

## JSNA Factsheet: Vitamin D – maternity and early years

### Tower Hamlets Joint Strategic Needs Assessment 2010-2011

#### Executive Summary

Vitamin D is a fat soluble vitamin which unlike the water-soluble vitamins can be stored by the liver and fatty tissues for use over longer periods of time without the need for frequent replacement.

Vitamin D has important effects on calcium and phosphate regulation and thus helps ensure healthy bone growth and mineralization. Vitamin D deficiency typically presents with bony deformity (rickets) or hypocalcaemia in infancy and childhood, and with musculoskeletal pain and weakness in adults (osteomalacia).

Although vitamin D can be made by the body in two ways (by the effect of sunlight UV B rays on the skin or through dietary intake), vitamin D made by the effect of UVB sunlight on cholesterol in skin accounts for more than 90% of the body's vitamin D.

There is a greater need for vitamin D during periods of growth which means that pregnant women and children are more susceptible to deficiency. Vitamin D deficiency is even more likely to develop in women who have had several full-term pregnancies with short gaps between them.

Babies of mothers who are deficient in vitamin D, particularly breastfed babies are at risk of deficiency. Breastfeeding is the best choice for babies however, if vitamin D deficient, breastfeeding mothers and their babies should take a vitamin supplement, this is healthier than using infant formula.

All weaned babies who take cow's milk need vitamin D supplements as it contains little natural vitamin D. Other high risk groups for vitamin D deficiency include naturally dark skinned people; people who wear clothing that fully conceals them; people who don't go outside very much and elderly people. Some medical conditions can affect the way the body handles vitamin D and vitamin D deficiency can also occur in people taking certain medicines.

A nationwide survey in the United Kingdom showed that more than 50% of the adult population have insufficient levels of vitamin D and that 16% have severe deficiency during winter and spring.

The estimated prevalence of vitamin D insufficiency and deficiency in Tower Hamlets, based on an audit of all tests performed in routine clinical practice in primary care during 2009, is about 80-97% which is considerably higher than in the UK population. The higher risk of vitamin D insufficiency and deficiency in Tower Hamlets is likely to be due to having a high proportion of: children and young people, people with darker skin, people who cover their skin for cultural reasons and relative disinclination to spend time outdoors.

The costs of vitamin D treatment have been escalating year on year and include a significant number of special items for vitamin D as either individually prepared liquids for children or imported medicines.

Healthy Start Vitamins for women and children contain all the vital nutrients for pregnant women and young children, with vitamin D being a key element. It is a means tested statutory scheme which provides a nutritional safety net. It aims to encourage breastfeeding and healthy eating during pregnancy, as well as healthy weaning to give the child the best start in life.

## Recommendations

- Continued primary prevention, i.e. promotion of outdoor activities to increase sun exposure and increased consumption of foods that are good sources of vitamin D
- Continue to raise awareness of the Healthy Start scheme with key stakeholders
- Annually review the implementation and uptake of the Healthy Start scheme
- Pilot a Healthy Start Champions project, recruiting and training women from local communities to provide information and support as volunteers to women during pregnancy, and with young families.
- Implementation of RLH vitamin D during pregnancy guidelines and audit of implementation.
- Review the implementation of the CEG vitamin D guidance
- Further explore the possibility of:
  - HSV being universally free to all women until child's first birthday and children under 4 or selling to those not eligible for the scheme.
  - Distribution via pharmacies
  - For pregnant women, a 'voucher' from GP's for Healthy Start (in place of commencing on folic acid); to be collected at local pharmacy.
- Review of need for change in secondary care admission coding to reflect Vitamin D status (given high local prevalence and contribution to many other conditions). Alternatively, consideration of a local disease register and initiation of a large cohort study.

## 1. What is vitamin D?

Vitamin D is a fat soluble vitamin. There are three other fat-soluble vitamins - vitamins A, E and K. These are unlike the water-soluble vitamins (Vitamin B complex, and C) in that they can be stored by the liver and fatty tissues for use over longer periods of time without the need for frequent replacement. They are essential for many important cellular functions in the body.

The two major forms of vitamin D are Ergocalciferol ('Vitamin D2') and Cholecalciferol ('Vitamin D3').

Vitamin D has important effects on calcium and phosphate regulation and thus helps ensure healthy bone growth and mineralization. Vitamin D deficiency typically presents with bony deformity (rickets) or hypocalcaemia in infancy and childhood, and with musculoskeletal pain and weakness in adults (osteomalacia).

In addition to this, there is increasing evidence linking vitamin D deficiency to wider morbidity and mortality including bowel and other cancers, cardiovascular disease, multiple sclerosis, diabetes types 1 and 2, tuberculosis and all-cause mortality<sup>1</sup>.

The symptoms of insufficiency and deficiency can be non-specific and thus difficult to differentiate from general tiredness or aches, but they may include:

In babies and children:

- Muscle spasms (cramps), seizures and breathing difficulties if severe Vitamin D deficiency (related to consequent low levels of calcium).
- Rickets (bow or curved shaped legs) or soft skull
- Poor growth. Height is usually affected more than weight. Affected children might be reluctant to start walking.
- Late teething
- Irritability
- Infections and respiratory symptoms
- Weak chest muscles and a soft ribcage (thus difficulty breathing) if severe
- Cardiomyopathy (rare) and resultant heart failure

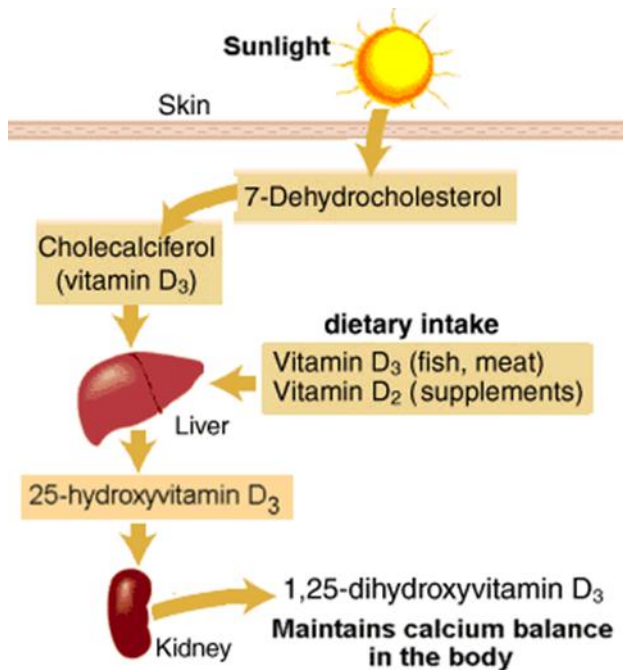
In adults:

- Muscle pains or muscle weakness
- Osteomalacia and resultant waddling gait
- Bone pains (typically felt in the ribs, hips, pelvis, thighs and feet)

Although vitamin D can be made by the body in two ways (by the effect of sunlight UV B rays on the skin or through dietary intake), vitamin D made by the effect of UVB sunlight on cholesterol in skin accounts for more than 90% of the body's vitamin D. Figure 1 summarises the process of synthesis of vitamin D.

