

# Healthy start vitamins: special report on cost effectiveness

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## Executive summary

### *What was NICE asked to do?*

In response to a recommendation from the Chief Medical Officer for England ([Our children deserve better: prevention pays](#)), the Department of Health asked the National Institute for Health and Care Excellence to examine the cost effectiveness of moving the [Healthy Start](#) vitamin programme from the current targeted offering to a universal offering. (See the [scope](#).)

This report summarises the findings of a [cost effectiveness review](#) and an economic modelling exercise. The methods and range of data sources used to develop the economic model are described in detail in the [modelling report](#).

The economic model tested 2 universal scenarios in which people would be offered supplements regardless of income level or entitlement to qualifying benefits. An incremental cost-effectiveness ratio (ICER) of less than £20,000 per quality-adjusted life year (QALY) gained was used to indicate that an intervention was cost effective.

### *What were the findings?*

The economic model indicates that, compared with current provision:

- It is **not** cost effective to offer Healthy Start supplements universally to the current target group – that is, to extend the offering to all:
  - pregnant women from 10 weeks
  - women with a child aged under 12 months
  - children over 6 months and under 4 years.

This is because the best estimate of the ICER is £620,898 per QALY gained, compared with the current scheme.

- It is cost effective to extend the offering of Healthy Start supplements universally to the current target group if it is also extended to all:
  - women who are planning a pregnancy
  - women less than 10 weeks pregnant

- infants aged 0–6 months
- children aged from 4 to 5 years.

This is because the best estimate of the ICER is £6528 per QALY gained compared with the current scheme.

Offering the supplements universally to the current target group **plus** the additional subgroups outlined above is **only** cost effective if **both** of the following criteria are met:

- Women planning a pregnancy and those who are less than 10 weeks pregnant are included. This is because folic acid reduces the risk of a large number of women having a pregnancy affected by a neural tube defect. Hence there is a large gain in QALYs and a reduction in the future costs of caring for those born with neural tube defects.
- The cost per head of including women planning a pregnancy and those who are less than 10 weeks pregnant is not considerably higher<sup>[1]</sup> than the cost per head for women already in the scheme. A mechanism would need to be identified to deliver a universal scheme to these 2 groups. In the meantime, the true cost of including these additional groups of women is unknown and may have a substantial impact on overall cost effectiveness.

## *Limitations*

There are some significant limitations to the conclusions of this report. Lack of data for some of the model inputs meant that many assumptions had to be made and some of the assumptions are crucial in determining cost effectiveness. Sensitivity analyses identified the following 3 factors that particularly influence the findings. Any new evidence in these areas will influence estimates of cost effectiveness:

- Quality of life data for vitamin D deficiency. A lack of data meant it was not possible to assign a QALY value to the effects of vitamin D in the model. This is a key limitation. As a consequence, folic acid had a dominant impact because it was the only nutrient that could be assigned QALYs. There are some cost savings from reducing the need to treat vitamin D deficiency but these are relatively small.
- Extent of uptake of Healthy Start supplements by women and children who are not already taking other supplements that have been bought or been prescribed for them. Increasing uptake among these groups is key to cost effectiveness but it is not possible to predict this.

- Proportion of pregnancies affected by a neural tube defect that are terminated. The aim of folic acid supplementation is to reduce the risk of a pregnancy being affected by a neural tube defect. It is estimated that around 80% of these pregnancies, when they do occur, are terminated. The model suggests that the more affected pregnancies that are terminated, the less cost effective the scheme becomes, because the costs for the treatment and care of those born with a neural tube defect are reduced.

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<sup>[1]</sup> Additional analyses would be needed to determine the actual cost per head beyond which it would no longer be cost effective to include these women in the scheme. This was beyond the scope of the work on which this report is based.

## Introduction

In response to a recommendation from the Chief Medical Officer for England, 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. (See the [scope](#).)

The impetus for this work was growing concern about the prevalence of disease related to vitamin D deficiency, for example the occurrence of rickets and hypocalcaemic fits among children ([Diagnosis and management of vitamin D deficiency](#) Pearce and Cheetham 2010; [Incidence of symptomatic vitamin D deficiency](#) Callaghan et al. 2006).

In addition, there were concerns about the proportion of women following advice on folic acid supplementation ([Prevention of neural tube defects: a cross-sectional study of the uptake of folic acid supplementation in nearly half a million women](#) Bestwick et al. 2014).

