

Prevention of rickets and vitamin D deficiency in Birmingham: The case for universal supplementation

Prepared on behalf of the Vitamin D Steering Group by Eleanor McGee, Public Health Nutrition Lead, Birmingham Community Nutrition and Dietetic service; eleanor.mcgee@benpct.nhs.uk; Tel: 0121 446 1021

1.0 Purpose

This paper puts the case for rolling out universal vitamin D supplementation to the whole of Birmingham for women during pregnancy and up until their child is 12 months old, and to all children under 4 years old, using the Department of Health-issued Healthy Start supplements. The case for this is the relatively high number of cases of rickets and hypocalcaemic fits in Birmingham children due to vitamin D deficiency, and the cost of treating them. This paper does not deal with vitamin D deficiency secondary to liver, renal or gastrointestinal disorders.

2.0 Background

2.1 Vitamin D deficiency and its consequences

With only an average of 10% of daily requirement coming from food sources, humans rely on the majority of their vitamin D requirement being made in the skin by the action of sunlight (UVB). However this process is only effective if sufficient skin area (hands, arms and face) is exposed in the middle of the day during the summer months (April to October), which is the only time UVB is available in the Midlands and all locations further north. If this exposure does occur, enough of the vitamin is formed and stored to provide for the winter months. Darker skins filter UVB more effectively, so longer exposure is required. Large numbers of the Birmingham population will not be getting this exposure for a range of reasons including traditional dress, disinclination to spend time outside due to culture or fear of crime, use of sun block, and poor weather and working patterns militating against outdoor lunch breaks. Whilst the high rate of vitamin D deficiency in infants and children, and suboptimal vitamin D status in all age groups, is most marked in areas of the UK such as Birmingham which have experienced increasing ethnic, religious and cultural diversity, the problem is not restricted to ethnic minority groups or the population living in the Midlands and further north (1).

There is emerging evidence linking vitamin D deficiency to mortality and morbidity including all cause mortality (2), bowel and other cancers (3), cardiovascular disease (4,5), multiple sclerosis (6), diabetes types 1 and 2 (7,8), and tuberculosis (9), as well as to bone diseases (rickets, osteomalacia and osteoporosis). Treating symptomatic vitamin D deficiency in adults has become a significant cost for Birmingham PCTs (communication from BEN and HoB Medicines Management teams, 2010). Whilst there is not yet a strong evidence base for routine supplementation of adults, it seems logical to address prevention in mothers and young children where there are national recommendations, cheap supplements, and a relatively straightforward process via the routine contact with health services of these population groups. Nationally, there have been at least 3 infant deaths from cardiomyopathy secondary to vitamin D deficiency since 2000 (10).

2.2 Vitamin D deficiency in Birmingham children

Rickets and hypocalcaemic fits have begun to re-emerge in Birmingham, with 65 cases in children under five between 2001 and 2003, 48 of which had a HoB tPCT post code (unpublished). This finding led to the formation of the Vitamin D working group, and the launch of the HoB tPCT vitamin D policy in 2006.

A further survey of lab results for children tested during the year 2005 and aged under five with vitamin D deficiency (defined as $<10\mu\text{g/l}$), identified 29 cases with a HoB post code (unpublished). This has been repeated for the financial year to 2009-10 and has revealed 21 children under five with Birmingham post codes (see appendix A for split by PCT, and incidence rates). For HoB, the number of cases has dropped by over 50% from 29 in 2005, to just 12, suggesting some possible impact of the HoB policy and campaign.

An additional 12 cases of rickets or hypocalcaemic fits in Birmingham children were reported by paediatricians, for whom lab results showed vitamin D levels above the $10\mu\text{g/l}$ cut off, suggesting this is not a comprehensive measure of the problem. However it was used for the latest survey in order to allow comparison with 2005 data.

2.2 National recommendations

Most recent national recommendations on vitamin D are to be found in NICE PH 11: Maternal & Child Nutrition (11), NICE CG: Antenatal Care (12), and the Scientific Advisory Committee on Nutrition (SACN) Position Statement on Vitamin D (13).

