Vitamin D Management in Children

NOTTINGHAMSHIRE GUIDELINES ON THE PREVENTION, DIAGNOSIS AND MANAGEMENT OF VITAMIN D DEFICIENCY IN PRIMARY CARE

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V4.0 Last updated: 05/2024

Review date: 05/2027

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Appendix 1: Clinical features and risk factors for vitamin D deficiency or insufficiency

Box 1: Symptoms and clinical features of vitamin D deficiency in children and young people

- Suspected rickets: swollen ankles/wrists, rachitic rosary (swelling of the costochondral junctions), progressive bowing of legs, progressive knock knees, craniotabes (skull softening with frontal bossing and delayed fontanelle closure), delayed tooth eruption and enamel hypoplasia.
- Suspected osteomalacia: persistent bone pain, muscle pain, proximal muscle weakness causing difficulty climbing stairs or rising from a chair, delayed walking, or waddling gait.
- Radiological features of pathological fracture.
- Hypocalcaemic seizures (usually in infancy).
- Tetany due to low serum calcium.
- Infantile cardiomyopathy.
- Incidental investigation finding (osteopenia, low serum calcium or phosphate, high Alk Phos).

Table 1: Risk factors for vitamin D deficiency

Inadequate UVB light exposure	Inadequate dietary intake or absorption	Metabolic factors
 Pigmented skin (non-white ethnicity). Lack of sunlight exposure or atmospheric pollution. Skin concealing garments or routine use of sun protection factor 15 or above. Housebound or indoor living (e.g. care homes). Seasonal. 	 Prolonged breastfeeding, even if mother has sufficient vitamin D level. Vegetarian (or other fish-free diet). Exclusion diets e.g. milk allergy. Malabsorption (e.g. coeliac disease, Crohn's disease etc.). Short bowel. Cholestatic liver disease, jaundice. Children and young people with family members with proven vitamin D deficiency. 	 Co-prescribed drugs with potential to affect vit D levels e.g. antacids, anticonvulsants (carbamazepine, oxcarbazepine, phenobarbital, phenytoin, primidone and valproate), calcium channel blockers, cholestyramine, digoxin, glucocorticoids, highly active antiretroviral treatment (HAART), isoniazid, orlistat, rifampicin, sucralfate, thiazide diuretics. Severe liver disease/failure. Chronic/end stage renal disease. Cystic fibrosis. Pregnancy or breast feeding. Obesity with BMI>30kg/m² (vitamin D trapped in adipose tissue).

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Appendix 2: Patient information about vitamin D and lifestyle advice

Link to printable local patient information leaflet: Notts APC website / Patient Info / Vitamin D - Patient information leaflet

Advice on lifestyle measures to maintain and prevent low vitamin D levels consist of:

- safe sun exposure
- self supplementation
- dietary advice

Advice on safe sun exposure:

From late March/early April to the end of September, most children above the age of 5 years should be able to get all the vitamin D they need from sunlight (same as adults). The body creates vitamin D from direct sunlight on the skin when outdoors exposing minimum of face/hands/forearms WITHOUT sunscreen. The sunlight exposure time should be less than the time taken to redden or burn (in Caucasian children approx. 10 minutes but the exact time will depend on skin pigmentation, pollution, age). If children have sun-sensitive conditions or are using medication which may predispose this, exposure should be restricted as per dermatologist advice. Between October and early March there is not enough sunlight to produce enough vitamin D in the skin and it is difficult to get the recommended daily intake from diet alone. Therefore, to prevent deficiency, children over the age of 5 years and young people should be advised daily supplementation of vitamin D during winter months, unless advised all year round supplementation by the healthcare professional. See <u>Vitamin D</u>: welcome to the 'sunlight zone' for advice on how to get vitamin D from sunlight.

Advice on supplementation of vitamin D in babies, children, and young people – see <u>appendix</u> $\underline{3}$

Advice on dietary sources of vitamin D:

Diet can provide only 10-15% of recommended vitamin D intake. Vitamin D can be found in a small number of foods including:

- formula milk,
- egg yolks,
- fortified foods such as most fat spreads, soy yogurts, soy milk, almond milk, some orange juices and some breakfast cereals,
- liver,
- mushrooms,
- oily fish such as salmon, sardines, herring, and mackerel,
- fresh or canned tuna,
- red meat,
- ricotta cheese.