The Chief Medical Officer's annual report for 2012 [Our children deserve better: prevention pays](#) (Department of Health) 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'.

This special report summarises the findings of an economic modelling exercise and a [cost effectiveness review](#)<sup>[2]</sup> of the vitamins contained within the Healthy Start supplements. (These supplements are referred to throughout this report as Healthy Start vitamins.) It has not considered the cost effectiveness of the Healthy Start food vouchers or other components of the scheme. The methods and range of data sources used to develop the economic model are described in detail in the [modelling report](#).

The report has been produced for the Chief Medical Officer. It is also relevant for the Department of Health and others responsible for public health policy.

The Scientific Advisory Committee on Nutrition (SACN) is currently reviewing the dietary reference values for vitamin D. This report should be read in conjunction with SACN's final recommendations.

In addition, it should be noted that other options for increasing the folate status of women planning, or in the early stages of, a pregnancy, have been proposed. For example, SACN's proposal

to fortify flour with folic acid in the UK, while retaining existing advice on supplementation ([SACN Report to CMO on folic acid and colorectal cancer risk](#) Public Health England).

This report is not intended to inform development of a NICE guideline but will complement NICE's existing guideline on increasing the uptake of [vitamin D](#) supplements among at risk groups.

For more details see the cost effectiveness review and the modelling report.

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<sup>[2]</sup>The effectiveness of giving the groups of interest supplements containing these nutrients, and the composition of the supplements, was previously considered in the [Scientific review of the Welfare Food Scheme](#) published by the Department of Health.

## 1 Scenarios modelled and key questions

The aim of this report is to estimate the differential cost effectiveness of continuing to offer Healthy Start vitamins to the current target audience, compared with offering them on a 'universal' basis (see below). This report does not aim to determine the cost effectiveness of the current scheme.

The report considers 2 universal scenarios.

### *Scenario 1*

Healthy Start vitamins are offered to the following groups (as happens now) but regardless of people's income level or entitlement to qualifying benefits:

- all pregnant women (from 10 weeks)
- women with a child aged under 12 months
- children over 6 months and under 4 years.

### *Scenario 2*

Healthy Start vitamins are offered to the following groups, regardless of income level or entitlement to qualifying benefits:

- women planning a pregnancy
- pregnant women
- women with a child aged under 12 months
- infants aged from 0–6 months
- children aged from 6 months to 5 years.

In this scenario, Healthy Start vitamins are offered to various groups not included in the current scheme. This reflects:

- UK dietary recommendations that advise women planning a pregnancy and those in the first 12 weeks of pregnancy to take a daily 400 microgram folic acid supplement.

- The 2012 UK Chief Medical Officers' recommendation that all pregnant and breastfeeding women, and infants and young children aged from 6 months to 5 years, take a daily supplement of vitamin D ([Vitamin D – advice on supplements for at risk groups](#) Department of Health).
- SACN's 2007 recommendations that breastfed babies whose mothers have not taken vitamin D supplements during pregnancy should be given vitamin D supplements. SACN also recommended that formula-fed infants who may be receiving less than 500 ml of infant formula daily are given vitamin D supplements ([SACN update on vitamin D – 2007](#) Public Health England).

### *Key and subsidiary questions*

The following key question was asked:

- 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 above?

The subsidiary questions were:

1. Is universal provision of Healthy Start supplements to women seeking to become pregnant cost effective, compared with no provision under Healthy Start?<sup>[3]</sup>
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? Would this be cost effective compared with the current targeted offering?
6. What is the incremental cost-effectiveness ratio (ICER) 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 4th and 5th birthday, compared with providing them until their 4th 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?

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<sup>[3]</sup> Note: the findings of the modelling exercise are reported for 'women planning a pregnancy and women less than 10 weeks pregnant'. This is because the only available data on the risk of having a pregnancy affected by a neural tube defect for women planning a pregnancy included those in the first trimester of pregnancy. In addition, it was thought unlikely that supplements would be offered to women before conceiving and from the 10<sup>th</sup> week of pregnancy onwards and not to women in the first 10 weeks of pregnancy.

## 2 Cost effectiveness

The economic modelling exercise tested the effect of offering the Healthy Start supplements on a universal basis as outlined in the 2 scenarios above. The methods and range of data sources used to develop the economic model are described in detail in the [modelling report](#). An ICER per quality-adjusted life year (QALY) gained of less than £20,000 was used to indicate that an intervention was cost effective.