<sup>1</sup> Pearce, S & Cheetham, T. BMJ 2010;340:b5664

**Figure 1: The Process of Vitamin D Synthesis<sup>2</sup>**



**Food sources**

There are some foods that are sources of vitamin D but it is very difficult to meet the bodily needs of vitamin D through diet alone without either supplementation through adequate sun exposure or dietary vitamin supplements.

- Oily fish such as salmon, sardines, pilchards, trout, kippers, eel, mackerel, ilish/hilsa and herring are the only foods which naturally contain reasonable amounts of vitamin D. (Women should not have more than two portions per week if pregnant or breastfeeding).
- Eggs, mushrooms and meat contain only small amounts.
- Margarine, some breakfast cereals and infant formula have added vitamin D.

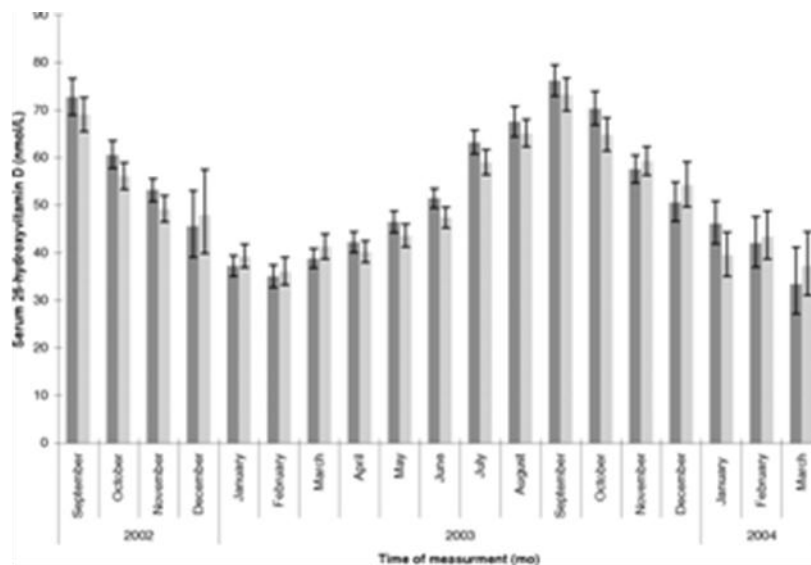
**Sun exposure**

The time required to make sufficient vitamin D varies according to a number of environmental, physical and personal factors, but is typically short and less than the amount of time needed for skin to redden and burn. Enjoying the sun safely, while taking care not to burn, can help to provide the benefits of vitamin D without unduly raising the risk of skin cancer. 20-30 minutes spent outside a few days per week in the summer (between 10am and 3pm), if skin on the hands, face and arms are exposed is enough. People with naturally darker skin (rarely or never burns) will need 3-6 times the exposure level of fair to olive skin.

For six months of the year (October to April), all of Scandinavia, much of western Europe (including 90% of the UK), and 50% of the North American landmass lies above the latitude that permits exposure to the ultraviolet B wavelengths necessary for vitamin D synthesis, leaving millions of people reliant on exogenous sources of vitamin D. See graph 1 for seasonal variation in vitamin D levels.

<sup>2</sup> Antonio Zamora, 2010

**Graph 1. Seasonal variation in Vitamin D levels in white men and women from the 1958 UK birth cohort<sup>3</sup>**



### High risk groups

There is a greater need for vitamin D during periods of growth and so pregnant women and children are more susceptible to deficiency. Vitamin D deficiency is even more likely to develop in women who have had several full-term pregnancies with short gaps between them. This is due to the body's stores of vitamin D being used with little time for them to be built up before another pregnancy. In the last three months of pregnancy, babies are growing at their fastest and mothers often become short of vitamin D especially if these months occur during winter or early spring. Information from the 2005 Infant Feeding Survey however suggests that the majority of women do not take vitamin D supplements during pregnancy<sup>4</sup>.

Although infants are born with stores of vitamin D that will last until they are six months old, they are at risk of deficiency beyond this age, especially if solely breastfed as breast milk contains very little vitamin D. Breastfeeding is the best choice for babies however, if vitamin D deficient, breastfeeding mothers and their babies should take a vitamin supplement; this is healthier than using infant formula. All weaned babies who take cow's milk need vitamin D supplements as it contains little natural vitamin D.

Other high risk groups include:

- Naturally dark skinned people, such as Asian and black people, need more UV exposure to produce adequate levels of vitamin D as the pigment in their skin reduces UV penetration
- People who wear clothing that fully conceals them or overuse of sunscreen
- People who don't go outside very much such as those in hospital for a long time, or housebound people
- Elderly people have thinner skin than younger people and so are unable to produce as much vitamin D. This leaves older people more at risk of vitamin D deficiency.
- People with some medical conditions that can affect the way the body handles vitamin D, e.g. Crohn's disease, coeliac disease, and some types of liver and kidney disease.
- People taking certain medicines, e.g. carbamazepine, phenytoin, primidone, barbiturates and some anti-HIV medicines.

<sup>3</sup> Hyponnen and Power 2007

<sup>4</sup> Bolling K, Grant C, Hamlyn B, Thornton A (2007). Infant Feeding Survey 2005. The Information Centre

### Determining vitamin D deficiency and insufficiency

Vitamin D status is most reliably determined by assay of serum 25-hydroxyvitamin D (25-OHD).

Deficiency is defined as a plasma concentration of 25-hydroxyvitamin D of below 25nmol/l (equal to 10 ng/ml)<sup>5</sup>. Table 1 details levels of deficiency and insufficiency and their impact on health.

