#### **NICE** National Institute for Health and Care Excellence



## Vitamin D: supplement use in specific population groups

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www.nice.org.uk/guidance/ph56

## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

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This guideline partially replaces PH11 and CG62.

## Overview

This guideline covers vitamin D supplement use. It aims to prevent vitamin D deficiency among specific population groups including infants and children aged under 4, pregnant and breastfeeding women, particularly teenagers and young women, people over 65, people who have low or no exposure to the sun and people with dark skin.

For recommendations on vitamin D use in the context of COVID-19, see our <u>COVID-19</u> rapid guideline on vitamin <u>D</u>.

## Who is it for?

- Commissioners, managers and other professionals with public health as part of their remit
- Manufacturers and providers of vitamin D supplements
- Members of the public

## What is this guideline about?

## Introduction

This guideline aims to increase supplement use to prevent vitamin D deficiency among <u>specific population groups</u>, as identified in 2012 by the UK Health Departments (<u>Vitamin D</u> – advice on supplements for at risk groups – letter from UK Chief Medical Officers Department of Health), and in 2016 by the <u>Scientific Advisory Committee on Nutrition's</u> <u>vitamin D and health report</u>).

Vitamin D is essential for skeletal growth and bone health. Severe deficiency can result in rickets (among children) and osteomalacia (among children and adults).

Dietary sources of vitamin D are limited. The main natural source is from the action of sunlight on skin. However, from October to the beginning of April in the UK there is no ambient ultraviolet sunlight of the appropriate wavelength for skin synthesis of vitamin D. National surveys suggest that around a fifth of adults and 8 to 24% of children (depending on age and gender) may have <u>low vitamin D status</u>. (See <u>context</u> for more details.)

The risks and benefits of sunlight exposure (including exposure to prevent vitamin D deficiency) are covered in a separate guideline (see <u>related NICE guidance</u>).

## Definition of supplement

For the purpose of this guideline, a supplement refers to supplements of vitamin D, either alone or contained in multi-vitamin products (including <u>Healthy Start supplements</u>). It includes licensed products available only on prescription or through pharmacies and (unlicensed) food supplements available from a range of pharmacies and retail outlets.

## SACN review

The Scientific Advisory Committee on Nutrition (SACN) reviewed the <u>dietary reference</u> <u>values for vitamin D intake in the UK population</u> in 2016. They recommend that vitamin D supplements are made available for the entire population (4 years old or more) throughout the year. The recommendations should be read in conjunction with the <u>SACN vitamin D</u> and health report 2016.

## **Clinical judgement**

Clinical judgement will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency.

## Who is this guideline for?

The guideline is for: commissioners, managers and other professionals with public health as part of their remit, working within the NHS, local authorities and the wider public, private, voluntary and community sectors. It is also aimed at manufacturers and providers of vitamin D supplements. (For further details, see <u>who should take action?</u>) In addition, it may be of interest to members of the public.

See <u>about this guideline</u> for details of how the guideline was developed and its current status.

## 1 Recommendations

This guideline replaces recommendation 3 in the NICE guideline on maternal and child nutrition.

## Recommendation 1 Increase access to vitamin D supplements

The Department of Health should:

- Work with manufacturers to ensure vitamin D supplements providing the <u>reference</u> <u>nutrient intake</u> (RNI) as recommended by the Scientific Advisory Committee on Nutrition, are widely available for the following <u>specific population groups</u>:
  - infants and children aged under 4
  - pregnant and breastfeeding women, particularly teenagers and young women
  - people over 65
  - people who have low or no exposure to the sun, for example, those who cover their skin for cultural reasons, who are housebound or confined indoors for long periods
  - people with dark skin, for example, people of African, African-Caribbean or South Asian family origin.

Suitable supplements should also be available for people with particular dietary needs (for example, people who avoid nuts, are <u>vegan</u> or have a <u>halal</u> or <u>kosher</u> diet). Supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.

• Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for specific population groups are available on prescription and are listed in the <u>British National Formulary</u>.

- Amend existing legislation to allow <u>Healthy Start</u> vitamins to be more widely distributed and sold. This includes encouraging manufacturers to sell them direct to pharmacies.
- Encourage manufacturers of multivitamin food supplements to include the recommended reference nutrient intake for vitamin D in their preparations.

