

# National Institute for Health and Care Excellence

## Healthy Start vitamins: special report on cost effectiveness

### Scope

#### 1 Title

Healthy Start vitamins: is a targeted or a universal approach more cost effective?

##### 1.1 *Short title*

Healthy Start vitamins: cost effectiveness

#### 2 Background

- a) In response to a recommendation from the Chief Medical Officer, the Department of Health asked the National Institute for Health and Care Excellence (NICE) to examine the cost effectiveness of moving the Healthy Start vitamin programme from the current targeted offering, to a universal offering.
- b) [Healthy Start](#) is a UK-wide, government scheme that provides ‘a nutritional safety net’ for pregnant women and families on benefits and tax credits. Women who are at least 10 weeks pregnant and families with children under 4 years old qualify if the family receives the relevant benefits. Pregnant women under 18 are also eligible, regardless of whether they receive benefits. The scheme includes food vouchers and vitamin supplements.
- c) In her annual report for 2012 [Our children deserve better: prevention pays](#) (Department of Health 2013), the Chief Medical Officer highlights growing concerns about the prevalence of disease related to vitamin D deficiency. In addition, there are

concerns about the proportion of women following current advice on folic acid supplementation (Bestwick et al. 2014; McGovern et al. 2012). The CMO report notes: 'There is a growing body of evidence to suggest that providing free vitamins to targeted groups has not led to high enough levels of uptake. This, in turn, has therefore not impacted on reducing the morbidity associated with vitamin deficiency'. The CMO has therefore recommended that NICE carry out this special cost effectiveness report.

- d) NICE is developing [guidance](#) on how to implement existing advice to prevent vitamin D deficiency<sup>1</sup>. This special report will complement NICE's existing work on vitamin D. It is not intended to inform the development of a NICE guideline.

This report will be developed using the process and methods for reviewing cost effectiveness described in [Methods for development of NICE public health guidance](#) (2012) and [The NICE public health guidance development process](#) (2012).

### **3 The need for this estimate of cost effectiveness**

- a) Healthy Start was introduced in 2006. The Healthy Start supplements for women contain vitamins C and D and folic acid. Vitamin C is included due to the strong social class gradient in intake. Vitamin D is included because of the increased need for it in pregnancy and while breastfeeding. Women from minority ethnic groups may be at greater risk of deficiency ([Scientific review of the Welfare Food Scheme](#) Department of Health 2002). The Healthy Start children's supplement contains vitamins A, C and D. The aim is to provide a safety net for children who may have a low intake of

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<sup>1</sup> NICE consulted on the draft guideline with registered stakeholders from 13 May to 24 June 2014. The final guideline may differ as a result of the findings of the consultation.

these vitamins linked to a 'failure to thrive'<sup>2</sup>. Or they may have increased needs (for example, during infections), or they may be vulnerable to low vitamin D status due to ethnic origin ('Scientific review of the Welfare Food Scheme').

- b) There has been concern that rickets may be re-emerging among children in the UK (Pearce and Cheetham 2010). National survey data show that there is evidence of low vitamin D status among survey participants of all ages and genders, especially in the winter months. For example, 7.5% of children aged 18 months to 3 years and around 22% of women aged between 19–64 have a low vitamin D status<sup>3</sup> ([National Diet and Nutrition Survey: results from Years 1 to 4 \(combined\) of the rolling programme for 2008 and 2009 to 2011 and 2012](#) Public Health England and Food Standards Agency 2014).
- c) The Scientific Advisory Committee on Nutrition recommends<sup>4</sup> that the following should be offered vitamin D supplements:
- all pregnant and breastfeeding women
  - breastfed babies from the age of 6 months (or earlier if the mother's vitamin D status in pregnancy was not adequate)
  - formula-fed babies receiving less than 500 ml formula a day
  - all children aged 1–4 years ([Update on vitamin D](#) Scientific Advisory Committee on Nutrition 2007).

More recently, the UK Chief Medical Officers wrote to health professionals to highlight the importance of vitamin D supplementation among at-risk groups. They recommended that all pregnant and breastfeeding women and infants and young children aged from 6 months to 5 years take a daily supplement of vitamin

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<sup>2</sup> 'Failure to thrive' in infants and young children, is characterised by failure to gain weight at an appropriate rate. It is associated with being under-nourished.

<sup>3</sup> Low vitamin D status is defined by the Department of Health as a plasma concentration of 25 hydroxyvitamin D (25[OH]D, the main circulating form of the vitamin) of below 25 nmol/litre (equal to 10 ng/ml).

<sup>4</sup> The Scientific Advisory Committee on Nutrition is currently reviewing the dietary reference values for vitamin D.

D. ([Vitamin D – advice on supplements for at risk groups](#)

Department of Health 2012).

