Guidelines on the Diagnosis and Management of Vitamin D Deficiency in Children and Adults

Policy Statement

To ensure the Health Board delivers its aims, objectives, responsibilities and legal requirements transparently and consistently, we will ensure that prescribers have guidance on the appropriate diagnosis and management of Vitamin D deficiency.

Policy Commitment

This guidance is for use in primary and secondary care for infants, children and adults who are either at risk of vitamin D deficiency or with established vitamin D deficiency

Supporting Procedures and Written Control Documents

This guidance (including appendices) covers

- The investigation and management of vitamin D deficiency
- Clinical and cost effective prescribing of vitamin D therapy and the choice of supplements
- An appropriate balance between patient lifestyle, self management and medical treatment

The guidelines are not exhaustive and may not cover every possible clinical scenario and a degree of clinical judgement is required. The prescriber of any treatment is always responsible for outcomes and monitoring.

Other supporting documents are:

• N/A	
Scope	

This guidance applies to all of our staff in all locations including those with honorary contracts

Equality Impact	An Equality Impact Assessment (EqIA) has not been completed
Assessment	

Health Impact Assessment	A Health Impact Assessment (HIA) has not been completed
Policy Approved by	Medicines Management Group
Group with authority to	Medicines Management Group

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approve procedures written to explain how this policy will be implemented		
Accountable Executive	Medical Director [Consultant in Metabolic Medicine]	
or Clinical Board		
Director		
Disclaimer		

<u>Disclaimer</u> If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the <u>Governance Directorate.</u>

Summary of reviews/amendments			
Version Number	Date Review Approved	Date Published	Summary of Amendments
1	Medicines management group 24 September 2015		
2	Medicines management group 21 st January 2016	12 Feb 2016	Revised Dr Datta has co-ordinated the review of V1. V2 now includes licensed preparations only and also incorporates the Calcium/Vitamin D combinations

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AIM

This guidance is for use in primary and secondary care for infants, children and adults who are either at risk of vitamin D deficiency or with established vitamin D deficiency and will advise on the following:

- The investigation and management of vitamin D deficiency
- Clinical and cost effective prescribing of vitamin D therapy and the choice of supplements
- An appropriate balance between patient lifestyle, self management and medical treatment

The guidelines are not exhaustive and may not cover every possible clinical scenario and a degree of clinical judgement is required. The prescriber of any treatment is always responsible for outcomes and monitoring.

This guidance has been updated in 2016 due in recognition of newer Vitamin D preparations and to incorporate UHB guidance on combined calcium and vitamin D preparations.

Algorithms to aid diagnosis, investigation and management for adults and children are provided in the appendices of this document.

1. GENERAL INFORMATION FOR CHILDREN AND ADULTS

- Adequate amounts of vitamin D are needed for bone health. This is normally obtained by a combination of diet and skin exposure to sunlight. Severe prolonged vitamin D deficiency may result in inadequate bone mineralization which manifests as osteomalacia in adults and rickets in children
- Low blood concentrations of vitamin D have been reported to be associated with a wide range of other medical conditions. There is currently no evidence that vitamin D replacement has benefit in the treatment of non-bone related disorders. There has also been a tendency to conflate the issues of public health nutrition, pharmacological dosing with vitamin D and blood testing.
- In Cardiff and Vale UHB vitamin D blood test requests and prescribing have increased significantly in recent years. Widespread testing can be harmful in that the result can "medicalise" otherwise healthy individuals and distract from other medical issues. Unnecessary testing and prescribing is also wasteful of resources.
- Population screening by measuring Vitamin D concentrations is not justified.

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1.1 Risk factors for vitamin D deficiency

Vitamin D deficiency or insufficiency is very common in the UK with some studies suggesting that up to 50% of the UK population are insufficient and 1 in 6 adults having severe deficiency during winter months.

Some individuals are more prone to vitamin D deficiency outlined in Table 1.