**Table 1 | Serum 25-hydroxyvitamin D concentrations, health, and disease<sup>6</sup>**

Serum 25-OHD concentration*	Vitamin D status	Manifestation	Management
<25 nmol/l	Deficient	Rickets Osteomalacia	Treat with high-dose calciferol
25-50 nmol/l	Associated with disease risk		Vitamin D supplementation
50-75 nmol/l	Adequate	Healthy	Lifestyle advice
>75 nmol/l	Optimal	Healthy	None

\*To convert to µg/l divide by 2.5

## 2. What is the local picture?

### Demography

In the Tower Hamlets population, there is a higher risk of vitamin D deficiency due to a high proportion of children and young people, high proportion of people with darker skin, people who cover their skin for cultural reasons, and relative disinclination to spend time out doors (e.g. due to winter climate, fear of crime, sedentary lifestyles).

Since 1996, the number of births in Tower Hamlets has increased from 3,445 to 4,337 in 2009/10, a 25.9% increase. High fertility rates roughly correlate with the distribution of deprivation and child poverty across the Borough and a high proportion of the births are to Bangladeshi women where the birth rate is 1.52 times higher than average for all women in Tower Hamlets. Estimated numbers of Tower Hamlets residents, 0-4 years, 2011 is 20,116<sup>7</sup>

*See the maternal health fact sheet for further details of fertility rates in Tower Hamlets.*

Tower Hamlets has very high levels of deprivation with the fourth highest Index of multiple deprivation score and the highest level of child poverty in the country; 80% of the population lives in 20% of the most deprived areas in the country. At February 2010, 53% of income support claimants had been so for 5 years and over, 25% for 2 years and up to 5 years, 11% 1 year and up to 2 years and 11% less than 1 year<sup>8</sup>. Of these claimants, 67% were aged between 25-49 years, 23% 50-59, 10% 16-24<sup>9</sup>.

The claimant information is relevant to the eligibility criteria for the Healthy Start Scheme, a means-tested scheme which provides food vouchers to spend with local retailers and vitamin coupons to swap for free Healthy Start vitamins. The vitamins contain the recommended amount of vitamin D for pregnant and lactating women and children until their 4<sup>th</sup> birthday.

<sup>5</sup> Department of Health

<sup>6</sup> Pearce, S & Cheetham, T. BMJ 2010;340:b5664

<sup>7</sup> GLA Population Projections 2011 Round

<sup>8</sup> DWP information Directorate. By 2003 ward boundaries.

<sup>9</sup> DWP information Directorate. By 2003 ward boundaries.

### Vitamin D insufficiency and deficiency

The estimated prevalence of vitamin D deficiency and insufficiency in Tower Hamlets is 80-97%, based on an audit of all tests performed in routine clinical practice in primary care during 2009. See table 2 below.

This is substantially higher than average for the United Kingdom where an estimated 50% of the adult population have insufficient levels of vitamin D and 16% have severe deficiency during winter and spring<sup>10</sup> The National Diet and Nutrition Survey found that up to a quarter of people in the UK have low levels<sup>11</sup> of vitamin D in their blood, which means they are at risk of the clinical consequences of vitamin D deficiency<sup>12</sup>

**Table 2 Deficiency and insufficiency in Tower Hamlets, 2009 (13, 183 tests from a total population of 250,692)**

Ethnicity	Vit D test count	Deficient (<25nmol/L)	Insufficient (25-75 nmol/L)	Optimal (>75nmol/L)
White	2630	17%	63%	20%
Black	941	47%	49%	4%
Asian	8361	42%	54%	3%
Mixed	144	29%	62%	8%
Other	299	24%	66%	10%
Not Stated	808	41%	50%	8%
	<b>13183</b>	<b>37%</b>	<b>56%</b>	<b>7%</b>
Age	Count	% deficient	% insufficient	% optimal
Child (<16)	1084	45%	49%	7%
Adult (16-64)	10328	38%	56%	6%
Elderly (>64)	1771	26%	62%	12%
	<b>13183</b>	<b>37%</b>	<b>51%</b>	<b>7%</b>

Data collected retrospectively<sup>13</sup> from 497 pregnant women booking during August 2009 and February 2010 found:

- 74% to be deficient
- 11% to be insufficient and
- 15% to have a normal vitamin D level.

As there is no consensus on the optimal concentrations of 25(OH) vitamin D in pregnancy, and levels of deficiency vary, the widely-used cut-offs of insufficiency 50-75nmol/L, and deficiency ≤50nmol/L were chosen for this audit. Data was collected prior to the introduction of Healthy Start for mothers.

<sup>10</sup> Hyppönen E, Power C. Hypovitaminosis D in British adults at age 45 5 y: nationwide cohort study of dietary and lifestyle predictors. Am J Clin Nutr 2007;85:860-8

<sup>11</sup> Below 25nmol/l

<sup>12</sup> Data from years 1 & 2 of the National Diet and Nutrition Survey (NDNS) rolling programme

<sup>13</sup> Results of antenatal vitamin D screening at Barts and the Royal London NHS Trust, April 2010

Vitamin D levels per ethnic category<sup>14</sup> for pregnant women booking during August 2009 and February 2010 at the Royal London Hospital:

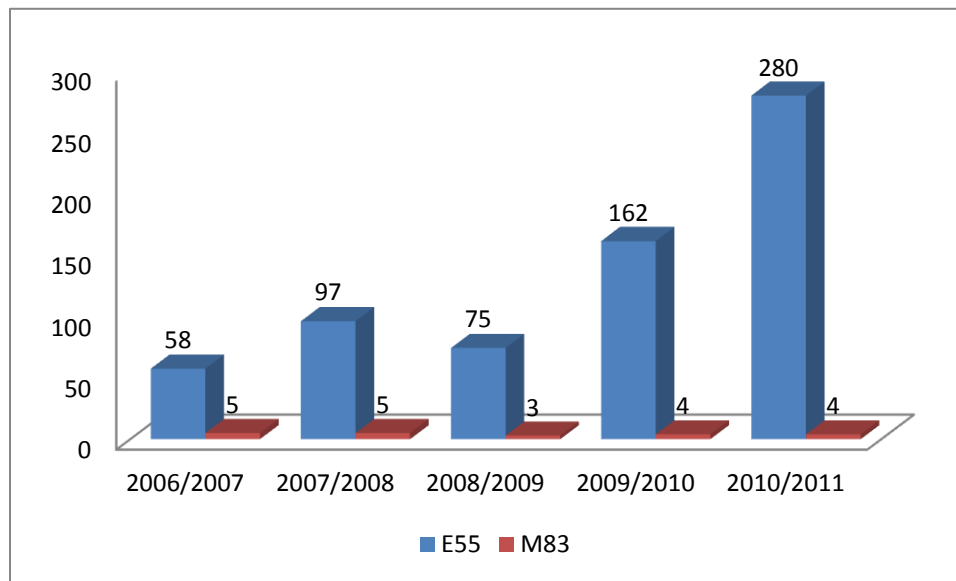
	<b>Number</b>	<b>Median</b>	<b>Interquartile range</b>
Asian/Asian origin	307	21	14-36
White/European	106	59	40-80
African/Caribbean	43	18	14-40
Unspecified	40	36.5	25-63