In the UK, dairy products from cows' milk are not routinely fortified, so are not regarded as good sources of vitamin D but are great dietary sources of calcium.

More information for patients is available on the following websites:

- NHS Website Vitamin D
- Royal National Orthopaedic Hospital: Vitamin D in children
- The Association of UK Dietitians: Vitamin D
- Osteoporosis: Nutrition for bones (theros.org.uk)
- Royal College Obstetrics and Gynaecologists: Healthy eating and vitamin supplements in pregnancy

V4.0 Last updated: 05/2024

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Appendix 3: Vitamin D products for maintenance / prevention available without prescription

Patients should buy vitamin D supplements unless they meet one of the specific vitamin D exception criteria in the NHS England guideline: <u>Conditions for which over the counter items should</u> not routinely be prescribed in primary care (on pg. 17).

Note that maintenance or preventative supplementation is not an exception for vitamin D prescribing. Exceptions to self-care are also listed in the <u>local ICB vitamin D position statement</u>.

Prescriptions for vitamin D should be reserved for the treatment of patients with confirmed deficiency or insufficiency that require **treatment** with loading doses. **Subsequent maintenance doses should then be purchased over the counter.**

Vitamin D supplements or vitamin drops containing vitamin D for children (including those suitable for young children under the age of 5 years) are available to buy at most pharmacies, supermarkets, and some discount stores and patients should be advised to purchase those. Advise families to check vitamin D strength as this may be relatively low in multivitamin or combined preparations. Women and children who qualify for Healthy Start scheme can get free supplements containing the recommended amounts of vitamin D (see below for more info).

Products and supplements available over the counter are suitable for prophylaxis and prevention of deficiency during winter, as well as, all year round maintenance therapy if required.

Age group	Daily vitamin D dose recommended for prevention and maintenance	
Newborn up to 1 year old (including	8.5-10 microgram (340-400 units) daily all year round.	
exclusively and partially breastfed infants receiving less than 500ml of formula milk a day)	Maximum safe dose recommended for supplementation is 25 micrograms (1,000 units) a day.	
Babies who have more than 500ml of formula milk a day	No additional vitamin D supplementation required – as the formula milk is already fortified with vitamin D.	
Children aged 1-4 years	10 microgram (400 units) daily all year round.	
	Maximum safe dose recommended for supplementation is 50 micrograms (2,000 units) a day.	
From age of 5-18 years	10 microgram (400 units) daily during winter months and all year round if presented with at least one risk factor for vitamin D deficiency (e.g. limited sun exposure) or has previously been diagnosed with vitamin D deficiency.	
	Maximum safe dose recommended for supplementation in children 5-10 years old is 50 micrograms (2,000 units) a day.	
	Maximum safe dose recommended for supplementation in young people 11-18 years old is 100 micrograms (4,000 units) a day.	
From 1 month old	25 micrograms (1000 units) daily is regarded as a safe dose and may be recommended for the prevention and maintenance. Supplements containing 25 micrograms (1000 units) may be considerably cheaper to buy than those containing 10 micrograms (400 units) or 20 micrograms (800 units).	

Table 2: Prevention and maintenance doses of vitamin D for children and young people

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Healthy Start vitamins

Healthy Start vitamins (<u>www.healthystart.nhs.uk</u>) for women and children are free of charge for low income families and are available from Sure Start centres and <u>some other health centres</u>. You can also ask your midwife or health visitor for where they are available locally.

Women qualify for free Healthy Start vitamins from the tenth week of pregnancy or if they have a child under four years old, and if she or her family receives any of the following:

- Income Support
- Income-based Jobseeker's Allowance
- Income-related Employment and Support Allowance
- Child Tax Credit (but only if the family's annual income is £16,190 or less)
- Universal Credit (but only if the family earns £408 or less from employment)
- Working Tax Credit (but only if the family is receiving the 4 week 'run-on*' payment)

*Working Tax Credit run-on is the payment received for a further 4 weeks immediately after ceasing to qualify for <u>Working Tax Credit</u>.

Women who are under 18 and pregnant also qualify, even if they do not get any of the above benefits or tax credits.

Some Sure Start centres will also sell them to other customers (at minimal charge), but not all have the facility to take money.

