NHS GGC – Vitamin D Supplementation
Frequently asked Questions

In February 2012 the Scottish Government issued advice on supplements for groups at risk of vitamin D deficiency. This advice can be viewed [here](#).

NHSGGC has subsequently published 2 guidelines to aid clinicians in the management of patients who are deficient in vitamin D, who may get insufficient vitamin D from sunlight or diet or have osteoporosis.

**VITAMIN D: Measuring and Prescribing GGC Osteoporosis Subgroup/ Biochemistry Joint Protocol** can be viewed [here](#).

**VITAMIN D Deficiency/ Insufficiency Management for Adult Patients** can be viewed [here](#).

The aim of these guidelines is to assist clinicians in:

- the identification of patients in which there is a robust evidence base for increasing vitamin D levels
- decision making around the most appropriate method of increasing their vitamin D e.g. through increased sun exposure, dietary sources, over the counter vitamin D supplements or prescribed vitamin D supplements

Post publication there have been a number of queries from clinical staff around the practical application of these guidelines. The Prescribing Management Group: Primary Care has reviewed these queries and has, where required, sought consensus from local experts and guideline authors. The publication of these frequently asked questions and patient information leaflet will, it is hoped, pull together these two guidelines and offer practical advice to prescribers.
1. Which products/formulations containing vitamin D are included in the NHSGGC Formulary?

- CALCIUM & VITAMIN D – for patients with osteoporosis unless contra-indicated, prescribe calcium and vitamin D supplementation e.g. Adcal D3, Accrete D3 or Calcichew D3 Forte
- COLECALCIFEROL 800 IU (capsules, tablets) – in the absence of osteoporosis prescribe colecalciferol alone

Licensed vitamin D preparations - also see Appendix 1

**Fultium-D3 800 IU Capsule®** and **Desunin 800 IU tablet®** are licensed preparations containing 800 units (20micrograms) of colecalciferol. It should be noted that these preparations contain double the daily recommended dose of Vitamin D for adults who are considered to be at risk of vitamin D deficiency as outlined in guidance issued from the Chief Medical Officer for Scotland in February 2012.

N.B. The gelatin used in the capsule shell of Fultium-D3 800 IU Capsules is certified to Halal standards. Excipients include Arachis oil (peanut oil): 124.5 mg

Over the counter preparations are inexpensive and are widely available from pharmacies, supermarkets and health food shops. For eligible patients, consider Healthy Start vitamins via the coupon scheme.

Where vitamin D prescribing is indicated, LICENSED calcium/vitamin D preparations or LICENSED colecalciferol preparations should be used first line.

Unlicensed vitamin D preparations (also see Appendix 1)

There are currently no licensed single 400 unit (10micrograms) colecalciferol preparations or high dose colecalciferol preparations available. Clinicians are advised that those listed on clinical systems are unlicensed specials. Costs of specials are variable and can be extremely high.

NHS GGC Specials guidance states "if clinical reason exists for not using licensed product: unlicensed special preparations of colecalciferol capsules/tablets and oral liquids in various strengths are available".

In October 2012 ergocalciferol was removed from the NHS GGC Formulary. ADTC Formulary and New Drugs Committee recognised that low levels of use and unavailability of licensed preparations rendered this product less suitable for general use. It was acknowledged however, that appropriate use of unlicensed preparations might continue in secondary care under specialist supervision.

2. The CMO recommendations state all pregnant women should take a daily vitamin D supplement. Should I issue prescriptions for vitamin D supplements to all pregnant patients?

No.

Explanation

NHS GGC Formulary preparations that contain 800 units of colecalciferol are not licensed for use in pregnancy. At the time of publication there is no licensed, single vitamin D supplement available for supplementation in pregnant women.
First line recommendation – Women eligible for Healthy Start vouchers can get free supplements containing vitamin D. (*Healthy Start women’s vitamin tablets* contain 400 units of vitamin D, 70 milligrams of vitamin C and 400 micrograms of folic acid).

Second line recommendation – For pregnant and breastfeeding women who are not eligible for free vitamins via the Healthy Start coupon scheme, Healthy Start women’s vitamin tablets can be purchased over the counter. There are many other vitamin supplements available that are specially tailored for pregnancy (containing 400 units of vitamin D) and these are widely available to buy in pharmacies and supermarkets.

3. **The CMO recommendations state all infants and young children aged 6 months to 5 years of age take a daily vitamin D supplement. Should I issue prescriptions for vitamin D supplements to all children in this group?**

   No.

   **Explanation**
   Children who are having 500ml or more of formula a day do not need additional vitamin D supplementation.