## Recommendation 2 Clarify existing guidance

Public Health England and the Department of Health should:

- Consider whether there are any risks to infants from taking a supplement containing the RNI when they are consuming more than 500 ml of infant formula per day. Be aware that the complexity of existing advice (based on feeding type and maternal supplementation) may hinder uptake.
- Make it clear which type of supplement most people would benefit from. Be aware that people may be more likely to take a vitamin D-only supplement than one that is combined with calcium. Supplements containing vitamin D and calcium may be harder to swallow and cause side effects such as constipation.

## Recommendation 3 Develop national activities to increase awareness about vitamin D

Public Health England should:

- Lead development of national action to raise the population's awareness of the importance of vitamin D. This should start as soon as <u>existing recommendations on</u> <u>vitamin D</u> have been clarified and made consistent (see recommendation 2). Awareness-raising activities should:
  - Emphasise the importance of <u>vitamin D</u> for good health.
  - Emphasise the limitations of other UK sources of vitamin D (it is only contained in a few foods and sunlight is only effective from the beginning of April to October).
  - Emphasise the importance of a daily supplement providing the <u>reference nutrient</u> <u>intake</u>.
  - Explain existing advice as clearly as possible, particularly if it may be misinterpreted. This includes making clear: what a term such as 'low sun exposure' means; who is covered by 'dark skin'; which women and children are at risk (note that children aged 4 to 5 years are not usually eligible for <u>Healthy Start</u> supplements).
- Let people know where they can get vitamin D supplements free or as cheaply as possible.
- Develop resources that are accessible and easy to adapt for local use by a range of agencies, to ensure a consistent message and to minimise duplication of effort.

## Recommendation 4 Ensure a consistent multiagency approach

Directors of public health should:

- Ensure a consistent, multiagency approach is adopted to improve the vitamin D status of the local population. This should include commissioners and senior managers in local authorities and the NHS, council leaders, elected members, public health teams and voluntary and community organisations. They should:
  - address local needs, as identified by the joint strategic needs assessment and other local data
  - target specific population groups
  - target health, social care and other practitioners in contact with specific population groups
  - work with relevant community and voluntary groups
  - ensure mechanisms are in place to increase the availability and uptake of supplements
  - ensure mechanisms are in place to increase awareness of vitamin D
  - ensure action is <u>culturally appropriate</u> (for example, involve community organisations and develop messages that resonate with the community or take account of any cultural barriers to taking supplements).

# Recommendation 5 Increase local availability of vitamin D supplements for specific population groups

Local authorities should ensure vitamin D supplements containing the recommended <u>reference nutrient intake</u> are widely available by:

- Establishing arrangements with a range of settings to promote and distribute them. This could include local pharmacies, children's centres, midwifery and health visiting services and GP reception areas.
- Considering providing free supplements for specific population groups.
- Encouraging pharmacies and other outlets selling food supplements (such as supermarkets) to stock the lowest cost vitamin D supplements and promote them to specific population groups.

• Ensure improvements in the availability of vitamin D supplements are supported by local awareness-raising activities (see recommendations 9 and 10).

## Recommendation 6 Improve access to Healthy Start supplements

Local authorities should:

- Review current accessibility, availability and uptake of <u>Healthy Start</u> supplements.
- Consider how accessibility, availability and uptake could be improved. For example:
  - Encourage a range of outlets where pregnant and breastfeeding women and families and carers of under-4s may go to stock and promote Healthy Start supplements. This includes high street and supermarket pharmacies, children's centres, schools and clinics with a range of opening times. Many of them should also be accessible by public transport.
  - Consider offering free Healthy Start supplements to all pregnant and breastfeeding women and children aged under 4 years.
  - Encourage pharmacies to sell the Healthy Start supplement to:
    - $\diamond$  pregnant and breastfeeding women and children under 4 years
    - ♦ children aged over 3 who are in 1 of the other specific population groups
    - women planning a pregnancy and women of child bearing age (see recommendation 1).
  - Set up a central point for ordering, storing and distributing Healthy Start supplements across the local authority area. Individual distribution sites should be encouraged to order supplements from the central distribution point, rather than managing their own stock.
  - Consider using an electronic card system to distribute supplements and use the data collected to improve the supply chain and for system monitoring.