There are two different Healthy Start products:

- Healthy Start **children's** vitamin **drops**. The daily dose of five drops contains: 300 units (7.5 micrograms) of vitamin D3 (as well as 233 micrograms of vitamin A and 20 milligrams of vitamin C). Suitable for vegetarians and free from milk, egg, gluten, soya, and peanut residues. 10ml pack will last for 56 days.
- Healthy Start **women's** vitamin **tablets.** The daily dose of one tablet contains: 400 units (10 micrograms) of vitamin D3 per tablet (as well as 70 micrograms of vitamin C and 400 micrograms of folic acid)

For those people in whom Healthy Start vitamins are not suitable, a range of vitamin D3 supplements are available for purchase over the counter.



Appendix 4: Vitamin D preparations available for prescribing in line with this guideline

- Full treatment course to be prescribed on an acute prescription by brand name.
- To help absorption, vitamin D should be taken with food.
- All products listed below are licensed in the UK, although dosing in children may be off-label.

Table 3: Recommended vitamin D preparations for correction of vitamin D level with high dose treatment/loading regimens in deficiency/insufficiency

Age	Once a week dosing for 8 weeks	Total cost of full course	Daily dosing for 8 weeks	Total cost of full course
Below 6 months	InVita D3 25,000 unit/1ml oral solution unit dose ampoules sugar free DOSE: 1 ampoule once a week for 8 weeks Total qty to be prescribed: 8 ampoules	£11.86	Thorens 10,000 unit/1ml oral drops DOSE: 0.3ml (15 drops) once a day for 8 weeks (3,000 units daily) Total qty to be prescribed: 20ml	£11.70
6 months – 12 years	InVita D3 50,000 unit/1ml oral solution unit dose ampoules sugar free DOSE: 1 ampoule once a week for 8 weeks Total qty to be prescribed: 8 ampoules	£16.64	Thorens 10,000 unit/1ml oral drops DOSE: 0.6ml (30 drops) once a day for 8 weeks (6,000 units daily) Total qty to be prescribed: 40ml	£23.40
	InVita D3 25,000 unit/1ml oral solution unit dose ampoules sugar free DOSE: 2 ampoules (50,000 units) as a single dose, once a week for 8 weeks Total qty to be prescribed: 16 ampoules	£23.72		
Over 12 years	InVita D3 25,000 unit/1ml oral solution unit dose ampoules sugar free DOSE: 3 ampoules (75,000 units) as a single dose, once a week for 8 weeks Total qty to be prescribed: 24 ampoules	£35.58	Thorens 10,000 unit/1ml oral drops DOSE: 1ml once a day for 8 weeks (10,000 units daily) Total qty to be prescribed: 60ml	£35.10

ADDITIONAL PRODUCT INFORMATION:

InVita D3 oral solution unit dose ampoules sugar free - not licensed for under 18 years old, gelatin free, suitable in peanut, soya allergy, suitable for vegetarians, Kosher and Halal certified.



Patients simply 'snap' the top off the ampoule... and 'squeeze' the full contents into their mouth before swallowing

Thorens 10,000 IU/ml oral drops - licensed in paediatric population, treatment doses are off-label, gelatin free, suitable in peanut, soya allergy, suitable for vegetarians, Kosher and Halal certified.

There is currently no licensed oral vitamin D preparation available that would be suitable for a vegan diet. There are unlicensed products available that may be suitable, please see the Specialist Pharmacist Service document <u>"Choosing an oral vitamin d preparation for vegetarians or vegans"</u> for more information.

Note:

- Activated preparations of Vitamin D such as alfacalcidol or calcitriol are NOT indicated for the treatment of simple vitamin D deficiency.
- Combination preparations of vitamin D/calcium are not required to treat vitamin D deficiency however it is important to assess that dietary intake of calcium is sufficient and to supplement where insufficient or where there is documented hypocalcaemia (see hypocalcaemia guideline).

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Table 2: Maintenance and prevention of deficiency

Products listed below are only to be prescribed if the patient meets the exception criteria listed in the <u>local position statement</u> e.g. the patient has bone disease, or at risk of vitamin D deficiency or malabsorption secondary to chronic condition or surgery (excluding bariatric surgery). All other patients should be advised to **purchase** a vitamin D supplement which will provide 400 to 1000 IU (10-25 micrograms) per day (click <u>here</u> for patient information leaflet). – see <u>appendix 3</u>.