- d) Since 1992, all women have been advised to take 400 micrograms of folic acid daily from when they start planning a pregnancy until the 12th week of their pregnancy (DH 1992) <sup>5</sup>. This is to reduce the risk of their baby being born with a neural tube defect (see below). But a recent study suggests the number of women taking folic acid supplements may be in decline. A study of almost half a million women attending a London clinic showed that between 1999 and 2001, 40% were taking folic acid supplements – compared with only 28% between 2011 and 2012. Uptake was lower among younger women and women from some minority ethnic groups (Bestwick et al. 2014). The women least likely to take folic acid supplements are those most likely to have an unplanned pregnancy – and around 50% of all pregnancies are unplanned ('Scientific review of the Welfare Food Scheme'). In addition, uptake of folic acid advice is not always timely (Barbour et al 2012; McGovern et al 1997).
- e) Folic acid supplements help prevent neural tube defects, the second most common group of birth defects. They include: anencephaly, which leads to stillbirth or death shortly after birth; and spina bifida which is very likely to lead to physical and mental disabilities (Postma et al. 2002). The direct medical costs and the indirect costs for the lifelong care of those born with spina bifida have been estimated to be substantial (Yunni et al. 2011). Peri-conceptual supplementation with folic acid is estimated to be cost effective (Postma et al. 2002; Yunni et al. 2011).
- f) Many of those eligible for the Healthy Start scheme redeem their food vouchers (72–86%) ([Healthy Start vouchers study: the views](#)

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<sup>5</sup> Women are advised to take a 5mg/day supplement of folic acid if: they have previously had a baby with a neural tube defect; if they or their partner have a neural tube defect or a family history of neural tube defects; or if the woman has diabetes.

[and experiences of parents, professionals and small retailers in England](#) University of Bristol 2013). But 2 studies suggest that less than 10% redeem their vitamin vouchers ('Healthy Start vouchers study: the views and experiences of parents, professionals and small retailers in England'; and a study by Jessimen et al. 2013). Another puts this at less than 3% (Moonan et al. 2012). Suggested reasons include: lack of awareness of the importance of the vitamins among women and some practitioners; difficulties for practitioners in obtaining supplies; the complicated assessment of eligibility; and difficulties finding an accessible location for distribution. ('Healthy Start vouchers study: the views and experiences of parents, professionals and small retailers in England'; and [Healthy Start: understanding the use of vouchers and vitamins](#) University of Dundee 2013.) The time health professionals devote to overcoming such difficulties is often at the expense of promoting other aspects of the scheme and other public health work ('Healthy Start vouchers study: the views and experiences of parents, professionals and small retailers in England' and; 'Healthy Start: understanding the use of vouchers and vitamins').

- g) Health professionals have raised concerns that women must be at least 10 weeks pregnant to be eligible for the Healthy Start scheme. This is because the opportunity to benefit from the folic acid supplements may have passed by the time women have registered for and can get the vitamins. This is particularly the case for first time pregnancies, ('Healthy Start: understanding the use of vouchers and vitamins'; and the study by Jessimen et al. 2013). Health professionals suggest that a way to overcome these issues is to make the Healthy Start vitamins freely available to all pregnant women, mothers and young children ('Healthy Start vouchers study: the views and experiences of parents, professionals and small retailers in England'; 'Healthy Start: understanding the use of vouchers and vitamins'; and Jessimen et al. 2013). It has been

suggested that this may be more cost effective ('Healthy Start: understanding the use of vouchers and vitamins').

## **4 Estimating cost effectiveness**

This document defines what this special report on cost effectiveness will (and will not) examine, and what the Expert Reference Group will consider. The scope is based on a request from the DH in response to a recommendation to NICE from the Chief Medical Officer (see appendix A).

### **4.1.1 What will be covered**

The cost effectiveness of moving the Healthy Start vitamin programme from the current 'targeted' offering to a 'universal' offering. Two universal scenarios will be examined where the vitamins are offered to:

- a) All pregnant women (from 10 weeks), women with a child aged under 12 months and children over 6 months and under 4 years (as now). **But** regardless of their income level or their entitlement to the current qualifying benefits and tax credits.
- b) All women planning a pregnancy, pregnant women, women with a child aged under 12 months, infants aged from 0–6 months and children aged from 6 months to 5 years. (This is to reflect the UK dietary recommendations for folic acid supplementation and the CMO's recent recommendations for vitamin D.)

### **4.1.2 What will not be covered**

- a) The cost effectiveness of the Healthy Start food vouchers or any other aspect of the Healthy Start scheme.
- b) The cost effectiveness of providing any vitamins or minerals, such as iron or calcium, not included in the Healthy Start supplements.