   First line recommendation – children receiving Healthy Start vouchers qualify for free vitamin supplements from six months old until their fourth birthday. The daily dose of five drops contains: 300 units 7.5 micrograms of vitamin D3, 233 micrograms of vitamin A and 20 milligrams of vitamin C. Healthy Start vitamins are for children from six months old or who are having less than 500ml (one pint) of infant formula a day. Babies under six months old who are fully breastfed or in other high risk groups might benefit from them earlier. For more advice on healthy start click including eligibility please click [here](#).

   Second line recommendation – Not all children are eligible for healthy start vouchers. For children who are not eligible for free vitamins via the Healthy Start coupon scheme, supplements can be purchased over the counter or prescribed. A wide range of inexpensive palatable and chewable children’s vitamin supplements containing appropriate doses of vitamin D are available over the counter at pharmacies and supermarkets.

   N.B Healthy start vitamins should not be prescribed on GP10. Where clinicians consider that prescribing vitamin D is more appropriate for at risk children, Dalivit® drops are included in the [NHSGGC Paediatric Formulary](#) and contain 400 units of ergocalciferol.

4. **The CMO issued guidance detailing high risk groups who should take a daily vitamin D supplement. Should all patients in these groups be treated regardless of symptoms and without checking vitamin D levels?**

   No.

   **Explanation**
   If, as part of a routine review, a patient in one of these groups is identified then daily supplements would be indicated. This would be regardless of symptoms. There is **no need to check vitamin D levels**. Vitamin D 400 - 800 units daily (as detailed in the table below) would be recommended for these patients while they remain in this at-risk category. If patient circumstances change then treatment can be reviewed. Vitamin D 400-800 units daily is a physiological dose and there is **no need to monitor** vitamin D levels.

   N.B Treatment of very frail people with vitamin D should be guided by individual circumstances and co-morbidities and need not follow guideline recommendations.
At risk group as per NHSGGC Vit D insufficiency guidance

<table>
<thead>
<tr>
<th>Treatment advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with vitamin D &lt; 25nmol/l or 25-50nmol/l and symptoms of osteomalacia or osteoporosis present</td>
</tr>
<tr>
<td>See VITAMIN D: MEASURING AND PRESCRIBING in the context of osteomalacia guidance</td>
</tr>
<tr>
<td>Pregnant or breastfeeding women</td>
</tr>
<tr>
<td>See Question 2 above</td>
</tr>
<tr>
<td>Housebound patients aged 65 years and older</td>
</tr>
<tr>
<td>For patients with osteoporosis unless contra-indicated, prescribe calcium and vitamin D supplementation e.g. Adcal D3, Accrete D3 or Calcichew D3 Forte</td>
</tr>
<tr>
<td>In the absence of osteoporosis prescribe colecalciferol tablets/capsules 800 units daily</td>
</tr>
<tr>
<td>Other high-risk asymptomatic patient groups</td>
</tr>
<tr>
<td>Give advice on regular sun exposure dietary sources of vitamin D and over the counter vitamin D supplements (particularly in the winter)</td>
</tr>
</tbody>
</table>

5. The NHSGGC vitamin D deficiency in the presence of osteomalacia/osteoporosis guidance recommends that patients with a history of cardiovascular disease or cerebrovascular disease are commenced on colecalciferol 800 units once daily rather than a combined calcium and vitamin D preparation. Are combined supplements contra-indicated in this patient group?

No.

Explanation
There has been no change in the licensing of combined calcium and vitamin D supplements and there is no need to review your practice population on combined supplements. The MHRA statement can be found by clicking here [MHRA Oct 2011](#). However since the MHRA statement, there has been continued concern and uncertainty around the safety of combined supplements. Local expert consensus was that for newly initiated patients, or during ad hoc review, such patients could be treated with single vitamin D supplement as the risks of continuing calcium supplements in this group were likely to outweigh the benefits. Dietary calcium intake should be optimised if possible particularly for patients on bisphosphonates.

6. Where patients present with symptoms suggestive of osteomalacia, what tests should be done?

- PTH
- ALP
- Calcium
- Vitamin D

All tests can be done in Primary Care including PTH (only lavender topped EDTA specimens will be accepted for PTH analysis). Please ensure that the above are tested and reviewed in patients presenting with symptoms of osteomalacia. Vitamin D levels in
isolation are not a helpful test as the prime aim in giving vitamin D to our patients is to prevent osteomalacia. See also explanation in Q9.

7. If vitamin D has been measured in groups not covered by these guidelines and are found to be insufficient (< 25nmol/l or 25-50nmol/l), is vitamin D treatment always indicated?

No.

Explanation
Asymptomatic patients should not have vitamin D levels measured. Symptomatic patients should not have vitamin D measured in isolation. Local expert consensus was that as the prime aim in giving vitamin D to our patients is to prevent and treat osteomalacia, vitamin D supplementation is only necessary in patients with, or at risk of osteomalacia.