Table 1 Risk Factors for Vitamin D Deficiency

Inadequate UV light exposure	Gastrointestinal	Metabolic risk
Occlusive garments	 Vegetarian (or fish- free diet) 	 Older people*
 Pigmented skin Institutionalised or housebound 	 Malabsorption, short bowel or liver disease Cholestyramine use 	 Drugs (Rifampicin, anticonvulsants, antiretroviral therapy, high dose glucocorticoids)
		 Multiple, short interval pregnancies
		 Prolonged breast feeding without vitamin D supplementation

* See DOH advice for individuals aged >65 in section 1.3

1.2 Laboratory Reporting for Vitamin D

Table 2 Laboratory Reporting

Serum 25-hydroxy vitamin D concentration	Vitamin D Status
<30 nmol/L	Deficiency
30-50 nmol/L	Insufficiency
>50 nmol/L	Adequate

Note that assays for 25-hydroxyvitamin D do **not** detect Alfacalcidol or Calcitriol. 25-hydroxyvitamin D measurements are not indicated as a method for measuring treatment outcomes in patients taking these

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preparations. Insufficiency means suboptimal vitamin D levels which can adversely affect bone health, eg secondary hyperparathyroidism or bone loss, but not severe enough to cause osteomalacia or rickets. Note that results were reported in nmol/L from April 2013. To convert results from mcg/L to nmol/L multiply by 2.5.

1.3 Lifestyle Advice and Therapeutic Intervention

80-90 % of vitamin D is derived from sunlight with only 10-20% of vitamin D derived from dietary sources. Lifestyle advice should include information on diet and safe sun exposure.

- Oily fish including trout, salmon, mackerel, herring, sardines, anchovies, pilchards or fresh tuna.
- Cod liver oils and other fish oils are a good source
- Egg yolk contains a small amount
- Some breakfast cereals are supplemented
- Margarine and infant formula have statutory supplementation in the UK, but not cow's milk
- Two or three short sunlight exposures per week (20 minutes) are sufficient to achieve healthy vitamin D levels for most people between April and September in the UK

Over the counter (OTC) vitamin D

Individuals may wish to buy OTC vitamin D and health professionals can discuss this option with patients. There are now many nutritional supplements available from retailers which contain differing strengths of vitamin D.

Vitamin D supplementation in groups at risk of deficiency

In the following groups nutritional supplements are recommended by Department of Health Guidance, adopted by Welsh Government. Individuals who are not eligible for Healthy Start vitamins should be signposted to OTC preparations.

- All pregnant and breastfeeding women should take a daily supplement containing 400 units (10mcg) of vitamin D
- All infants and young children aged 6 months to 5 years should take a daily supplement containing vitamin D in the form of vitamin drops, to help them meet the requirement set for this age group. This requirement can be met with 5 drops per day of Healthy Start Vitamins (contains 300 units vitamin D and 700

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units vitamin A). However, those infants who are fed infant formula will not need vitamin drops unless they are receiving less than 500ml of infant formula a day, as these products are fortified with vitamin D. Breastfed infants may need to receive drops containing vitamin D from one month of age if their mother has not taken vitamin D supplements throughout pregnancy.

- Older people aged 65 years and over and those who have little or no exposure to the sun should take a daily supplement containing 400 units (10mcg) of vitamin D
- Healthy Start vitamins are specifically formulated for the following groups:

Women's vitamin tablets for pregnant and breastfeeding women Children's vitamin drops for children under 4 years.

These vitamins are available free to healthy start recipients. People on low incomes can register for Healthy Start online <u>http://www.healthystart.nhs.uk</u>

Registered individuals will receive a vitamin coupon every 8 weeks that can be exchanged for vitamins through the health visitor, midwife or through a community clinic. For further information people should contact their midwife or health visitor. **Healthy Start vitamins are not available to buy or via prescription.**

In the absence of specific clinical concern, individuals in these groups do NOT routinely need laboratory testing for blood vitamin D concentrations.