These all support the Dietary Reference Values for vitamin D set in 1991, or the Reference Nutrient Intakes re-issued in 1998 by SACN (14), which are as follows: for infants aged 0-6 months, $8.5\ \mu\text{g/d}$; from 7 months to 3 years, $7.7\ \mu\text{g/d}$; and for pregnant and lactating women, and adults over 65, $10\ \mu\text{g/d}$; with no RNI for those aged 4 to 65 years. In addition, NICE guidance suggests pregnant and lactating women may need to take suitable supplement in order to meet their requirements.

The Chief Medical officer's update of summer 2005 (15) reiterated the COMA (1991) recommendation (16), suggesting children need supplementation up to 5 years of age.

2.3 National Healthy Start scheme

The national Healthy Start scheme provides vouchers which can be exchanged for fruit, vegetables and milk for families on low incomes where there is a pregnant woman, and/or one or more children under 4 years old. In addition, these families are entitled to Healthy Start vitamin supplements for women from start of pregnancy until 12 months post-natally, and to Healthy Start vitamin drops for all children aged under 4. Since October 2009, in order to increase uptake of the vitamins (which has been poor across the country) beneficiaries have been sent a voucher or token for vitamins to take to their Health Centre. Vitamins can be ordered via NHS supplies as a stock item, and are reimbursed via a monthly claim made by Shared Service Finance on behalf of each Birmingham PCT. The cost of vitamins is 82p per bottle for women's tablets, and £1.61 per bottle for children's drops.

2.4 Current PCT policy

The HoB tPCT vitamin D policy provides for supplementation of all women during pregnancy and up until their child is 12 months, and to all children under 5 years old, with tablets and drops containing vitamin D. Currently the most suitable preparations in terms of dose and cost are Healthy Start vitamins for women, and Healthy Start children's vitamin drops. There is a year on year increase in the number of supplements distributed, and in the year 2009-10, 18% of women and 11 % of children eligible under the HoB scheme received supplements.

BEN PCT has a scheme of universal supplementation for pregnant and post-natal women in certain “target wards”, whilst children can get the drops if covered by the national Healthy Start scheme. Uptake has improved this year.

South PCT makes both types of vitamins available to those eligible under the national scheme, with a small number of discretionary issues by Health Visiting staff to families not eligible where they believe there is need. Both uptake and access to vitamins have improved recently.

3.0 Why a universal policy for vitamin D?

3.1 Quality

The DH requires PCTs to make Healthy Start supplements available to those on the national Healthy Start scheme. A number of people registered with GPs in South and BEN PCTs have contacted the Department of Health since March 2010 to report being unable to obtain the vitamins at their local health centres, and many more are likely to have experienced this and taken no action. Given that the national scheme, including the children's drops, was launched in October 2006 and that the women's tablets became available from March 2007, this demonstrates a need for change if a high quality service is to be provided across South and BEN PCTs. Recent work done by the Public Health departments in BEN and South has resulted in improved access and awareness, and consequent increases in vitamins issued to families.

However there is a target set by the DH to increase numbers of eligible women taking the tablets to 10% by March 2011, and 25% by March 2012. On the latest available data, BEN and South PCTs will struggle to reach these modest targets.

3.2 Innovation

HoB tPCT is one of very few PCTs in the country funding a universal eligibility scheme for Healthy Start supplements. The DH describes the HoB policy in their booklet (17) as an example of good practice. It would be relatively easy for BEN and South PCTs to use the learning from the HoB experience and introduce a cost-effective universal scheme.

3.3 Productivity

At present, supplements are available at limited NHS venues and some Children's Centres outside of HoB, often only when health visiting staff are on the premises. Motivation of women to take up the scheme may have been damaged by difficulty or inconsistency in being able to obtain the vitamins at venues convenient to them. As

people do not experience symptoms of vitamin D deficiency in most cases, their commitment to taking supplements will be limited, so it is essential to success to make it easy for them to do so.

As the Healthy Start vitamins can be given out by admin staff, the current restriction on access is unnecessary. However it is probably due to the complexity of the scheme, requiring staff giving out the vitamins to “police” the system, as the supplements are available only to certain clients. Giving universal access to all women with proof of pregnancy, or that they have a child under one, or under 4 years old, and requesting the Healthy Start vitamin vouchers from those on the scheme, would be simple to administer and could be part of the admin or receptionist role in all PCT premises across the city, and potentially in Children’s Centres too. This requires minimum paperwork, and reduces the need for uncomfortable conversations with clients.