It should be noted that there are some significant limitations to the findings because a lack of data for some of the model inputs meant that many assumptions had to be made. Some of these assumptions could be crucial in determining cost effectiveness.

For more details see the [sensitivity analyses](#) section and the [conclusion](#).

### *Universal provision (scenario 1) compared with current targeted provision*

Based on the assumptions made, the model suggests that it is not cost effective to make Healthy Start supplements universally available to: pregnant women (from 10 weeks), women with a child aged under 12 months, and children aged over 6 months and under 4 years.

There are 2 reasons for this.

First, lack of data meant it was not possible to assign a quality of life measure to the effects of vitamins A, C and D supplementation. This does not mean that they do not provide benefits, but that the benefits could not be quantified as QALYs.

Second, only a small number of QALYs are gained from providing folic acid to this group to prevent neural tube defects. This is because it is too late for folic acid supplements to reduce the risk for women who are at least 10 weeks pregnant. So only the small number of women who become pregnant within a year of giving birth, while still taking the supplements gain QALYs.

### *Universal provision (scenario 2) compared with current targeted provision*

The model suggests that it is cost effective to make Healthy Start supplements universally available to all: women planning a pregnancy, pregnant women, women with a child under 12 months, infants aged from 0–6 months and children aged from 6 months to 5 years.

But the findings have some significant limitations because a lack of data for some of the model inputs meant that many assumptions had to be made. Some of these assumptions are crucial in determining cost effectiveness. These are:

- Women planning a pregnancy and those who are less than 10 weeks pregnant are included. This is because folic acid reduces the risk of a large number of women having a pregnancy affected by a neural tube defect. Hence there is a large gain in QALYs plus a reduction in the future costs of caring for those born with a neural tube defect. There are some cost savings from reducing the need to treat vitamin D deficiency, but these are relatively small.
- The cost per head of including women planning a pregnancy and those who are less than 10 weeks pregnant is not considerably higher<sup>[4]</sup> than the cost per head for women already in the scheme. A mechanism would need to be identified to deliver a universal scheme to these 2 groups. In the meantime, the true cost of including these additional groups of women is unknown and may have a substantial impact on overall cost effectiveness.

## **Scenario 2: adding each group in turn to the current target group**

The economic modelling exercise also tested the effect of offering Healthy Start supplements to the current target group on a universal basis, plus each of the following groups, in turn, on a universal basis.

### ***Women planning a pregnancy and women less than 10 weeks pregnant***

The model suggests that it is cost effective to extend provision of Healthy Start supplements to all women planning a pregnancy and to those who are less than 10 weeks pregnant.

This is because a large number of women would benefit from the reduced risk of a pregnancy affected by a neural tube defect. However, the model made some fundamental assumptions that may have a crucial impact on cost effectiveness. See the [sensitivity analyses](#) section and the [conclusion](#).

### ***Women less than 10 weeks pregnant***

The model suggests that it is not cost effective to provide Healthy Start supplements to women who are less than 10 weeks pregnant without also extending provision to those who are planning a pregnancy.

That is because, in the model, there is a lower risk of a neural tube defect when women are given folic acid both **before and during** the first 10 weeks of pregnancy compared with during the first 10 weeks of pregnancy only.

In addition, fewer women will benefit because this group is smaller. Costs are also incurred from giving supplements to infants and children in the current subgroup.

So the benefits do not outweigh the costs and the best-estimate ICER per QALY gained is above £20,000.

### ***Infants aged 0–6 months***

Based on the assumptions made, the model suggests that it is **not** cost effective to extend the provision of Healthy Start supplements to infants aged 0–6 months alone. This is because they do not benefit from the prevention of neural tube defects. In addition, a lack of data meant it was not possible to assign QALY gains to the effects of vitamins A, C and D supplementation.

Preventing vitamin D deficiency does lead to some cost savings and there may be some practical benefits from offering Healthy Start supplements to infants aged 0–6 months (see [section 3](#)). But based on the data available, and in particular the absence of any data on QALY gains for vitamin D, extending the offering to this group alone is not cost effective.

### ***Children aged 4–5 years***

The model suggests that extending the provision of Healthy Start supplements to children aged 4–5 years alone is **not** cost effective, for the same reasons as for extending it to infants aged 0–6 months.

### ***'Spill over effect' on current target group***

It was not possible to model any 'spill over' effect of a universal scenario in terms of encouraging more people in the current target group to take the supplements. This is discussed in [section 3](#).

