only be used for folic acid supplements that provide at least 400mcg of folic acid per daily portion. Use of the claim should be accompanied with information stating that the target group is women of childbearing age and that the benefit is obtained with a supplemental folic acid daily intake of 400mcg for at least one month before and up to three months after conception.

## CONCLUSION

Obtaining an authorised EU disease risk reduction claim that can be used on products and in advertising is a much needed initiative that will be in the public interests of European consumers, as it will enable manufacturers to explain to women why folic acid is beneficial. The claim is an important step forward in helping to raise awareness of this vitally important public health message.

For article references please email:  
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be a monthly half-day in Birmingham to fill a few bills and check a few cheques. When motherhood pulled away the Treasurer at the time, Edith accepted promotion to the post.

1976 was not the easiest time to be Treasurer of the BDA. There was a backdrop of inflation rates of nearly 20 percent and terms of the IMF bail-out required a UK government agreement to austerity = public sector wage maintenance. Counter to the normal laws of economics, dietetic salaries were very poor, despite a great shortage, and BDA subscriptions had not been increased for a while, leaving BDA finances very tight. Further, there was great membership support for plans to expand BDA activities, such as employment of additional administrative staff and the newly agreed newsletter (which has now become the monthly *Dietetics Today*). Edith presented the case that annual subscriptions needed to be increased very significantly, from £12.75 to £20.50. In 'today's money', this would be as though there was a proposal to increase the current full annual subscription from £284 to £455! Needless to say, there was a lot of debate and Edith as treasurer was the centre of both an extraordinary council meeting and an extraordinary members meeting. The counter view was that such steep increase in fees would lead to so many non-renewals, that the total income from subscriptions could, in fact, be reduced. Clearly Edith's figures were persuasive enough to demonstrate the case and members voted to support the increased subscriptions (and there were very few non-renewals).

In 1985, Edith became honorary chairman of the BDA. Because the BDA became a listed trade union in 1983, there had been an increase in work, and the decision was made to employ a professional administrator. Mr John Grigg was appointed in February 1985, and was in post to support the significant 50th year 'Golden Jubilee' celebrations of the BDA in 1986. The BDA annual conference that year was an International Symposium held at the Barbican in London and enjoyed by more than 450 delegates (more than 100 of whom were international attendees).

On completion of her chairing responsibilities, Edith became Treasurer for the European Dietitians Association (EFAD) for 12 years until 2000. Her many years of experience and her many European contacts also put Edith in a strong position to support the Edinburgh hosting of the International

Confederation of Dietetic Associations (ICDA) congress in 2000.

Professional retirement from her post at the University Hospital in Nottingham may have happened in 1996, but Edith's activities for the BDA continue to a degree that can hardly be matched. Edith is the current archivist of the BDA and, for many years, has systematically sorted into keep-or-dump piles, all paper records of BDA history up to 2000. All back copies of newsletters, all council minutes and briefing papers, all committee records, all branch and group annual reports and any other documents of possible interest. "I don't want the past to be lost," explains Edith and, without doubt, future researchers wanting to access any aspect of BDA history will be grateful to her, for the thorough and meticulous sorting of the records of our profession. This summer (July 2014), 69 sealed boxes were sent to the professional care of the archiving department of the Wellcome Institute; any future researcher will find the dietetic family tree easy to access.

Of course, dietetics in the future will be different, but Edith has no concerns over the essential strengths and contributions that our profession makes to human health and welfare (the themes of her professional life). "Where there is a coming together of foods and people, as individuals, as families, as groups or as communities, there will always be the need for support and advice on how to best do this, to protect health. This is what dietitians have done, and will continue to do." A great endorsement for the optimistic future of dietetics, from someone who has seen its' development over a long time.

Edith Elliot's support for our profession has been constant and practical. Of course she would be the first to insist that there have been others equally dedicated. But it is nonetheless a small, but valid recognition that she is dietitian number one and that the current tome of MDP is dedicated to her.

#### THE BDA CAREER OF EDITH ELLIOT

Honorary Treasurer; 1976-1981

Honorary Vice-Chair; 1984; 1988

Honorary Chairman; 1985-1987

Trustee: BDA General and Education Trust; 2000-2012

BDA Archivist; 2000-