A citywide universal policy could be promoted free on local radio stations and via press releases, raising public awareness at no cost. To date, the use of these channels has been limited by the difficulty of explaining to the public the different approaches taken by each Birmingham PCT.

Currently Birmingham Children’s Hospital issues the supplements to children registered with a HoB GP, and City Hospital have recognised their role in improving access to the vitamins for women whose antenatal care is at the hospital and not in the community. Both of these Trusts could support this public health intervention better if the scheme was universal and so simpler to administer.

Until now the HoB scheme has included children up until their 5th birthday, in line with COMA (1991) recommendations (16). However this proposal suggests lowering the age to 4 in order to reduce potential cost, and because of the logistical difficulties of reaching the 4-5 age group, who may attend school or nursery and are more likely to have parents in work and not visiting Health or Children’s Centres.

3.4 Prevention

In order to ensure that the target population is taking supplements, thus minimising cases of rickets and hypocalcaemic fits, the following are required:

- Public awareness, and motivation to take the supplements
- Professional awareness and understanding of the scheme
- Easy access to the supplements

All of these are facilitated by a universal policy, as explained above.

Nutritional rickets is an entirely preventable disease, and the cost of treating it is estimated to be £5,000 per case. In addition, there will be hidden costs to society caused by the developmental delay which results from a child not learning to walk at an appropriate age. For cases identified last year, it is estimated that Birmingham spent £165,000 treating 33 cases (12 symptomatic but with vitamin D levels above 10µ/l, plus 21 with lower vitamin D levels).

One third of the 2001-3 vitamin D deficiency cases recorded in Birmingham in infants under 6 months occurred in babies fed on formula milk (a source of vitamin D),

suggesting that maternal vitamin D sufficiency during pregnancy is key to preventing vitamin D deficiency in infants. In view of likely limited UVB exposure during the growing years, children probably need on-going supplementation. However for pragmatic and cost reasons, this paper proposes universal supplementation for pregnant and post natal women and for children just up to age 4, as a strategy to minimise cases of rickets and hypocalcaemic fits in children aged under 4.

4.0 Cost of universal supplementation for the Birmingham population

4.1. Estimating budget required for a universal policy

Option 1: Universal supplementation for all pregnant and postnatal women and children under the age of 4 (see appendix B for calculations)

The maximum potential cost of supplementing all pregnant women, and children under four citywide can be calculated, using local data on population numbers for target groups, then subtracting the cost of the Healthy Start beneficiaries using numbers provided by the DH. Adding the cost of delivery to existing HoB sites plus 30 additional premises in BEN and South brings the cost to £659,952.

This is a huge over estimate of what a universal policy might cost as, after 4 years and much awareness-raising in HoB, only 18% of women and 11% of eligible children are receiving the vitamins. Hence it is unlikely that all three PCTs will reach 100% of the target population in the next 2-3 years.

- Assuming 10% uptake for both women and children in South and BEN, plus 25% uptake in HoB for the year 2011-12 would cost **£102,984**.
- Assuming 25% take up for both women and children citywide in subsequent years takes the cost to **£164,988**.

These figures could be used as safe maximum estimates of the annual cost for the next three years.

Option 2: Universal supplementation for all pregnant and postnatal women, and only those children covered under the National Healthy Start Scheme

This would cost £124,414, assuming full reclaims from the DH and 100% uptake, and just £31,103.45 assuming 25% uptake.

4.2 Savings anticipated from a universal policy

The data available for the year 2009-10 reveals that 33 cases of vitamin D deficiency leading to rickets and hypocalcaemic fits in children under five with Birmingham post codes were treated during the year. The cost of treating these 33 cases would have been about £165,000, so a scheme costing £164,988 seems justifiable, especially if hidden costs incurred through developmental delay are considered. In addition, increased awareness of the problem of vitamin D deficiency in the local population might reduce number of cases being treated in older children and adults, which currently incur significant prescribing costs in Birmingham.