## **4.2 Key questions and outcomes**

Below is the overarching question that will be addressed:

**Question 1:** Would it be cost effective to move the Healthy Start vitamin programme from the current targeted offering to a universal offering, according to the 2 scenarios defined in section 4.1.1 above?

The subsidiary questions are as follows:

1. Is universal provision of Healthy Start supplements to women seeking to become pregnant cost effective, compared with no provision under Healthy Start?
2. Is universal provision of Healthy Start supplements to women who are less than 10 weeks pregnant cost effective, compared with no provision under Healthy Start?
3. Is universal provision of Healthy Start supplements for infants aged 0 to 6 months cost effective, compared with no provision under Healthy Start?
4. Is universal provision of Healthy Start supplements for children aged 4 to 5 years cost effective, compared with no provision under Healthy Start?
5. Would universal provision of supplements create a 'spill over' effect by increasing uptake in the current target group and would this be cost-effective compared with the current targeted offering?
6. What is the incremental cost effectiveness ratio of extending the eligibility for universally available vitamins to:
  - infants from birth to 6 months compared with providing them for those aged over 6 months
  - children between their fourth and fifth birthday compared with providing them until their fourth birthday
  - women less than 10 weeks pregnant compared with providing them to those over 10 weeks pregnant (the current target)
  - women intending to become pregnant?

### 4.2.1 Expected approach

Outcome measures will reflect the original rationale for including vitamins A, C and D and folic acid in the Healthy Start vitamin programme. For example, it is anticipated that:

- a) The prevention of neural tube defects such as spina bifida, anencephaly and encephalocele will be the main outcomes used to assess the cost effectiveness of providing folic acid supplements. Direct costs to the NHS and wider societal costs will be taken into account. (For example, the latter will include the costs to local authorities, social care and education of caring for those born with these conditions.) Both length and quality of life will be included. These will be expressed as quality-adjusted life years (QALYs).
- b) Moving people with sub-optimal plasma levels to adequate levels of vitamin D will be taken into account when assessing the cost effectiveness of providing vitamin D supplements.

### 4.3 Status of this document

This is the final scope.

## 5 Related NICE guidance

### *Published*

- [Antenatal care](#) NICE clinical guideline 62 (2008)
- [Maternal and child nutrition](#) NICE public health guideline 11 (2008)<sup>6</sup>
- [Postnatal care](#) NICE clinical guideline 37 (2006)

### *Under development*

- [Implementing vitamin D guidance](#) NICE public health guideline. Publication expected November 2014<sup>7</sup>.

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<sup>6</sup> The economic report for this guideline specifically considers the cost effectiveness of folic acid supplementation.

<sup>7</sup> The draft economic review for this guideline evaluates interventions to improve the uptake of vitamin D supplements.

- [Sunlight exposure – benefits and risks](#) NICE public health guideline.  
Publication expected July 2015.

## Appendix A Request from the Department of Health

The Department of Health asked NICE to produce this special report, in response to a recommendation from the Chief Medical Officer for England that NICE:

‘Examine the cost effectiveness of moving the Healthy Start Vitamin Programme from the current targeted offering, to a universal offering.’

## Appendix B Potential considerations

It is anticipated that the Expert Reference Group will consider the following issues:

- The cost effectiveness of each separate vitamin for each of the population groups, as relevant, described in section 4.1.1.
- The number of women not eligible for Healthy Start under the targeted scenario who pay for supplements for themselves or their children.

## Appendix C References

Bestwick JP, Huttley WJ, Morris JK et al. (2014) [Prevention of neural tube defects: a cross-sectional study of the uptake of folic acid supplementation in nearly half a million women](#) PLoS ONE 9(2): e89354

Department of Health (1992) Folic acid and the prevention of neural tube defects. Report of an expert advisory committee. London: Department of Health

Jessimen T, Cameron A, Wiggins M (2013) A qualitative study of uptake of free vitamins in England. Archives of disease in childhood 98(8): 587–91

McGovern E, Moss H, Grewal G et al. (1997) [Factors affecting the use of folic acid supplements in pregnant women in Glasgow](#) British Journal of General Practice 47(423): 635–7.

Moonan M, Hanratty B, Whitehead M (2012) [Which is more effective, a universal or targeted approach, to implementing the National Healthy Start](#)

[Programme? A mixed methods study](#) Journal of Epidemiology and Community Health 66: A44–5

Pearce SHS, Cheetham TD (2010) [Diagnosis and management of vitamin D deficiency](#) BMJ 340: b5664

Postma MJ, Londeman M, Veenstra HEK et al. (2002) Cost effectiveness of periconceptional supplementation of folic acid. Pharmacy World and Science 24(1): 8–11

Yunni Y, Lindeman M, Colligs A et al. (2011) Economic burden of neural tube defects and impact of prevention with folic acid. European Journal of Paediatrics 170: 1391–400