### ***Estimated ICER per QALY gained of extending eligibility for universally available vitamins to the current target group plus each subgroup***

**Table 1 Estimated ICER for current target group plus each new subgroup**

This table shows the estimated ICER per QALY gained of offering Healthy Start supplements on a universal basis to the current target group plus each of the new subgroups in turn. Bold text indicates where the offering is cost effective, that is, the estimated ICER is below £20,000 per QALY gained.

Universal offering is extended to	Incremental costs	Incremental QALYs	ICER
Current subgroups	£7,874,978	13	£620,898
Current subgroups + women planning a pregnancy and less than 10 weeks pregnant	£4,211,201	750	<b>£5618</b>
Current subgroups + women less than 10 weeks pregnant	£6,839,279	243	£28,185
Current subgroups + infants aged 0–6 months	£7,868,568	13	£620,392
Current subgroups + children aged 4–5 years	£8,564,095	13	£675,230
Current subgroups + all new subgroups	£4,893,907	750	<b>£6528</b>

## *Sensitivity analyses*

Sensitivity analyses tested the effect of varying the model inputs. These identified 3 factors that strongly influenced cost effectiveness:

- The extent of uptake of Healthy Start supplements, in particular by those who are not already taking other supplements that they have bought or been prescribed. Increasing uptake among these groups is key to cost effectiveness but it is not possible to predict this.
- The proportion of pregnancies affected by a neural tube defect that result in termination. The aim of folic acid supplementation is to reduce the risk of a pregnancy being affected by a neural tube defect. It is estimated that around 80% of these pregnancies, when they do occur, are terminated. The model suggests that the more affected pregnancies that are terminated, the less cost effective the scheme becomes, because the costs for the treatment and care of those born with a neural tube defect are reduced.
- Lack of quality of life data for vitamin D deficiency meant QALYs could not be assigned to the effects of vitamin D supplementation in the model. Because the original impetus for this work

was concern about the prevalence of disease related to vitamin D deficiency, a sensitivity analysis tested the hypothetical effect of applying a QALY loss to those with symptomatic vitamin D deficiency. This showed that the higher the QALY loss, the more cost effective the scheme would be. This also reduced the impact of the factors cited above.

## Conclusion

The model suggests that making Healthy Start vitamin supplements universally available is cost effective, as long as women who are planning a pregnancy and those in the first 10 weeks of pregnancy are included. This is based on the assumptions made in the model.

Although the original impetus for this work was concern about the prevalence of disease related to vitamin D deficiency, a lack of data meant it was not possible to assign QALYs to the effects of vitamin D in the model.

Consequently, folic acid has a dominant impact on the findings. This is because folic acid was the only nutrient with a measurable outcome – the prevention of neural tube defects – to which a QALY could be assigned. In addition, the number of QALYs saved by preventing pregnancies affected by a neural tube defect was high enough to outweigh the costs of including the other groups.

There are some cost savings from preventing vitamin D deficiency and although QALYs could not be assigned to vitamins A or C, increasing some people's intake of these above the lower reference nutrient intake could be an added benefit.

However, a lack of data for some of the model inputs meant that many assumptions had to be made. Some of these were fundamental and could have a crucial impact on cost effectiveness:

- A delivery mechanism can be identified through which a universal scheme can be successfully implemented with women planning a pregnancy and those in the first 10 weeks of pregnancy. These women are not currently included in the Healthy Start scheme and it was beyond the scope of this work to identify an effective delivery mechanism for this group.
- The cost per head of including these groups of women is not considerably higher than the cost per head for women already in the scheme<sup>[4]</sup>. The true costs are unknown and may have a substantial impact on overall cost effectiveness.

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<sup>[4]</sup> Additional analyses would be needed to determine the actual cost per head beyond which it would no longer be cost effective to include these women in the scheme. This was beyond the scope of the work on which this report is based.

<sup>[5]</sup>To identify the cost per head at which it would no longer be cost effective to include these women in the scheme, would need additional analyses. This was beyond the scope of the work on which this report is based.

### 3 Considerations

This section describes the factors and issues the Expert Reference Group (ERG) considered when examining the cost effectiveness of moving the Healthy Start vitamin programme from the current targeted offering to a universal offering. For further details see the [modelling report](#).

#### *Model inputs*

3.1 The [cost effectiveness](#) review of the vitamins contained in the [Healthy Start](#) supplements only identified 9 studies. Most were local evaluations and only 2 studies – 1 on folic acid and 1 on vitamin D – were formal economic evaluations. As a result, it was necessary to build a de novo economic model to answer the questions outlined in [section 1](#). The methods and data used in the model are discussed in detail in the modelling report.