PRODUCT Prescribe by brand name	Dose	Cost per pack (NHS)	Pack size	Monthly cost (NHS)	Allergy / dietary info
ValuPak Vitamin D3 1000 units tablets (food supplement)	One to be taken daily	£0.75	60	£0.35	Food supplement.
Fultium D3 drops 2,740 units/ml	6 drops once a day (400 units= 10 micrograms)	£10.70	25ml	Approx £1.26	25ml provide 6 months supply (1025 drops per bottle). Shelf life once opened is 6 months. POM. Licensed from birth. Suitable for a vegetarian diet and Kosher and Halal certified.
Abidec Multivitamin Oral Drops	Under 1 year old: 0.3ml once daily (200 units vitamin D) 1-12 years old: 0.6ml once daily (400 units vitamin D)	£4.32	25ml	Approx £1.48 or £2.95	GSL. Licensed product only for under 12 years old patients. Not suitable for children with peanut or soya allergy. Suitable for a vegetarian diet.
Dalivit Multivitamin Oral Drops	Under 1 year old: 0.3ml (7 drops) once daily (200 units vitamin D) Over 1 year old: 0.6ml (14 drops) once daily (400 units vitamin D)	£7.69 £13.11	25ml 50ml	Approx £2.29 to £5.38 50ml pack is more cost effective	GSL. Licensed product. Not suitable for children with intolerance to some sugars. Suitable for children with peanut or soya allergy. Suitable for a vegetarian diet.

Colecalciferol is derived from lanolin (wool fat). Products originating from wool fat are not suitable for vegan diet - there are no licensed vitamin D preparations which are suitable for vegans. Some products contain vitamin D derived from the wool of live sheep, and those are considered suitable for vegetarian diet. Please see the Specialist Pharmacist Service document "<u>Choosing an oral vitamin D</u> <u>preparation for vegetarians or vegans</u>" for more information.

SECONDARY CARE RAPID HIGH DOSE TREATMENT / RAPID LOADING REGIMEN – not to be implemented within Primary Care – for information only

For clinical reasons vitamin D loading regimens within the Secondary Care in the local trusts may vary from the dosing route or intervals specified in this guideline. The alternative options may include:

a) High dose oral treatment: higher single oral doses can be given instead of daily or weekly dosing e.g. daily dose x 30 given as one single dose (mainly used in older children, where compliance may be an issue).

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b) Vitamin D Stoss Therapy: a high dose vitamin D therapy given intramuscularly in a single dose (secondary care only).

Advantages:

- compliance is not an issue
- faster improvement in biochemical marker (4-7 days), compared with daily dose (2-3 weeks)
- overcome malabsorption problems

Disadvantages:

- IM injection (needle phobia issues)
- some concerns regarding risk of intoxication (In the context of confirmed vitamin D deficiency there is no evidence of increased risk of vitamin D intoxication with the single high doses suggested below)

IM doses over the age of one month:

1 month up to 6 months:	Ergocalciferol 150,000 units
6 months up to 12 years:	Ergocalciferol 300,000 units
12 years and over:	Ergocalciferol 500,000 units

Maintenance Stoss therapy:

In older children and adolescent patients with poor compliance, a maintenance treatment can be given over winter period to prevent the relapse of vitamin D deficiency.

Doses: Two (IM) doses of 100,000 units. First dose at the beginning of autumn (Oct) and second dose 3 months later (Jan).

References and further resources:

- Guide for Vitamin D in Childhood, Royal College of Paediatrics and Child Health. October 2013
 https://www.rcpch.ac.uk/resources/vitamin-d-infants-children-young-people-guidance
- Vitamin D and Bone Health: A practical clinical guideline for management in children and young people, National Osteoporosis Society. December 2018 <u>ros-vitamin-d-and-bone-health-in-children-november-2018.pdf (theros.org.uk)</u>
- NICE CKS: Vitamin D deficiency in children. Last revised in November 2016. https://cks.nice.org.uk/vitamin-d-deficiency-in-children
- NICE PH56: Vitamin D: supplement use in specific population groups. Published: November 2014, last updated: August 2017 <u>https://www.nice.org.uk/guidance/ph56</u>
- NICE NG34: Sunlight exposure: risks and benefits. Published: 09 February 2016 <u>https://www.nice.org.uk/guidance/ng34</u>
- NHS England: Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs. March 2018 <u>https://www.england.nhs.uk/medicines-2/conditions-for-which-over-the-counter-items-should-not-routinely-be-prescribed/</u>