5.0 How would a universal policy be implemented?

Implementing and promoting the policy would need to be part of the Service Specification for health visiting and midwifery. Because it is a PCT responsibility to ensure access to supplements for Healthy Start beneficiaries, the requirements would differ (as follows):

- Health Visiting teams would be required to take vitamin drops to primary visits and to ensure that there is adequate access to both drops and tablets from an agreed number of centres open to the public at least from 9am to 5pm. In view of differing arrangements for admin support to health visiting, local agreement would be required. The citywide vitamin D group could advise and support the other PCTs to achieve this.
- Midwives, who are acute Trust employed, would be required to recommend Healthy Start supplements to women at their first appointment, signpost them to where they are available, and to document that they have done so. At subsequent visits, they should check that the women are taking the supplements.

6.0 Monitoring and evaluation

Robust mechanisms for collecting vouchers for those eligible for the Healthy Start scheme would need to be in place both to ensure reimbursement and to enable the DH to record progress towards the targets set. These are developing across the city already. In addition, total number of issues would need to be recorded, and then collated centrally to provide an estimate of the percentage of the population eligible under the universal scheme that were receiving supplements. This needs to be agreed with those managing front line reception staff and with health visiting for their admin staff. This will be possible in a citywide Provider Trust. Service specifications would need to include the KPIs for midwifery and health visiting staff, and these would need to be reported performance managed.

Further case-finding exercises would be important in order to show health benefit and savings through reduced cases of vitamin D deficiency. There is a role for a citywide Vitamin D group in overseeing the policy and monitoring its implementation and impact. This group is in place, with representatives from BEN, South and HoB Public Health, as well as Community and Children's hospital paediatricians and staff from the Provider services of the PCTs and the midwifery departments.

References

1. Javaid MK, Crozier SR, Harvey NC, Gale CR, Dennison EM, Boucher BJ, Arden NK, Godfrey KM, Cooper C. *Maternal vitamin D status during pregnancy and childhood bone mass at age 9 years: a longitudinal study*. Lancet, 07 January 2006, vol./is. 367/9504(36-43), 1474-547X
2. Gioannucci, E., *Can vitamin D reduce total mortality?* Arch Internal Med, 2007. **167**:p1709-10
3. Lappe, J.M., et al., *Vitamin D and calcium supplementation reduces cancer risk: results of a randomised trial*. Am J Clin Nutr, 2007. **85** (6):p1586-91

4. Wang, T., et al., *Vitamin D deficiency and risk of cardiovascular disease*. *Circulation*, 2008. **117**:p503-511
5. Artaza, J.N., Mehrotra, R., & Norris, K.C., *Vitamin D and the cardiovascular system*. *Clinical Journal of The American Society of Nephrology*, 2009. *CJASN*, **4**, (9) 1515-1522
6. Ramagopalan SV, Maugeri NJ, Handunnetthi L, Lincoln MR, Orton S-M, et al. *Expression of the Multiple Sclerosis-Associated MHC Class II Allele HLA-DRB1*1501 Is Regulated by Vitamin D*. *PLoS Genet*, 2009. **5**(2): e1000369. doi:10.1371/journal.pgen.1000369
7. Zepitis, C., Akobeng, A., *Vitamin D supplementation in early childhood and risk of type 1 diabetes: a systematic review and meta-analysis*. *Arch. Dis Child*, 2007
doi:10.1136/adc.2007.128579
8. Pittas, A.G., et al., *The role of vitamin D and calcium in type 2 diabetes. A systematic review and meta-analysis*. *J Clin Endocrinol Metab*, 2007. **92**(6):p2017-29
9. Nnoaham, K., Clarke, A., *Low serum vitamin D levels and tuberculosis: a systematic review and meta-analysis*. *International Journal of epidemiology*, 2008. **37** (1):p113-9
10. Maiya S, Sullivan I, Allgrove J, Yates R, Malone M, Brain C, Archer N, Mok Q, Daubeney P, Tulloh R, Burch M. *Hypocalcaemia and vitamin D deficiency: an important, but preventable, cause of life-threatening infant heart failure*. *Heart*. 2008. **94**(5):p540-1
11. NICE Public Health Guidance 11: Maternal & Child Nutrition (March 2008)
12. NICE Clinical guideline 62: Antenatal care (March 2008)
13. Update on Vitamin D. Position Statement by the Scientific Advisory Committee on Nutrition. (SACN), 2007: London
14. Nutrition and bone health with particular reference to calcium and vitamin D: Report of the Subgroup on Bone Health (Working Group on the Nutritional Status of the Population) of the Committee on Medical Aspects of Food and Nutrition Policy (COMA). 1998. The Stationary Office. London
15. www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/CMOupdate/DH_411566
3. Department of Health, Chief Medical Officer's Update, Issue 42, Summer 2005 (accessed 2nd November 2010)
16. Committee on Medical Aspects of Food Policy. Dietary reference values for food energy and nutrients for the UK (COMA). Department of Health. London: HMSO, 1991.
17. Healthy Start Vitamin Supplements: A mini guide for health professionals. Department of Health, 2009