**Vitamin D related hospital admissions**

Due to current data coding methods and the multiple diseases that may be attributable to Vitamin D deficiency, it is hard to predict with great certainty the prevalence of vitamin D deficiency related secondary care cases in Tower Hamlets. As a proxy, we used the E55 (Rickets, active) and M83 (Adult osteomalacia) indicator data which looks at the number of admissions coded as being vitamin D related. The data for the period 2006 to 2011 for E55 and M83 as either a primary or secondary diagnosis is summarized in Figure 2 and shows a sharp increase in admissions related to adult osteomalacia in Tower Hamlets since 2008. The number of admissions for rickets has remained relatively stable.

Where a child is identified to have rickets it is likely other members of family are also vitamin D deficient.

**Figure 2. Persons admitted within financial year for E55 or M83 in Tower Hamlets Between 2006 and 2011<sup>15</sup>**



**Cost of treating vitamin D deficiency - acute**

HRGs<sup>16</sup> and total cost of episodes are available for admissions with the primary/secondary diagnosis E55 or M83 for Tower Hamlets residents. As the HRG will be heavily influenced by primary diagnosis or procedure, and may

<sup>14</sup> Kruskal Wallis (used as non-parametric data): medians are significantly different between the 4 ethnicity categories, p<0.0001

Post-hoc analysis (Dunn’s test) identifies significant (p<0.05) differences in comparisons of all groups, except when comparing Asian/Asian origin vs. African/Caribbean and White/European vs. Unspecified.

<sup>15</sup> Hospital Episode Statistics (HES) data



ignore/discount some secondary codes, not many spells are recorded with a primary vitamin D diagnosis. It is therefore not possible to assign an admission cost directly to vitamin D deficiency.

### Cost of treating vitamin D deficiency – primary care

The costs of vitamin D treatment has been escalating year on year and include a significant number of ‘special items’<sup>17</sup> for vitamin D as either individually prepared liquids for children or imported medicines. Table 3 shows the costings for all vitamin D prescribed in Tower Hamlets PCT across 5 financial years.

**Table 3. All Vitamin D prescribed in Tower Hamlets PCT 2007/08 to 2011-12<sup>18</sup>**

Period Name	BNF Name	Total Items	Total Actual Cost
Financial 2007/2008	Vitamin D	47,481	£279,298.46
Financial 2008/2009	Vitamin D	64,602	£405,646.06
Financial 2009/2010	Vitamin D	85,514	£590,634.94
Financial 2010/2011	Vitamin D	112,468	£1,140,262.66
Financial 2011/2012*	Vitamin D	123,803	£1,242,664.61
		<b>433,868</b>	<b>£3,658,506.73</b>

\* April 2011 – February 2012

### Knowledge and practices of vitamin D treatment and prevention locally through Primary Care

In order to assess the knowledge and practices of Vitamin D treatment and prevention locally through Primary Care, a cross sectional study (survey) was conducted in November 2010. The sample size, or number of GPs to survey, was calculated (95% confidence intervals, 80% power). Using coded lists of GPs in each practice in Tower Hamlets and an online random number generator tool, GP practices were selected to participate until the sample size was reached. The selected practices were then contacted (practice managers and GPs) with email and faxed requests to participate. 31 GPs returned their questionnaires and the key findings relating to prevention are summarised in this section. *Full details are available on request.*

- There was general consensus (97% agreement) amongst GPs surveyed that Vitamin D deficiency is an important local problem. Additionally, there was good general awareness of the groups at higher risk of Vitamin D deficiency.
- Although there was general consensus about the symptoms warranting Vitamin D testing, there was marked variation in the screening practices of individual GPs.
- 61% of GPs test all high risk patients routinely for Vitamin D deficiency even when asymptomatic, whereas 39% only test when patients present with symptoms such as malaise, bone pain, weakness, or symptoms relating to Osteomalacia or Rickets.

At the time of the survey there seemed to be much less knowledge and understanding about the Healthy Start Vitamin scheme.

- The majority (77%) of GPs surveyed did not feel that they know about the HSV scheme well enough to be able to confidently direct a patient to it.
- Although some GPs report having queries about HSV as regularly as weekly, roughly half of all the GPs

<sup>16</sup> Healthcare Resource Groups (HRGs) are standard groupings of clinically similar treatments which use common levels of healthcare resource

<sup>17</sup> Specials are unlicensed medicines created for patients for whom there are no existing suitable licensed products available, for reasons of formulation and/or presentation.

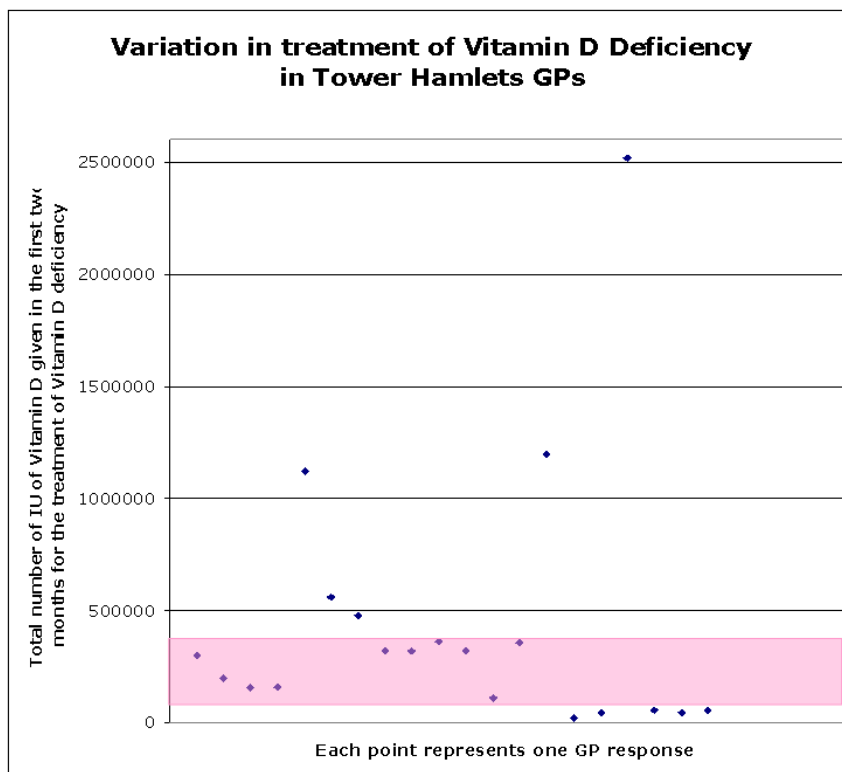
<sup>18</sup> ePACT

surveyed had a low awareness about the groups who are currently entitled to receive HSV