#### **Limitations in the data: outcome measures**

3.2 The review did not identify any data on the cost effectiveness of multivitamins of the same composition as those provided by the Healthy Start scheme. So the cost effectiveness of providing the relevant population groups with each vitamin contained in the supplements had to be modelled.

3.3 The ERG provisionally agreed 3 outcome measures for each nutrient. These related to: the lower reference nutrient intake (LRNI), nutritional status and a functional outcome measure. The Group agreed the functional outcome measure should reflect the original rationale for including these nutrients in Healthy Start supplements (see [Scientific review of the Welfare Food Scheme](#) Department of Health). (Members noted that supplements containing these nutrients may also provide additional benefits.) It was not possible to identify all 3 outcome measures for each nutrient, however. Most vitamin D, for example, is produced through skin synthesis and no LRNI has been set. Measures of nutritional status could not be used because the national survey data are not analysed according to whether supplements were or were not taken. It was not possible to carry out meaningful additional analyses because the numbers of participants in each of these groups (takers and non-takers of supplements) who provided a blood sample were too small. In addition, there were no suitable functional outcomes for vitamins A or C: being generally unwell, having poor immunity or 'growth faltering' (failure to thrive, for more detail see the

introduction to [section 4](#)) may be associated with poor nutritional status, but this is not only attributable to a poor vitamin A or C status. It would also be difficult to assign costs or QALYs to these states. So the outcome for vitamins A and C focused on the proportion of the population with intakes below the LRNI<sup>[6]</sup>.

- 3.4 There are concerns about rickets re-occurring in the UK ([Diagnosis and management of vitamin D deficiency](#) Pearce and Cheetham 2010) and the occurrence of hypocalcaemic fits due to vitamin D deficiency. But these conditions are still relatively rare. For example, the incidence of hypocalcaemic fits in children aged 0–15 years in the UK and Ireland has been reported as 3.49 per million ([Incidence of hypocalcaemic seizures due to vitamin D deficiency in children in the United Kingdom and Ireland](#) Basatemur and Sutcliffe 2014). Symptomatic vitamin D deficiency<sup>[7]</sup> is more common. For example, a survey in the West Midlands found an annual incidence of 7.5 per 100,000 in children under 5. Because costs can be assigned to symptomatic vitamin D deficiency, this was selected as the functional outcome for vitamin D. But due to a lack of data, it was not possible to assign quality-adjusted life-year (QALY) data for this outcome in the main analysis. The hypothetical effect of adding quality of life benefits for the effects of vitamin D was tested in a separate sensitivity analysis. Neural tube defects were used as the outcome for folic acid, because this was added to the supplements to reduce the risk of conditions such as spina bifida and anencephaly. In addition, it is possible to assign both costs and quality of life measures to these conditions.
- 3.5 A major limitation of the model is that, with the exception of folic acid, it was not possible to assign QALYs to the outcome measures. It was only possible to consider a cost–consequence analysis of vitamins A, C and D. This means folic acid has a strong impact on the results.

### Limitations of the data: model inputs

- 3.6 The age range of the children being modelled and the 'life-stage' of the women did not always correspond exactly with the ages and life stages reported in national surveys. 'Life stage' here refers to: planning a pregnancy, being more or less than 10 weeks pregnant or having a child aged under 1 year. The ERG agreed that the model should use the closest possible match. See pages 13–15 of the modelling report.

3.7 The ERG had to make assumptions if surveys reported that supplements were taken but didn't specify what they contained. For example, the Infant Feeding Survey does not report specifically on vitamin C supplements, but it does collect data on the use of 'multivitamins' and these have been assumed to contain vitamin C.