APPENDIX A: Incidence of vitamin D deficiency in under fives 2009-10

Results of 2009-2010 survey of cases of children under five treated for vitamin D deficiency, with vitamin D level below 10µg/L

PCT	BCH	BHH	City	Total by PCT	Total under fives population	Incidence Rate
HoB	6	1	5	12	24,728	49/100,000
BEN	3	3	0	6	31,613	19/100,000
South	3	0	0	3	21,550	14/100,000
Birmingham total				21	77,891	27/100,000

APPENDIX B

Calculations

Cost per bottle of Healthy Start tablets for women = **82p**

Cost per bottle of Healthy Start children's drops = **£1.61**

Each bottle lasts 8 weeks

To supplement a woman for 82 weeks (30 weeks of pregnancy plus 52 weeks post-natally) = $82 / 8 \times 0.82 = £8.40$

To supplement a child from 4 weeks of age to 4 years of age i.e. 204 weeks = $204 / 8 \times £1.61 = £41.06$

Cost per child per year = £10.27

PCT	Number of live births per year (2008, source: HWBP)	Cost of supplementing during pregnancy and postnatally	Potential reclaims per annum extrapolated from quarterly data from DH on Healthy Start (April-June 2010)	Cost allowing for reclaims
HoB	5,707	£47,938.8	£ 9,526.4 (19.8%)	38,412.8
South	4,728	£39,715.2	£ 7,990.5 (20%)	31,724.7
BEN	6,876	£57,758.4	£ 11,481.72 (19.9%)	46,339.68
Total	17,311	£145,412.4	£28,998.6	

a. Cost of supplementing all women = £145,412.4 - £28,998.6 = £116,413.8 per annum

b. Cost of supplementing 10% of women in South and BEN, and 25% in HoB

$0.1 \times (31,724 + 46,339.68) + (38,412.8 \times 0.25) = 7806.368 + 9603.3 = £17,409.6$

PCT	Number of children aged under 4	Costs of supplementing per PCT per annum	Potential reclaims per annum, extrapolated from quarterly data from DH on Healthy Start (April-June 2010)	Cost allowing for reclaims
HoB	21,008	£215,647.12	£55,509.44 (25.7%)	160,137.68
South	22,670	£232,820.9	£46,560.04 (20%)	186,260.86
BEN	24,931	£256,041.37	£66,902.84 (26%)	189,138.53
Total	68,609	£704,509.39	£ 168,972.32	

c. Cost of supplementing all children under 4 =
 $£704,509.39 - £168,972.32 = £535,537.07$ per annum

d. Cost of supplementing 10% of children in South and BEN, and 25% in HoB=
 $0.1 \times (186,260.86 + 189,138.53) + (0.25 \times 160,137.68) =$
 $37,539.939 + 40,034.42 = £77,574.359$

e. Cost of delivery of supplements:

If HoB continues with current 60 venues (to exclude pharmacies, as these incur extra costs), and South and BEN add 15 each, deliveries are required to 90 venues. If Devon Street continues to provide this service, cost would be = **£8,000**

Total cost if 100% take up = a + c + e = **£659,950.87** per annum

Cost if 10% take up in BEN and South, plus 25% take up in HoB = b+d+e = **£102,984**

Assume 25 % take up = (a + c)/4 + e = **£164,988** per annum