Particular attention should be paid to pregnant women and children who have darker skin and/or may not be exposed to sunlight, where the risks of the clinical consequences of vitamin D deficiency are greater.

1.4 Repeat Testing for Vitamin D

Repeat blood testing for vitamin D is only required for a small number of clinical indications. There is usually no need to monitor blood vitamin D blood levels in patients on supplements, unless there are particular circumstances as below. Therefore the laboratory will review all requests for <u>repeat</u> blood vitamin D tests and will only process those that meet these guidelines. For repeat tests that are not processed, a report will be sent to the clinical requestor and the sample stored for up to 1 week so that the laboratory can be contacted if there are special clinical indications for individual cases.

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Patients taking treatment doses of vitamin D should have serum calcium measured periodically and testing after 1 month is recommended.

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Table 3 Retesting Vitamin D Levels During Treatment

	Clinical Situation	Recommendation
1.	No clinical signs and symptoms	Do not test/retest unless otherwise clinically indicated <i>e.g.</i> as in 4.
2.	Vitamin D therapy for whatever clinical indication where baseline Vitamin D concentration was adequate	Do not retest, unless otherwise clinically indicated <i>e.g.</i> as in 4.
3.	Vitamin D therapy for whatever clinical indication where baseline Vitamin D concentration was low	Do not retest, unless patients symptoms have not resolved or otherwise clinically indicated <i>e.g.</i> as in 4. Repeats will not be allowed before
		3 months. All requests for repeat measurement will be reviewed. Clinical indication for repeat testing should be clearly mentioned on the request form
4.	 Vitamin D therapy and patient in one of the following categories (usually in conjunction with secondary care): Osteoporosis Malabsorption (to include cystic fibrosis and coeliac disease) 	Repeat after 3-8 months on recommended replacement dose where baseline was low. Annual monitoring for patients on adequate replacement.
	 Chronic hepatic and renal disease Taking anticonvulsants or similar medications Children with clinical rickets 	Repeats will not be allowed before 3 months. All requests for repeat measurement will be reviewed. The clinical indication for repeat testing should be clearly mentioned on the request form.

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2. DIAGNOSIS AND MANAGEMENT IN CHILDREN

An algorithm to aid diagnosis, investigation and management is provided in Appendix 1

2.1 Clinical Features of Vitamin D Deficiency in Children

Table 4 Clinical Features of Vitamin D Deficiency in Children

- Deformed bones (bow legs or knock knees)
- Poor growth, delayed fontanelle closure
- Delayed walking or a waddling gait
- Tender or swollen joints, classically the wrists or costochondral junctions
- Bone pain and tenderness
- Delayed eruption of teeth or enamel hypoplasia
- Carpopedal spasm, seizures or irritability
- Breathing difficulties (apnoea or stridor)

2.2 Investigation and treatment in infants, children and young people

- Daily supplements of up to 400 units (10 mcg) vitamin D are safe on an ongoing basis and should be used in at risk groups (see Table 1) *without* the need for blood tests. Healthy Start Vitamins are available for those eligible. (Section 1.3)
- Population screening by measuring vitamin D concentrations is not justified
- All children with suspected metabolic bone disease, with relevant clinical features should have their vitamin D levels measured. If a child has clinically manifest metabolic bone disease, siblings and other family members are also likely to require clinical assessment.
- If clinician elects to do blood tests due to increased clinical concern of metabolic bone disease then measure: Vitamin D, renal, liver and bone profiles, PTH, FBC, coeliac screen.
- Wrist X ray if there is clinical concern of rickets e.g. bow legs or wrist swelling or tenderness

Therapeutic intervention for vitamin D deficiency is outlined in Table 5

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Table 5 Treatment in Infants, Children and Young People