The survey of local GPs revealed a marked variation in the treatment of Vitamin D deficiency and insufficiency in adults (Figure 3). If the CEG guidelines are used, then the minimum of 800IU daily for adults with Vitamin D deficiency is recommended, and a maximum of a 300,000IU oral loading dose in 5 days followed by 200IU daily thereafter. This equates to a total number of IU in the first 8 weeks of between 44,000 and 402,000IU (this is the pink area in Figure 3).

In this study group alone (approximately 26% of all Tower Hamlets GPs), a range of between 22,400IU and 2,520,000IU was found. When compared to the CEG guidance, this represents under-treatment and marked excess.

**Figure 3: Individual GP’s Preferred Treatment of Vitamin D Deficiency in their Patients<sup>19</sup>**



Each point represents one GP’s preferred treatment of Vitamin D deficiency in their patients. The number of units prescribed over the initial two month period has been calculated from their responses and charted as shown (includes the loading dose when it is used, as does the CEG maximum shown in the pink area upper limit).

**Knowledge and practices related to vitamin D and Healthy Start vitamins amongst Midwives and Health Visitors<sup>20</sup>**

This section presents some key findings from a survey undertaken by Health visitors in 2011. Surveys opportunistically taken to midwifery and Health Visitor forums.

- 19 community midwives participated in the survey.
- 3 of the 4 Health Visitor locality teams participated in the survey with a total of 37 respondents.

Full details will be available in the Vitamin D and Healthy Start Vitamins Health Needs Assessment report.

**Table 4: Awareness of the Healthy Start scheme in Tower Hamlets and eligibility criteria amongst Health**

<sup>19</sup> Vitamin D and HSV Primary Care Survey, 2010

<sup>20</sup> Selected findings from Midwives and Health Visitors surveys 2011

**Visitors and Midwives**

Question asked	Healthy visitors	Midwives
Aware of local set up and would feel confident directing a patient to it	76%	47%
Aware that at the time of the survey, the Tower Hamlets policy was for all newborn babies brought to their 6-8 weeks health check to be given first bottle of Healthy Start vitamins (HSV) free regardless of eligibility	65%	42%
Aware that all pregnant women on specified benefits (throughout pregnancy and until baby is 1 yr old) should receive the HSV	60%	47%
Aware that any child from families on specified benefits until they are 4 years old were entitled to HSV	78%	47%
Aware that pregnant women aged under 18 years (throughout pregnancy and until baby is 1 yr old)	73%	53%
Aware that all pregnant women provided at first antenatal care booking appointment (TH residents)	68%	100%

**Table 5: Groups perceived to be at increased risk of vitamin D deficiency by midwives and health visitors**

Population group	Midwives	Health Visitors
Black/Asian ethnicity	74%	84%
Pregnant Women	89%	73%
Children aged <5 yrs	68%	84%
Elderly	63%	73%
Housebound	68%	62%

**3. What are the effective interventions?**

Primary prevention through the promotion of outdoor activities to increase sun exposure and increased consumption of foods that are good sources of vitamin D should be a component of the wider strategy to promote healthy eating and physical activity.

Improving the nutrition of pregnant and breastfeeding mothers in low income families is a recognised priority<sup>21</sup>. Improved nutrition in pregnancy has the potential to improve infant health and reduce health inequalities.

Guidelines suggest dietary supplementation for higher risk groups (pregnant / breastfeeding women, children aged 6 months to 4 years old, people with low sun exposure, Mediterranean skin tone or darker, 65yrs+ age groups, obesity) to prevent vitamin D deficiency.

The Chief Medical officer’s update of summer 2005 reiterated the COMA (1991) recommendation, suggesting children need supplementation up 5 years of age. And again, in January 2012 the Chief Medical Officer England / Chief Scientific Adviser wrote to General Practitioners, Practice Nurses, Health Visitors and Community Pharmacists as a restatement of advice and to provide information about prescribing and recommending vitamin D supplements to those groups of the population at risk of vitamin D deficiency.

The most recent national recommendations on vitamin D are to be found in:

- NICE PH 11: Maternal & Child Nutrition (March 2008) - places the onus on PCTs to ensure supplementation happens
- NICE CG: Antenatal Care (June 2008)

<sup>21</sup> Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households. NICE Public Health Guidance 11, HMSO, March 2008.

- Scientific Advisory Committee on Nutrition (SACN) Position Statement on Vitamin D (2007)

The RCOG supports the use of 400IU/day (10mcg) vitamin D per day during pregnancy and breastfeeding in women at 'high risk' of vitamin D deficiency.

Supplementation is also supported by the European Society for Paediatric Endocrinology

**Table 6: Vitamin D Supplement Recommendation (to prevent rickets and osteomalacia) by all UK Health Departments. Recommendations only sufficient to prevent rickets and osteomalacia. In absence of skin synthesis will not provide optimal status.**

People at risk of vitamin D deficiency	Daily vitamin D supplement
All pregnant and breastfeeding women	10µg/day (400 IU)
All infants and children from 6 months to 5 years, unless they are drinking 500mls (a pint) of infant formula a day at any time during this age range	6 months to 5 years - 7µg/day (280 IU)
(If there is any doubt about the mother's use of vitamin supplements during pregnancy and/or breastfeeding, breastfed infants will benefit from vitamin D supplements from 1 month)	
People whom lack exposure to the sun e.g. people confined indoors for long periods and those who cover their skin for cultural reasons	10µg/day
People from ethnic minorities who have darker skin, because their bodies are not able to produce as much vitamin D. Clinical deficiency has been most reported among children of African-Caribbean and South Asian origin.	10µg/day
People aged 65 years and over	10µg/day

### The Healthy Start Scheme

Healthy Start Vitamins for women and children contain all the vital nutrients for pregnant women and young children, with vitamin D being a key element. The 400U of vitamin D contained in Healthy Start is sufficient to prevent neonatal rickets and seizures and maintain serum 25(OH)D concentrations >25nmol/l, but not >75nmol/l. This is important, because 1)<sup>22</sup> this dose is likely to be insufficient to reduce proximate adverse pregnancy outcomes, and<sup>23</sup> 2) many observational studies report that optimum outcomes in childhood are associated with maternal 25(OH)D >75 nmol/L.