## Recommendation 7 Only test vitamin D status if

## someone has symptoms of deficiency or is at very high risk

Health professionals should not routinely test people's vitamin D status unless:

- they have symptoms of deficiency
- they are considered to be at particularly high risk of deficiency (for example, they have very low exposure to sunlight)
- there is a clinical reason to do so (for example, they have osteomalacia or have had a fall).

## Recommendation 8 Ensure health professionals recommend vitamin D supplements

Local authorities, primary care, and clinical commissioning groups should:

• Ensure computerised prompts on vitamin D are integrated into health and social care systems.

- Ensure health professionals recommend and record vitamin D supplement use among <u>specific population groups</u> (and other family members, as appropriate) whenever possible. This could take place during registration appointments with new patients in general practice, flu, other vaccine and screening appointments. It could also take place during routine appointments and health checks including, for example:
  - NHS Health Check
  - diabetes check-ups
  - falls appointments and check-ups
  - health assessments for looked-after children
  - the first contact with someone who is pregnant
  - antenatal and postnatal appointments
  - medicine use and prescription reviews
  - health visitor appointments
  - developmental checks for infants and children.
- Developers of standardised electronic and handheld maternity notes and developers of personal child health records (the 'red book') should:
  - add specific questions about the use of vitamin D supplements.

## Recommendation 9 Raise awareness among health, social care and other relevant practitioners of the importance of vitamin D

Health Education England, Public Health England, clinical commissioning groups, health and wellbeing boards and local authorities should:

- Ensure health and social care practitioners receive information on the following as part of their registration and post-registration training and continuing professional development:
  - the importance of <u>vitamin D</u> for good health
  - sources of vitamin D in the UK (from safe sun exposure, supplements and limited dietary sources)
  - groups <u>at risk</u> of <u>low vitamin D status</u>
  - supplement recommendations for different groups (this should address any confusion about, for example, age groups or the type of supplement to recommend)
  - how to encourage people to start and continue taking supplements (see <u>medicines adherence</u> NICE guideline CG76).
- Ensure health, social care and other relevant practitioners in contact with <u>specific</u> <u>population groups</u> are made aware of the following:
  - local policies and procedures in relation to vitamin D
  - local sources of vitamin D supplements (including Healthy Start)
  - eligibility for <u>Healthy Start</u> vitamin supplements.

# Recommendation 10 Raise awareness of the importance of vitamin D supplements among the local population

Local public health teams, health and social care practitioners and voluntary and community groups working with <u>specific population groups</u> (see <u>who should take action?</u>) should:

- Increase people's awareness of:
  - the importance of vitamin D for good health
  - sources of vitamin D in the UK (from safe sun exposure, supplements and limited dietary sources)
  - specific population groups and the importance of a daily vitamin D supplement for some of those groups
  - local sources of vitamin D supplements (including Healthy Start)
  - eligibility for <u>Healthy Start</u> vitamin supplements
  - sources of further information.
- Adapt any national resources for local use to minimise the risk of inconsistent advice (see recommendation 3).
- Ensure awareness-raising activities meet the needs of all specific population groups. This includes:
  - addressing any misconceptions specific groups may have about their risk
  - working with local practitioners, role models and peers to tailor national messages for local communities to ensure information about vitamin D is <u>culturally</u> <u>appropriate</u>.

- Share vitamin D messages and information with specific population groups using:
  - local newspapers, social media and local radio channels targeted at these groups
  - local shops and businesses
  - community workers, groups and events
  - social establishments
  - nurseries and educational institutions
  - workplaces
  - places of worship
  - local health care establishments, for example, community health facilities, hospitals and urgent care centres.

## Recommendation 11 Monitor and evaluate the provision and uptake of vitamin D supplements

The Department of Health, Public Health England and local authority commissioners should:

- Monitor national and local awareness of, access to, and uptake of, vitamin D supplements among <u>specific population groups</u> (including those covered by <u>Healthy</u> <u>Start</u>).
- Use a range of sources to assess local uptake, for example, orders for supplements and information collected in personal child health records, maternal antenatal notes and computerised prompts (see recommendation 8).
- Use monitoring data to improve activities related to the awareness of, access to and uptake of vitamin D supplements.