Vitamin D	Age	Product choice	Treatment Dose		Notes
Status	- 5-				
Deficiency < 30 nmol/L	0 - 18 years	InVita D3 oral solution (Colecalciferol) 25,000 units per ml 1ml oral ampoule	25,000 units once weeks for six we three doses) This course may b if clinically indicate	eks (i.e.	Does not contain gelatin or peanut oil. Suitable for vegetarians. Can also be taken by mixing with a small amount of cold or lukewarm food immediately prior to use. £4.45 per course. Licensed for all ages
	Over 12 years	Stexerol D3 (Colecalciferol) 25,000 unit tablets	25,000 units once weeks for six we three doses) This course may b if clinically indicate	eks (i.e. be repeated	Does not contain gelatin or peanut oil. Suitable for vegetarians. Halal & Kosher approved. Tablets are crushable £4.25 per course. Licensed for over 12yrs only
	Over 12 years	Stexerol D3 (Colecalciferol) 1,000 unit tablets	2,000 units daily f weeks. This course may b if clinically indicate	be repeated	Does not contain gelatin or peanut oil. Suitable for vegetarians. Halal & Kosher approved. Tablets are crushable. Licensed for over 12yrs only. £8.26 per course
Once defic	ciency	corrected remer	nber to switch	n to long	term maintenance dose
Vitamin D	Age	Product choice	Treatment Dose	Notes	
Status					
Insufficiency 30-50 nmol/L Or	0-18 years	Healthy Start Vitamins	5 drops per day	300 units v	ontain gelatin or peanut oil. Contains itamin D and 700 units vitamin A. o recipients of Healthy Start Vouchers
Maintenance dose following loading dose for treatment	1-18 years	InVita D3 2,400 units per ml (36 drops per ml) 10ml bottles	9 drops daily ¹	or gelatin. opened bot	itamin D. Does not contain peanut oil Suitable for vegetarians. Use each ttle within 3 months. £2.47 per month. 10ml bottle). Licensed for all ages
of deficiency	Under 1 year	InVita D3 2,400 units per ml (36 drops per ml) 10ml bottles	6 drops per day	or gelatin. opened bot	itamin D. Does not contain peanut oil Suitable for vegetarians. Use each ttle within 3 months £1.65 per month 10ml bottle). Licensed for all ages
	Under 1 year old		0.3mls per day		eanut oil, but not gelatin. Contains itamin D and 666 units vitamin A. nonth
	Under 1 year old		0.3 mls per day		ontain peanut oil or gelatin. Contains itamin D and 2500 units vitamin A. nonth
	Under 1 year	InVita D3 oral solution 25,000 units per ml 1ml	25,000 units once every 8 weeks	gelatin or p	t dosing option. Does not contain eanut oil. Suitable for vegetarians. e taken by mixing with a small

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	oral ampoule	0.6mls per day	amount of cold or lukewarm food immediately prior to use. £0.74 per month. Licensed for all ages
Over 1 year old	Abidec		400 units vitamin D and 1333 units vitamin A. £1.63 per month
Over 1 year old	Dalivit	0.6 mls per day	400 units vitamin D and 5000 units vitamin A. \pounds 1.70 per month
Over 1 year	InVita D3 oral solution (Colecalciferol) 25,000 units per ml 1ml oral ampoule	25,000 units once every 6 weeks	Intermittent dosing option. Does not contain gelatin or peanut oil. Suitable for vegetarians. Can also be taken by mixing with a small amount of cold or lukewarm food immediately prior to use. £0.99 per month. Licensed for all ages
Over 12 years	Stexerol D3 (Colecalciferol) 1,000 unit tablets	1,000 units daily ¹	Does not contain gelatin or peanut oil. Suitable for vegetarians. Halal & Kosher approved. Tablets are crushable. £2.95 per month. Licensed for over 12yrs only

N.B. These doses may be inadequate for breastfed babies with low vitamin D stores at birth, it may be appropriate for this group to receive drops containing vitamin D from one month of age if their mother has not taken vitamin D supplements throughout pregnancy.