This means that (other than the at risk groups identified in the VITAMIN D DEFICIENCY / INSUFFICIENCY MANAGEMENT FOR ADULT PATIENTS GUIDANCE) vitamin D treatment is only recommended in the following patient groups:

- those with previous fragility fracture
- those with documented osteoporosis (supplement with calcium also)
- those treated with antiresorptive medication for bone disease symptoms suggestive of vitamin D deficiency
- patients with malabsorption such as coeliac, pancreatic insufficiency or chronic liver disease
- patients with chronic kidney disease – discuss with specialist

Where patients are judged not to be at risk of osteomalacia as detailed above, provide reassurance and give advice on maintaining adequate vitamin D levels through safe sunlight exposure and diet. NHS GGC patient information leaflet on vitamin D supplementation could also be provided.

8. Who should receive vitamin D injections and should this be done in primary care?

Only patients with osteomalacia who have been diagnosed with malabsorption syndromes – these patients should be under the care of a secondary care specialist.

Explanation
Oral administration of vitamin D is recommended in NHS GGC. While intramuscular administration results in 100% adherence, there are important factors to consider before usage, including lack of availability of licensed preparations, unpredictable bioavailability, slower onset of repletion and the additional administration burden in comparison to oral preparations.
9. How should I respond to a request from a secondary care specialist asking me to prescribe vitamin D supplements outwith the NHS GGC guidance?

Where requests lie out with the NHS GGC guidance then you may want to discuss the rationale with the requesting clinician.

Explanation
The prime aim in giving vitamin D to our patients is to prevent osteomalacia. Diverse health problems ranging from MS to heart disease, from TB to cancers at various sites have been ASSOCIATED with low levels of vitamin D (and with higher latitude) BUT there is NO or INSUFFICIENT evidence to support a causal link between low vitamin D and any of these problems; furthermore there is no evidence that giving vitamin D alters the incidence of any of these conditions.

10. What information can I give to my “worried well” patients?

NHS GGC prescribing team have produced a patient information leaflet to support this FAQ document. This can be handed to patients to explain who needs vitamin D supplements and which supplements are right for them.

For further information please contact prescribing@ggc.scot.nhs.uk
### Appendix 1 – preparations containing Vitamin D

<table>
<thead>
<tr>
<th>Preparation</th>
<th>Pack size</th>
<th>Cost</th>
<th>Licensed status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colecalciferol 20 microgram (800 unit) capsules (Fultium-D_3®)</td>
<td>30 capsules</td>
<td>£3.60*</td>
<td>Licensed</td>
</tr>
<tr>
<td>Colecalciferol 20 microgram (800 unit) tablets (Desunin®)</td>
<td>30 tablets</td>
<td>£3.60*</td>
<td>Licensed</td>
</tr>
<tr>
<td>Adcal D3 chewable tablets (equivalent to 600mg calcium and 400 units of vitamin D)</td>
<td>56 tablets</td>
<td>£3.65*</td>
<td>Licensed</td>
</tr>
<tr>
<td>Accrete D3 tablets (equivalent to 600mg calcium and 400 units of vitamin D.</td>
<td>60 tablets</td>
<td>£2.95*</td>
<td>Licensed</td>
</tr>
<tr>
<td>Dalivit (multivitamin preparation containing 10 microgram (400 unit)</td>
<td>25ml</td>
<td>£3.28*</td>
<td>Licensed</td>
</tr>
<tr>
<td>Colecalciferol 10 microgram (400 unit) capsules (E-D3®)</td>
<td>30 capsules</td>
<td>£78.50*</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Colecalciferol 10 microgram (400 unit) capsules (ColeVit®)</td>
<td>30 capsules</td>
<td>£4.99*</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Colecalciferol 15,000 units/5ml oral solution</td>
<td>12ml</td>
<td>£25.50***</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Ergocalciferol 1.25mg (50,000 unit) capsules</td>
<td>100 capsules</td>
<td>£61.90***</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Ergocalciferol 1.25mg (50,000 unit) capsules (TTO Pack)ª</td>
<td>2 capsules</td>
<td>£5.25***</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Ergocalciferol 7.5mg in 1ml (300,000 unit) injection</td>
<td>1 amp</td>
<td>£9.35**</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Ergocalciferol 15mg in 2ml (600,000 unit) injection</td>
<td>1 amp</td>
<td>£10.84**</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Ergocalciferol 250 micrograms (10,000 unit) tablets</td>
<td>100 tablets</td>
<td>£21.99**</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>Ergocalciferol 1.25mg (50,000 unit) tablets</td>
<td>100 tablets</td>
<td>£30.34**</td>
<td>Unlicensed</td>
</tr>
</tbody>
</table>

* MIMS (accessed online Dec 2013)
** BNF Online – accessed 23rd September 2013
*** Information from Pharmacy Distribution Centre, September 2013
**** Scottish Drug Tariff Specials Dec 2013
# Pre-labelled TTO pack-down from local Production unit