## 2 Who should take action?

## Introduction

The guideline is for: commissioners, managers and other professionals with public health as part of their remit working within the NHS, local authorities and the wider public, private, voluntary and community sectors. It is also aimed at the suppliers and providers of vitamin D supplements.

In addition, it may be of interest to people at risk of vitamin D deficiency, their families and carers and other members of the public.

Who should take action?	Recommendation
Clinical commissioning groups	8, 9
Commissioners and senior managers in local authorities and the NHS	4, 5, 6, 8, 9, 11
Council leaders and elected members	4
Department of Health	1, 2, 11
Developers of standardised medical notes	8
Directors of public health	4
Health and social care practitioners	7, 8, 10
Health and wellbeing boards	9
Health Education England	9
Primary care practitioners	8
Public health teams	4, 10
Public Heath England	2, 3, 9, 11
Supplement manufacturers	1

#### Who should do what at a glance

Who should take action?	Recommendation
Voluntary and community organisations	4, 10

## Who should take action in detail

#### Recommendation 1

Department of Health; supplement manufacturers

#### **Recommendation 2**

Public Health England, the Department of Health

#### Recommendation 3

Public Heath England

#### **Recommendation 4**

Council leaders; elected members; directors of public health; public health teams; commissioners and senior managers in local authorities and NHS trusts; and voluntary and community organisations

#### **Recommendation 5**

Local authorities

#### **Recommendation 6**

Local authorities

#### Recommendation 7

Health professionals

#### **Recommendation 8**

Developers of standardised medical notes; developers of personal child health records; health professionals; local authorities; primary care; clinical commissioning groups

#### Recommendation 9

Public Health England; Health Education England; clinical commissioning groups; health and wellbeing boards; local authorities

#### **Recommendation 10**

Local public health teams; voluntary and community groups; health, social care and other practitioners working with <u>specific population groups</u>. This includes: dietitians, district nurses, GPs, health visitors, midwives, nursing assistants, pharmacists, physiotherapists, practice nurses, registered nutritionists and social workers. It also includes people working in nursing or care homes, nurseries, schools, children's centres, and secure settings such as prisons

#### Recommendation 11

Department of Health; Public Health England; local authority commissioners

## 3 Context

## Background

<u>Vitamin D</u> is essential for skeletal growth and bone health. Dietary sources in the UK are very limited and oily fish is the only significant source. Small amounts are provided by egg yolk, red meat and fortified foods, such as formula milks for infants and toddlers, some breakfast cereals and fat spreads (margarine). The major natural source is from skin synthesis following exposure to sunlight.

From October to the beginning of April in the UK there is no ambient ultraviolet sunlight of the appropriate wavelength for skin synthesis of vitamin D. During this time, the population relies on both body stores from sun exposure in the summer and dietary sources to maintain vitamin D status (Scientific Advisory Committee on Nutrition's update on vitamin D 2007).

The National Diet and Nutrition Survey: results from Years 1 to 4 (combined) of the rolling programme for 2008 and 2009 to 2011 and 2012 (Public Health England and Food Standards Agency) shows that vitamin D status is highest among all age groups in the summer months and lowest in the winter. For example, only 8% of adults aged 19–64 had a low vitamin D status in July to September, compared with 39% in January to March. Similarly, around 2% of children aged 4 to 10 years had a low vitamin D status in July to September, compared a low vitamin D status in July to September, compared a low vitamin D status in July to September, compared a low vitamin D status in July to September, compared a low vitamin D status in July to September, compared a low vitamin D status in July to September, compared a low vitamin D status in July to September, compared back a low vitamin D status in July to September, compared back a low vitamin D status in July to September, compared back a low vitamin D status in July to September, compared back a low vitamin D status in July to September, compared back a low vitamin D status in July to September, compared back a low vitamin D status in July to September, compared to 32% in January to March.

Severe vitamin D deficiency can result in rickets among children: there has been concern that rickets may be re-emerging among children in the UK (Pearce and Cheetham 2010). It can also result in osteomalacia (soft bones, among children and adults) and hypocalaemia (low levels of calcium in the blood) in children. In addition, low vitamin D status has been associated with some diseases and other long-term conditions such as osteoporosis, diabetes and some cancers, although the evidence is inconclusive (<u>Update on vitamin D</u>).