### Limitations of the data: costs

- 3.8 The Department of Health provided the central administration costs of the vitamin aspects of the scheme in confidence. A survey was commissioned to estimate the local costs of running the scheme (see pages 10–11 of the modelling report). Only 8 partially completed responses were received and there was enormous variation in the costs.
- 3.9 The ERG recognised that there is more than 1 distribution route for universal provision. For example, the supplements could be distributed by health professionals, in community pharmacies and in supermarkets. But the costs of these approaches are unknown.
- 3.10 Healthy Start leads in 2 specific geographical areas provided data to estimate the costs of a targeted and universal scheme. Data from one that provided supplements via an electronic card system was used in the main analysis because the data were more robust. But the ERG was aware that these data may not be representative of other areas where different approaches may be used. They also noted that the approach and costs may vary from rural to urban areas. The modellers therefore carried out a separate sensitivity analysis (see pages 43 and 44 of the modelling report) to determine the effect of varying the costs.
- 3.11 The cost of expanding production for, and monitoring and evaluation of, a universal scheme was **not** included in the model. The model also excluded the possible costs that may be incurred if more manufacturers need to be licensed to produce the children's vitamin drops.
- 3.12 The main analysis focused on cost effectiveness from the public sector (local authority, central government and the NHS) perspective. A separate analysis was carried out to determine cost effectiveness from a wider societal perspective (including any costs to individuals). To inform the latter, an online survey aimed to ascertain the average price women pay for vitamins for

themselves and their children (see pages 9, 52 and 53 of the modelling report). The supplements they bought appeared to be relatively expensive (around £6–£8 per pack), given that lower cost supplements are available. Members had concerns about how representative these data were but because they were the best available, this information was used.

- 3.13 Additional sensitivity and scenario analyses were carried out to test the effect of varying some of the inputs on cost effectiveness. For example, one scenario analysis on the uptake of folic acid in women planning a pregnancy was based on data from a study by Bestwick 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'), in place of data from the Infant Feeding Survey. The study sample was larger and consisted of pregnant women as opposed to new mothers, but was not nationally representative. A scenario analysis using data on supplement use from the 'Born in Bradford' study was carried out to include more data on black and minority ethnic groups: these groups are under-represented in national dietary surveys. In both cases, the estimated ICER per QALY gained was slightly lowered, but using different data did not affect the overall findings of the model. See pages 60 and 61 of the modelling report.

## *Delivery*

- 3.14 The ERG noted that the important assumptions made in the model about delivery may have a crucial effect on the cost effectiveness findings. In particular, the model assumes that existing delivery mechanisms would be used for any new group included in the universal offering. This may be plausible for some groups, such as infants aged 0–6 months, because a delivery mechanism already exists. But for others, for example women planning a pregnancy and those in the first 10 weeks of pregnancy, different routes may be needed. The costs of these may differ and their impact on the overall cost effectiveness of a universal scheme is unknown.
- 3.15 The ERG noted that reaching women who are planning a pregnancy could be particularly difficult, because they may not be involved with health services. But these women and those less than 10 weeks pregnant, need to be included if the scheme is to be cost effective.

- 3.16 The ERG noted that including infants aged 0–6 months in a universal scheme may be feasible, because they are in regular contact with health professionals. This may have practical benefits too. A recent study showed that 27% of hypocalcaemic fits due to vitamin D deficiency occur in infants younger than 1 month ('Incidence of hypocalcemic seizures due to vitamin D deficiency in children in the United Kingdom and Ireland'). Offering Healthy Start supplements on a universal basis may help reduce this risk. However, no suitable data were identified to carry out a specific analysis on hypocalcaemic fits alone (see page 22 of the modelling report).
- 3.17 Currently, mothers who qualify receive Healthy Start supplements during pregnancy and infants receive them from age 6 months, so there is a 'break' in supplementation between 0 and 6 months. The ERG noted that avoiding this 'break' may encourage adherence to advice about vitamin D, because mothers would still be seeing health professionals. Having to resume contact with mothers at 6 months involves making a specific arrangement and that incurs a cost. The ERG noted that including children aged 4–5 years in a universal scheme may prove challenging, because they are no longer in contact with health visitors. The ERG discussed the feasibility of providing the supplements through the school nursing service. However, the model assumes that the costs of including this age group would be the same as for other children already engaged in the scheme. If it proves more expensive to reach this group then the overall cost effectiveness of the scheme will be affected.
- 3.18 The ERG noted that NICE's guideline on vitamin D makes recommendations on increasing uptake of supplements among pregnant and breastfeeding women and infants and children aged under 5. It also noted NICE's recommendations on encouraging the uptake of folic acid supplements among women planning and in the early stages of pregnancy (see NICE's guideline on [maternal and child nutrition](#)).
- 3.19 The model assumes that coupons would still be needed to get Healthy Start supplements. But the coupons have been a source of confusion ([Healthy Start: understanding the use of vouchers and vitamins](#) University of Dundee) and may not be needed for a universal scheme. A sensitivity analysis was carried out to test the impact on cost effectiveness of varying the cost of issuing coupons. This is discussed on page 46 of the modelling report.