The doses provided in this Table are based on licensed recommendations. There are many guidelines and protocols for treating Vitamin D deficiency/insufficiency in infants, children and young people which recommend differing treatment regimens and doses

Regimens for both daily dosing and intermittent dosing are indicated in this table. The clinician should decide with the individual or family which is more suitable

<u>Separate guidance on Vitamin D supplementation for preterm neonates is available - see 'Vitamin and Mineral supplementation in preterm neonates'. This gives information about supplementation required for preterm neonates depending on the feed they are having.</u>

http://nww.cardiffandvale.wales.nhs.uk/pls/portal/docs/PAGE/CARDIFF_AND_VALE_INTRANET/TRUST_ SERVICES_INDEX/NEONATOLOGY_CP/GIDOCS/FLUIDS_NUTRITION/VITAMIN%20AND%20MI NERAL%20IN%20PRETERM%20%20DEC%20%202015%20FINAL.PDF

¹Consider higher dose for maintenance if clinically required. Please refer to the relevant Summary of Product Characteristics for higher dose recommendations.

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3. DIAGNOSIS AND MANAGEMENT IN ADULTS

An algorithm to aid diagnosis, investigation and management is provided in Appendix 2

3.1 Clinical Features of Vitamin D Deficiency in Adults

Table 6 Clinical Features of Vitamin D Deficiency in Adults

- Bone pain
- Proximal myopathy
- Low bone mineral density +- fracture
- Laboratory features such as hypocalcaemia, hypophosphataemia and increased ALP are often a late presenting feature of vitamin D deficiency

Non-specific symptoms such as tiredness, malaise and depression are usually not caused by vitamin D deficiency and these symptoms rarely resolve with vitamin D supplementation.

3.2 Investigation and treatment in adults

Patient Characteristics	Advice and Management
Healthy, no risk factors, symptom free	No investigations requiredLifestyle advice
Risk factors only	 Lifestyle advice Supplement all pregnant/ breastfeeding women and adults aged over 65 Other individuals with risk factors may choose to take OTC vitamin D*
Risk factors AND clinical features OR	 Lifestyle advice Investigations: FBC, renal and bone profile, vitamin D
Risk factors AND significant risk of osteoporosis e.g. short gut	 Therapeutic intervention (see section on therapeutic intervention below)

Table 7 Investigation and Treatment in Adults

*OTC= over the counter vitamin supplementation. See section 1.3

 In patients with risk factors who present with non-specific myalgia, in whom vitamin D deficiency is likely, it may not be clear if the presenting symptoms are due to vitamin D deficiency. The presence of symptoms in individuals with vitamin D deficiency does not prove a causative effect. At present there is no recommendation to supplement all

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individuals with risk factors; however, a 3 month trial of vitamin D supplementation may be considered. Vitamin D supplementation should be discontinued if commenced in the context of musculoskeletal symptoms, if there is no evidence of benefit despite good compliance.

• Population screening by measuring Vitamin D concentrations is not justified.

Calcium & Vitamin D Recommendation:

See Table 9

1. Supplementation for frail older people and for those who are house bound or living in institutional care:

- The evidence is that supplementation with 1g of calcium and 800 units of vitamin D3 per day will reduce hip fractures
- Swallowing large tablets (eg. Accrete D3) can prove difficult, and preparation of dissolved formulation poses its own problems. Such patients are more likely to accept chewable tablets and these should be considered in this setting
 - Use Evacal D3 one BD

2. Supplementation alongside antiresorptive and bone stimulating therapies for osteoporosis

If patients with osteoporosis are found not to be reliably/regularly consuming at least 700 mg calcium per day, then titrated supplementation with calcium and vitamin D3 is recommended:

 For those with an intake equivalent to less than half a pint of milk per day
 Use Accrete D3 tablet or Evacal D3 chewable tablet one tablet twice a

day. If adherence is likely to be poor encourage increased dairy intake & give Kalcipos D one tablet once daily