Healthy Start vitamins are available for women from when they enter the scheme at 10 weeks till when the child is one and for children from 6 months to their 4<sup>th</sup> birthday. Infants under 6 months old getting vouchers are not legally entitled to the supplements, however if a health care professional considers that their natural vitamin stores are likely to be low and that the supplements would benefit them, then the supplements can be provided.

Healthy Start replaced Welfare Food Scheme in 2007 as it was recognised that there were some limitations to the scheme. Like the welfare food scheme it is a means tested statutory scheme which provides a nutritional safety net. It aims to encourage breastfeeding and healthy eating during pregnancy, as well as healthy weaning to give the child the best start in life. The scheme is also a vital public health tool as it is able to help us monitor the levels of need and support the most disadvantaged families to make healthy choices.

<sup>22</sup> Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households. NICE Public Health Guidance 11, HMSO, March 2008

<sup>23</sup> Brooke O et al. Vitamin D supplements in pregnant Asian women: effects on calcium and fetal growth. BMJ 1980;280:751-4.

Women and children from families who are eligible for the Government’s Healthy Start scheme can get free vitamin supplements which include vitamin D, in the form of tablets for women and drops for children.

**Table 7. Women’s Healthy Start vitamin tablets**

<b>Available to:</b>	Women; pregnant and until child is 1 year old
<b>Contains:</b>	70 mg Vitamin C 10 mcg Vitamin D 400 mcg Folic Acid
<b>One bottle:</b>	56 tablets (8 week supply)
<b>Daily Dose:</b>	1 tablet

**Table 8. Children’s Healthy Start vitamin drops**

<b>Available to:</b>	Children; 6 months – 3 years
<b>Contains:</b>	233mcg Vitamin A 20mg Vitamin C 7.5mcg Vitamin D
<b>One bottle:</b>	10 mls (8 week supply)
<b>Daily Dose:</b>	5 drops

They can also get one £3.10 voucher per week. Children under one year old can get two £3.10 vouchers (£6.20) per week.

The vouchers can be spent on:

- Plain cow’s milk – whole, semi-skimmed or skimmed. It can be pasteurised, sterilised, long life or UHT
- Plain fresh or frozen fruit and veg, whole or chopped, packaged or loose
- Infant formula milk that says it can be used from birth and is based on cow’s milk.

It is the statutory responsibility of PCTs to make Healthy Start vitamins available locally to women and children on the scheme.

**Healthy Start Scheme eligibility criteria**

Pregnant women and families with children under four getting:

- Income Support, or
- Income Based Jobseekers’ Allowance, or
- Income related Employment and Support Allowance, or
- Child Tax Credit (but not Working Tax Credit unless the family is receiving Working Tax Credit run-on only\*) and has an annual income of £16,190 or less (2011/12).

\*Working Tax Credit run-on is the Working Tax Credit received in the 4 weeks immediately after a person has stopped working for 16 hours or more per week.

And ALL pregnant under 18 year olds

#### Healthy Start vitamins for non-beneficiaries

In England and Wales, Trusts and health boards can sell Healthy Start Vitamins to non-beneficiaries for the following prices (which are inclusive of VAT).

Children's drops: £1.80 per bottle

Women's tablets: £0.91 per bottle

Cost of over the counter (OTC) vitamin D maintenance doses vs. HSV

Years supply OTC 400IU for children: £26-£36

Years supply HSV for children: £11

Years supply OTC 400IU for women: £43-£60

Years supply HSV for women: £5.50

## 4. What are we doing locally to address this issue?

### Health Needs Assessment

A vitamin D and Healthy Start Vitamins in Tower Hamlets, maternity and early years, health needs assessment (HNA) has been undertaken. *(Full report being completed)*

The principal objectives of this work included:

- assessment of the incidence and prevalence of vitamin D deficiency and insufficiency in Tower Hamlets using information about higher risk groups to guide the analysis.
- examining the effectiveness and cost-effectiveness of current service provision for the prevention and treatment of vitamin D deficiency and insufficiency in Tower Hamlets, with particular focus on the Healthy Start Vitamins programme.
- identifying gaps in vitamin D deficiency service provision and consideration of options to address these gaps using national and local guidelines, published evidence, local data, opinions from stakeholders and experiences from service users.

### Healthy Start Steering Group

This implementation of the Healthy Start scheme in Tower Hamlets is overseen by the multi-professional multi-agency Healthy Start Vitamins Steering Group. This group includes wide representation from Primary Care, Public Health, Pharmacy, Midwifery, Health Visitors, Secondary Care (Obstetrics), Dietitians, Early Year's leads and Children's Centres, and is chaired by the Senior Public Health Strategist for maternity and early years.

### Tower Hamlets Policy – Healthy Start Vitamins

A Healthy Start support worker was employed to assist with the implementation of the scheme in 2009.

Commencing in 2009, Tower Hamlets had a policy of providing the first bottle of HSV to all women free, regardless of eligibility, at the first antenatal booking appointment, together with the first bottle of children's drops free at the 6-8 week check. Following the HNA and the review of evidence and expert opinion from clinicians, it was agreed that Tower Hamlets would maximise the availability of Healthy Start vitamins for all pregnant women regardless of eligibility. In order to achieve this, from 2012, the first three bottles of Healthy Start vitamins are free for all pregnant women, regardless of eligibility, with the first bottle supplied at the antenatal booking appointment. The children's drops are only available to those eligible for the scheme. As a prompt to both women and staff, a sticker has been designed and is placed on the front of the maternity hand held record to record when the vitamins have been provided and when the next bottle is due.

Due to the high estimated prevalence of vitamin D deficiency in Tower Hamlets, all children are recommended to commence the Healthy Start vitamins, or a suitable alternative from 1 month regardless of feeding type. The two sections below the evidence related to vitamin D and vitamin A toxicity.