3.20 The ERG stressed the importance of addressing gaps in the evidence to accurately judge the cost effectiveness of adding any new group to a universal Healthy Start vitamin scheme. Evidence is lacking on the most effective and cost-effective routes for including women planning a pregnancy and those in the first 10 weeks of pregnancy. Evidence is also lacking on infants aged 0–6 months and children aged 4–5 years. The ERG agreed that pilot testing a universal scheme with these groups might help to fill these gaps in the data. Members also noted that various universal schemes are currently being tested but data were not available in time to inform the cost effectiveness model.

### *Potential adverse effects*

3.21 The model assumed that offering the Healthy Start supplements universally would do no harm. The ERG discussed the possibility of over-supplementation with vitamins A and D in infants aged 0–6 months who are formula-fed. They noted that the Committee on Toxicology has considered this for vitamin A. The Committee concluded that, given the relatively low dosage contained in Healthy Start supplements, if infants did exceed the tolerable upper limit, it would only be by very small amounts. ([Statement on the potential risks from high levels of vitamin A in the infant diet](#) Food Standards Agency Committee on Toxicity.) Members agreed that while the potential risk may be greater for vitamin A than vitamin D, Healthy Start supplements were unlikely to do any harm. Members noted the importance of parents being aware that they should not give other supplements in addition to Healthy Start vitamins.

### *Increasing uptake*

3.22 Getting all subgroups in the model to take up the offer of supplements, in particular, those who are not already taking other supplements they have bought or been prescribed, is key to cost effectiveness. Current uptake is very low (around 3–10%) and has been linked to levels of awareness and distribution. (See [section 4](#) and NICE's guidance on [vitamin D: increasing supplement use among at-risk groups](#).)

3.23 It was not possible to model any 'spill over effect' whereby a universal scheme might increase uptake among the current target group. But the ERG noted that a universal scheme is likely to make the supplements more accessible. For example, it might mean health professionals are trained to routinely discuss the

supplements with those who are eligible. In addition, a universal offering may involve more widespread publicity, so further raising awareness of the benefits of the supplements and their availability. It may also overcome any 'stigma' attached to the current offering by making use of the supplements the norm (rather than linking it to income). This, in turn, could increase uptake because it is the accepted thing to do.

## *Health inequalities*

- 3.24 The ERG discussed whether or not a universal scheme would encourage those most in need to take up the offer of supplements, because it is generally accepted that the 'worried well' are most likely to take them. However, this did not appear to be the case in Birmingham where Healthy Start supplements were offered to all pregnant women and for 12 months after they had given birth. They were also offered to all infants and children aged from 2–4 weeks up to the age of 4 years. Uptake increased to 17% of those who were eligible, but the number of cases of symptomatic vitamin D deficiency in children under 5 dropped by 59%. This may not have been entirely due to uptake of Healthy Start supplements: the associated publicity may have increased uptake of other supplements too. But it does suggest that Healthy Start supplements were being taken by those in most need of them ([Vitamin D supplementation: putting recommendations into practice](#) McGee and Shaw 2013).
- 3.25 The ERG agreed that those in need would benefit the most from a universal scheme. This includes asylum seekers and people who are on a low income but who are not eligible for the current scheme. It also includes women and children from black and minority ethnic groups – because many of them are at increased risk of vitamin D deficiency but they do not all currently qualify for the supplements.
- 3.26 The Group noted that a universal scheme may encourage greater uptake by people whose first language is not English and among those with poor literacy skills. This is because it would not involve a complicated assessment process and may not involve redeeming coupons.

## *Other policy issues*

- 3.27 The ERG noted that there may be other cost effective ways to improve the vitamin D status of at-risk groups. This includes improving awareness of this issue among health professionals and the public. Members noted that NICE has published a guideline on [vitamin D: increasing supplement use among at-risk groups](#).
- 3.28 The ERG was aware of other options for increasing the folate status of women planning, or in the early stages of, a pregnancy. For example, members noted SACN's proposal to fortify flour with folic acid in the UK supported by existing advice on supplementation ('SACN report to CMO on folic acid and colorectal cancer risk'). They agreed that it may be helpful to compare the cost effectiveness of other options with universal provision of Healthy Start supplements.
- 3.29 If flour was fortified with folic acid this would reduce the proportion of women at risk of having a pregnancy affected by a neural tube defect. This, in turn, would affect the cost effectiveness of the Healthy Start supplements as estimated in the model for this report.
- 3.30 Healthy Start supplements are only 1 aspect of the Healthy Start programme and uptake of the food vouchers is high (see section 4). In addition, the programme receives positive feedback ('Understanding the use of vouchers and vitamins'). Although the cost effectiveness of the wider programme was beyond the scope of this work, members felt its contribution to the health of women of child-bearing age and young children from low income families should not be overlooked.