- For those consuming the equivalent of half to 1 pint of milk per day Use Kalcipos D one tablet once daily - 600mg calcium plus 800 units of vitamin D3
- For those consuming more than 1 pint of milk per day (or the equivalent in other dairy products) Use Vitamin D alone as per table 8

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Table 8 Treatment in Adults

Status	Product choice	Treatment Dose	Ма	aintenance Dose	Notes	
Deficiency < 30 nmol/L	Stexerol (Colecalciferol) 25,000 unit tablets	50,000 units once weekly for six weeks	25 mo	,000 units every onth ¹	Does not contain gelatin or peanut oil. Suitable for vegetarians. Halal & Kosher approved. Tablets are crushable	
	Or			£17 for treatment course then £1.42 per month		
	Stexerol (Colecalciferol) 1,000 unit tablets Or	4,000 units daily for ten weeks	1,0	000 units daily ¹	Does not contain gelatin or peanut oil. Suitable for vegetarians. Halal & Kosher approved. Tablets are crushable £27.53 for treatment then £2.95 per month	
	InVita D3 oral solution (Colecalciferol) 25,000 units per ml	50,000 units once weekly for six weeks		,000 units every onth ¹	Does not contain gelatin, or peanut oil. Suitable for vegetarians but not vegans. Treatment cost £17.80 then £1.48 per month	
	When oral therapy not appropriate: Ergocalciferol intramuscular injections (on specialist advice)	300,000 units intramuscularly, single dose	int	0,000 units ramuscularly i ce or twice per ar	£9.35 per dose	
C	Once deficiency correct	ted remember to swit	ch to	o long term maint	enance dose	
Status	Product choice	Maintenance dose	e	Notes		
Insufficiency 30-50 nmol/L Or	Stexerol (Colecalciferol) 25,00 unit tablets	25,000 units every 0 month long term ¹	,	for vegetarians. H	gelatin or peanut oil. Suitable alal & Kosher approved. able. £1.42 per month	
maintenance dose following loading dose for treatment of deficiency	Or InVita D3 oral solutior (Colecalciferol) 25,00 units per ml		,	No peanut oil or gelatin. Suitable for vegetarians. £1.48 per month		
	Or	Or				
	Stexerol (Colecalciferol) 1,000 unit tablets	1,000 units daily long term ¹		Does not contain gelatin or peanut oil. Suitable for vegetarians, Halal & Kosher approved. Tablets are crushable £2.95 per month		
	When oral therapy no appropriate:	t 300,000 units intramuscularly on	се	Use on specialist	advice. £9.35 per dose	

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Ergocalciferol	or twice per year ¹	
Ergocalciferol intramuscular		
injections		

- ¹Consider higher dose if:
- Institutionalised or hospitalised individuals
- Dark skinned individuals
- Individuals with limited effective sun exposure due to protective clothing or consistent use of sun screens
- Obese individuals
- Patients being evaluated for osteoporosis
- Use of certain concomitant medications (e.g., anticonvulsant medications, glucocorticoids)
- Patients with malabsorption, including inflammatory bowel disease and coeliac disease

N.B. Please refer to the relevant Summary of Product Characteristics for higher dose recommendations.

Regimens for both daily dosing and intermittent dosing are indicated in this table. The clinician should decide with the individual or family which is more suitable

Table 9 Calcium and Vitamin D Combination Therapy

Name	Formulary status	Vit D	calcium	dose	Monthly cost	Notes
Accrete D3 tablet	1 st line	400 units 10 mcg	600mg	One BD	£2.95 (60)	Film coated tablet, may be broken in half
Evacal D3 chewable	1 st line	400 units 10 mcg	600mg	One BD	£2.92 (56)	Chewable alternative to Accrete D3
Kalcipos D Chewable tablet	2 nd line	800 units 20 mcg	500mg	One daily	£4.21 (30)	In good calcium intake, higher vitamin D content
Adcal D3 dissolve	3 rd line	400 units 10 mcg	600mg	One BD	£4.99 (56)	Soluble option