#### **Vitamin D toxicity<sup>24</sup>**

There is therefore no evidence that prophylactic doses of vitamin D of 400 iu (10µg) daily in addition to what is usually consumed in the diet (around 3µg/day for the average adult) would cause any toxic effects to pregnant women or the developing fetus.

Formula fed infants receive around 8.5 µg of vitamin D daily which in itself would be adequate to prevent rickets and no further supplementation with vitamin drops (which contain 7.15 µg: 286 iu vitamin D per dose) would be required. However there are unlikely to be any toxic effects if both are given (as long as the infant is not receiving additional doses of vitamin D in cod liver oil).

Formula Fed infants receiving 500ml/day would receive 5.5 – 7.5µg/day vitamin D. When this is increased to 1200ml/day they would receive 13.2 - 18µg/day. Healthy Start vitamins contain 7.5µg/dose and Abidec contains 10µg/dose.

Acute toxicity can still occur after excessive accidental intake (one 15 ml bottle of Mothers and Children's vitamin drops contains 750µ: 30,000 iu vitamin D) although a single excess dose is unlikely to have adverse effects.

#### **Vitamin A toxicity<sup>25</sup>**

Current guidelines about vitamin A supplementation dosage during early childhood are precautionary rather than related to clear risks of adverse effects due to over consumption.

During lactation the RNI of the mother is 950µg per day which is greater than the median dietary intake and so vitamin A supplementation would be advised for breast feeding mothers.

<sup>24</sup> Eleanor McGee, Public Health Nutrition Lead, Birmingham Community Healthcare NHS

1. Lightwood R. Idiopathic hypercalcaemia with failure to thrive. Arch Dis Child 1952;27:302
2. Bransby ER Berry WTC Taylor DM. Study of vitamin D intakes of infants in 1960. BMJ 1964;i:1661-3
3. British Paediatric Association. Infantile hypercalcaemia, nutritional rickets and infantile scurvy in Great Britain. BMJ 1964;i:1659-61
4. American Academy of Pediatrics Committee on Nutrition. The relationship between infantile hypercalcaemia and vitamin D; public health implications in North America. Pediatrics 1967;40:1050-61
5. Chesney RW. Requirements and upper levels of vitamin D intake in the term neonate, infant and older child. J Pediatrics 1990;110:159-66
6. Goodenday LS Gordon GS. No risk from vitamin D in pregnancy. An Intern Med 1975;75:807-8

<sup>25</sup> Eleanor McGee, Public Health Nutrition Lead, Birmingham Community Healthcare NHS

1. Bates CJ. Vitamin A. Lancet 1995; 345:31-35
2. Department of Health. Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. London: HMSO, 1994. Report on Health and Social Subjects: 41.
3. Gregory J Foster K Tyler H Wiseman M. The dietary and Nutritional Survey of British Adults. London: HMSO, 1990
4. Gregory J Collins D Davies P et al. National Diet and Nutrition Survey: children aged 1½ - 4½ years Volume 1: Report of the National Diet and Nutrition Survey. London: HMSO, 1995
5. Department of Health. Weaning and the Weaning Diet. London: HMSO, 1994. Report on Health and Social Subjects: 45.
6. Hathcock JN Hathan DG Jenkins MY et al. Evaluation of vitamin A toxicity. Am J Clin Nutr 1990;52:183-202

There is the potential for exclusively formula fed infants who consume vitamin drops as well to receive slightly above the maximum daily intake of 900µg per day, although there is no evidence that this level of intake is actually harmful. In fact vitamin A intake from the formula itself may well exceed the maximum daily allowance and be 3 times the RNI making vitamin A supplementation unnecessary. However it is more likely that a 6 month old infant would be reducing its milk intake as solid food becomes more prominent in the diet.

Dietary surveys have found that in a proportion of toddlers, vitamin A intake is less than the LRNI, presumably because of reduced milk intake and inadequate intake from diet. Vitamin A supplementation would then be required.

### **Guidelines and procedures**

CEG guidelines for primary care were launched February 2011.

- Designed to improve management of patients with vitamin D insufficiency or deficiency
- Promote supplements for all children under 5 years of age.
- Adequate supplementation during pregnancy and breastfeeding.
- Optimise treatment for children and adults with symptomatic deficiency disorders
- Safe advice on managing insufficiency
- Improve information for practitioners and patients
- Audit prevalence of vitamin D deficiency and treatment

These guidelines are currently being reviewed.

Royal London Hospital vitamin D replacement in pregnancy guidelines have been written in conjunction by maternity services and public health. This guideline was ratified in May 2012 and is currently being implemented.

Operational procedures have been agreed with midwives and health visitors. These were implemented in February 2012.

### **Monitoring and audit**

- Distribution system revised and details of all distribution points updated. Recording system for use by Healthy Start support worker revised.
- Monitoring stock records of issues of Healthy Start vitamins from distribution centres by the Healthy Start support worker. Now undertaken on a rotational basis between localities rather than ad hoc basis as previously.
- Quarterly claims made to the DoH for reimbursement of funding for those vitamins provided to women and children eligible for the scheme. Quarterly report produced by the DoH to enable trends in uptake of the scheme overall and the vitamins to be monitored.
- Midwives, Health Visitors and Distribution point named person maintain simple monitoring form of distribution to enable cross-check with stocktake.
- To repeat of CEG audits for vitamin D values in primary care (initially part of HNA)
- To undertake annual review of vitamin D related admissions (initially part of HNA)
- To repeat surveys of knowledge of the Healthy start scheme & vitamin D amongst
  - relevant professional groups (GPs, midwives & HV)
  - pregnant women and women with infants
- Audit of Health Visitors implementation of the scheme via EMIS. Currently being reviewed.
- To implement audit of maternity records for provision of HSV.

### **Communication**

*Health professionals and stakeholders*



- Regular sessions at midwives and health visitor’s forums undertaken during the development of the operational plans. To continue on a quarterly basis to update and provide an opportunity for discussion.
- Implementation of briefing papers for GPs
- Information and key message sessions with Early Years colleagues in the local authority, starting with Early Years coordinators and Early Years managers.
- To introduce annual update sessions for all Health Visitors as a component of the current breastfeeding update sessions
- Postcode based distribution centre posters developed for use in Health Centres, Children’s Centre and other relevant locations. Reviewed in February 2012.
- Operational procedures for nurses and midwives developed in both poster form for clinic rooms and as diary inserts.