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<sup>[6]</sup> The adequacy of vitamin or mineral intake can be expressed as the proportion of individuals with intakes below the lower reference nutrient intake (LRNI). This is the level considered likely to be sufficient for only 2.5% of the population.

<sup>[7]</sup> In the modelling report, symptomatic vitamin D deficiency is defined as a combination of conditions such as bow legs, rickety rosary, tetany, convulsions due to hypocalcaemia, radiological evidence, biochemistry results such as raised alkaline phosphatase (ALP) with or without high parathyroid hormone levels, or low levels (less than 25 nmol/litre) of 25-hydroxycholecalciferol

(25OHC). This is the definition used in the 2 papers (Moy et al. 2012 and Zipitis et al. 2006) from which effectiveness and cost data were obtained.

## 4 Context

### *Introduction*

Healthy Start is a UK-wide, government scheme that provides 'a nutritional safety net' for pregnant women and families on qualifying 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.

Healthy Start was introduced in 2006 to replace the previous Welfare Food Scheme. The Healthy Start supplements for women contain vitamins C and D and folic acid.

Vitamin C is included because of 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').

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 these vitamins linked to a 'failure to thrive'<sup>[6]</sup>. Or they may have increased needs (for example, during infections), or be vulnerable to low vitamin D status because of their ethnic origin ('Scientific review of the Welfare Food Scheme').

### *Vitamin D*

Rickets may be re-emerging among children in the UK ('Diagnosis and management of vitamin D deficiency'). Concerns have also been raised about hypocalcaemic fits due to vitamin D deficiency, particularly in children under 2 years.

However, these remain relatively rare ('Incidence of hypocalcemic seizures due to vitamin D deficiency in children in the United Kingdom and Ireland'). National survey data show that there is evidence of low vitamin D status among all ages and genders, especially in the winter months<sup>[9]</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).

In 2007<sup>[10]</sup>, the Scientific Advisory Committee on Nutrition (SACN) recommended 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.

('SACN update on vitamin D – 2007').

In 2012, the UK Chief Medical Officers 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 D ('Vitamin D – advice on supplements for at risk groups').

### *Folic acid*

Since 1992, all women have been advised to take 400 micrograms of folic acid daily from when they start planning a pregnancy until the end of week 12 of the pregnancy. The aim is to reduce the risk of their baby being born with a neural tube defect such as spina bifida ('Folic acid and the prevention of neural tube defects. Report of an expert advisory committee' Department of Health 1992 [not available online])<sup>[11]</sup>.

A recent study suggests the number of women taking folic acid supplements when they are planning a pregnancy may be in decline ('Prevention of neural tube defects: a cross-sectional study of the uptake of folic acid supplementation in nearly half a million women').

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; [Factors affecting the use of folic acid supplements in pregnant women in Glasgow](#) McGovern et al. 2012) 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).

### *Uptake of Healthy Start vitamins*

Many (72–86%) of those eligible for the Healthy Start scheme redeem their food vouchers. But 2 studies suggest that less than 10% redeem their vitamin coupons ('Understanding the use of vouchers and vitamins'; Jessimen et al. 2013). Another study puts the number redeeming vitamin

coupons at less than 3% (Which is more effective, a universal or targeted approach, to implementing the National Healthy Start Programme? A mixed methods study 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 process
- confusion surrounding use of the vitamin coupons
- difficulties finding an accessible location for distribution.

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'; 'Healthy Start: understanding the use of vouchers and vitamins').

Health professionals suggest that making the Healthy Start vitamins freely available to all pregnant women, mothers and young children would be a way to overcome this ('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'; Jessimen et al. 2013).

This approach may also be more cost effective ('Healthy Start: understanding the use of vouchers and vitamins').

See the [scope](#) for further details on the background to this work.

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<sup>[8]</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 undernourished. It is also referred to as 'growth faltering'.

<sup>[9]</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>[10]</sup> SACN is currently reviewing the dietary reference values for vitamin D.

<sup>[11]</sup> Women are advised to take a 5 mg/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.

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