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To discuss treatment options in adults please contact:

Dr Mike Stone, Consultant Physician, Bone Research Unit, Llandough Hospital. Telephone: 02920 716957

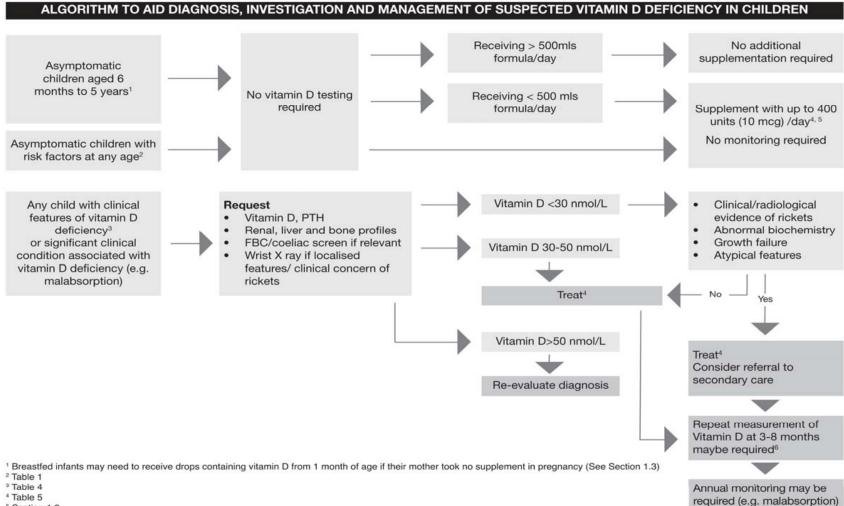
Dr Dev Datta, Consultant Metabolic Physician, Department of Medical Biochemistry, Llandough Hospital <u>Dev.Datta@wales.nhs.uk</u> Telephone: 02920 716844

To discuss treatment options in children please contact:

Dr Justin Warner/ Professor John Gregory, Consultants in Paediatric Endocrinology, or Dr Gilliam Body, Consultant Paediatrician, Noah's Ark Children's Hospital for Wales, UHW.

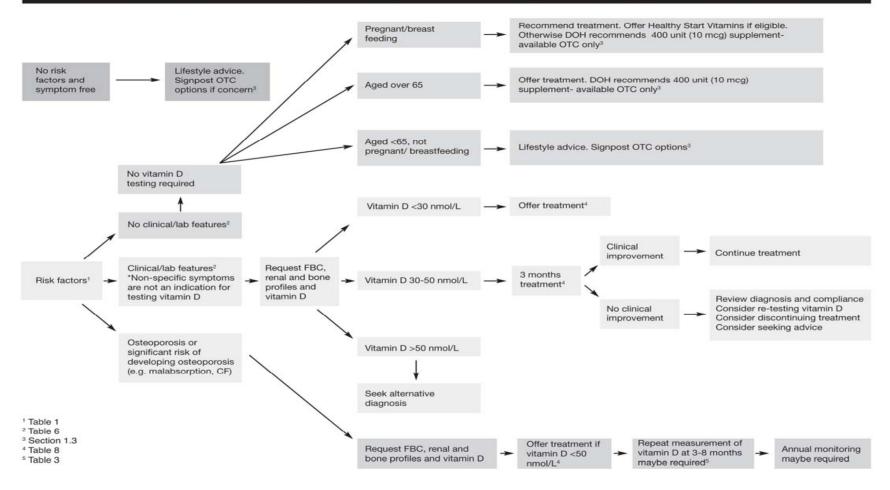
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- ⁵ Section 1.3
- 6 Table 3

ALGORITHM TO AID DIAGNOSIS, INVESTIGATION AND MANAGEMENT OF SUSPECTED VITAMIN D DEFICIENCY IN ADULTS



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