*Women and children*

- Health Start / vitamin D outreach project undertaken in 2011 (full report available)
- RLH vitamin D patient information sheet submitted for approval
- Healthy start information leaflet, including details of distribution centres in development. Due for launch June 2012.
- Whole of population vitamin D leaflet written in collaboration by public health, the CCG and medicines management. Reviewed by community members with the assistance of the Woman’s Family Health Service. Currently completing final design phase. Launched May 2012.
- Information column in East End Life, February 2012

Communication strategy in development for 2012/13. Will include a conference and workshops for health professionals, stakeholders and the community.

## 5. What evidence is there that we are making a difference?

Based on claims to the Department of Health for vitamins given out against vouchers in Tower Hamlets we have seen a gradual increase in the uptake of children’s drops and women’s tablets.

**Table 9. Uptake of Healthy Start in Tower Hamlets<sup>26</sup>**

	Healthy Start scheme uptake	Children's drops uptake	Women's tablets uptake
December 2010/11	85.2%	0.0%	0.0%
June 2011/12	85.1%	9.8%	7.7%
September 2011/12	84.0%	8.0%	11.0%
December 2011/12	85.6%	11%	14.3%
June 2012/13	58.9% <sup>27</sup>	12.5%	20.9%

Whilst over all the uptake remains inadequate there has been a significant positive trend in the increase of the

<sup>26</sup> [Healthy Start England: quarterly reports](#)

<sup>27</sup> Unusually, all PCTs in London saw a drop in the uptake of the scheme from Q4 2011/12. It is therefore unclear whether this is a reflection of an actual drop in uptake or an artefact due to a change in the assumptions and estimates made when compiling this data.

uptake; particularly over the last year. This is likely due to the considerable improvements in communication related to the scheme and as well as to the systems and processes in place to improve the distribution and monitoring.

Based on reports from the Department of Health re: Healthy Start in England, the trend in uptake of drops and tablets in Tower Hamlets appears to be considerably better than both the London and England averages. Due to concerns about data quality however the actual figures are not reported here. This data simply enables us to broadly compare Tower Hamlets with other PCTs in the London region.

## 6. What is the perspective of the public on services?

A Healthy Start vitamin / vitamin D outreach project was commissioned by Public Health in 2011 and undertaken by the Women's Family Health service. Final report completed in October 2010 followed an action planning event in October 2011 with key stakeholders (including community members). *Full report available.*

### Key messages from the project

- Women felt that they had not been given clear healthy eating information when pregnant
- General knowledge of vitamin D, with a majority of people knowing the main source is sunlight & oily fish in the diet.
- A minority of women understood who the at risk groups are e.g.:  
Not all women are aware that they were more at risk because of their cultural/religious preference to cover all or most skin or due to darker skin pigmentation
- Nobody knew how long they should be in the sunshine/daylight each day to get the benefit with regards to vitamin D absorption.  
Even less sure about their children's exposure to sunlight.
- Number of women reported being treated for deficiency
- Variability re: information provided both in terms of location and professional
- Most women named their midwife as the person who explained vitamin D to them
- Women who used Children's centres knew they could pick up vitamins there, got lots of advice about healthy eating in pregnancy, breast feeding and for their children, from the family support workers and had received help to apply for the Healthy Start Scheme from family support workers there.
- There was little mention of health visitors informing women about the Healthy Start Scheme and vitamin D supplements at baby clinics or health checks
- Women trying to collect their vitamins with Healthy Start coupons reported that they were turned away by health professionals, pharmacies, and GP reception staff without being sign-posted/advised where to get them from.

### Summary of recommendations

To increase user involvement and develop community ownership

- Improving Access
- Improving communication
- Review of current systems and processes

The action planning event resulted in key actions related to each of the above recommendations.

## 7. What are the priorities for improvement over the next 5 years?

- Continued primary prevention through:
  - Targeting of women, infants and children ; particularly those with dark skin
  - Continue to raise public awareness and uptake of the Healthy Start scheme

- Raise awareness of risks of vitamin D deficiency in all families
- Clear messages about appropriate sunlight exposure for whole of population; highlight different requirements of fair vs. darker skin and promotion of outdoor activities to increase sunlight exposure?
- Information about the use of vitamin D supplements and dietary sources for whole of population
- Pilot a Healthy Start Champions project, recruiting and training women from local communities to provide information and support as volunteers to women during pregnancy, and with young families.
- Continue to raise awareness of the Healthy Start scheme with Health professionals.
  - Ensure all health professionals, children centre staff, clerical staff in health centres are trained to the appropriate level to give out advice and sign-post families to distributing sites for healthy start.
- Annually review the implementation and uptake of the Healthy Start scheme with analysis by each step in the pathway (including activity by individual distribution centres) identifying further options for improvement.
- Implementation of RLH vitamin D guidelines with audit of implementation.
- Review the implementation of the CEG vitamin D guidance
- Further explore the possibility of:
  - HSV being universally free to all women until child's first birthday and children under 4 or selling to those not eligible for the scheme.
  - Distribution via pharmacies
  - For pregnant women, a 'voucher' from GP's for Healthy Start (in place of commencing on folic acid); to be collected at local pharmacy.
- Review of need for change in secondary care admission coding to reflect Vitamin D status (given high local prevalence and contribution to many other conditions). Alternatively, consideration of a local disease register and initiation of a large cohort study (following ethics approval).

## 8. What more do we need to know?

Nutrition in pregnancy remains a key area of preventive activity with substantial uncertainties e.g.

- The impact of supplementation on adverse pregnancy outcomes and infant health needs to be better defined, especially in high risk groups.
- Uncertainty surrounds optimal dosing of supplementation, particularly of vitamin D.

In short, it is vital to evaluate effects of higher dose vitamin D supplementation in pregnancy vs. standard 400 IU in a randomised trial to establish a) efficacy, and b) safety.

## 9. Key Contacts & Links to Further Information

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**Further information**

Healthy Start and Vitamin D insight Project Report (October 2011)  
 Healthy Start and Vitamin D insight Project - feedback event report (October 2011)  
 NICE CG: Antenatal Care (June 2008)  
 Scientific Advisory Committee on Nutrition (SACN) Position Statement on Vitamin D (2007)  
 Bolling K, Grant C, Hamlyn B, Thornton A (2007). Infant Feeding Survey 2005. The Information Centre

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		<b>Signed off by:</b>	Esther Trenchard-Mabere Associate Director of Public Health		