## People at risk

The National Diet and Nutrition Survey suggests that almost a fifth of UK adults have a low vitamin D status. This means they have less than 25 nmol/litre of the main circulating form

of vitamin D in their body – 25 hydroxyvitamin D (25[OH]D) ('National Diet and Nutrition Survey: results from Years 1 to 4 (combined) of the rolling programme for 2008 and 2009 to 2011 and 2012').

A newborn baby's vitamin D status is largely determined by the mother's level of vitamin D during pregnancy.

Breast milk is not a significant source of vitamin D. Formula milks for infants have to be fortified with vitamin D (this is voluntary for formula milks for toddlers).

Infants who are exclusively breastfed, or have less than 500 ml a day of infant formula, may not get enough vitamin D to meet their needs. (See NICE guidance on <u>antenatal care</u> and <u>maternal and child nutrition</u>.) Infants from Asian families are at particular risk. The Asian Feeding Survey (<u>Infant feeding in Asian families, 1994–1996</u> Office for National Statistics) found that up to a third of Indian, Bangladeshi or Pakistani children had low vitamin D status at age 2.

People with dark skin are at increased risk of deficiency as their skin is less efficient at synthesising vitamin D. In other words, they need to expose their skin to sunlight for longer to make the same amount of vitamin D as people with paler skin. People of African, African-Caribbean and South Asian family origin, and those who remain covered when outside, are at particular risk. Almost 75% of Asian adults may have low vitamin D status in the winter. (For more details see the expert paper <u>Vitamin D intakes and status</u>.)

Older people are also at increased risk, particularly if they are frail, because they may spend more time indoors and have limited sun exposure.

People who are housebound and others who have limited exposure to the sun all year round (for example, those in prison) are also at increased risk (<u>the SACN update on vitamin D</u>). For example, the National Diet and Nutrition survey suggests that between 10 and 20% of older adults have low vitamin D status. This can increase up to 38% among people living in institutions.

There is substantial variation in vitamin D status across England, with people living in more southerly regions tending to have a better vitamin D status. London is the exception.

The <u>Health Survey for England</u> (NHS Information Centre for Health and Social Care 2010) found that 35% of adults in London had low status compared to the national average of

24%. (For more details see the expert paper 'Vitamin D intakes and status'). This may reflect the higher number of people from the minority ethnic groups at risk of vitamin D deficiency living in London, compared to other parts of England.

### UK recommendations on vitamin D supplements

All UK health departments (for example, see the 2012 Chief Medical Officers' report <u>Vitamin D – advice on supplements for at risk groups</u>) and NICE (see our pathways on <u>antenatal care</u> and <u>maternal and child nutrition</u>) have issued evidence-based guidance on vitamin D supplements for various population groups. They have also provided guidance on how to distribute free <u>Healthy Start</u> supplements (that contain vitamin D) to eligible families.

The 4 UK chief medical officers have also flagged that health professionals could make 'a significant difference' if they ensure those at risk of vitamin D deficiency understand how important the vitamin is and how to get a daily supplement. They say that all at-risk groups should be made aware of how they can obtain the vitamins locally ('Vitamin D – advice on supplements for at risk groups').

The Chief Medical Officers also stress the need to ensure people who may be eligible for the Healthy Start scheme know how they can apply. Note: this scheme provides vouchers that can be used to buy infant formula, cow's milk and plain fresh or frozen fruit and vegetables. People also receive coupons that can be exchanged for vitamin supplements that include the recommended amounts of vitamin D.

Evidence suggests implementation of these recommendations has been limited ('Vitamin D – advice on supplements for at risk groups'). For example, a report commissioned by the Department of Health's Policy Research Programme (<u>Healthy start: understanding the use of vouchers and vitamins</u>) found that parents find it difficult to access Healthy Start vitamins, health professionals do not promote the scheme and eligible families are often unaware of it. It also found that the distribution system is complex, confused and weak, and mothers are not motivated to take the vitamins or to give them to their children.

The cost effectiveness of implementing interventions to prevent vitamin D deficiency also remains unclear. Testing for vitamin D insufficiency has been reported to have increased 2- to 6-fold in recent years and, at approximately £20 a test, is likely to be a considerable cost for the NHS (Sattar et al. 2012). Primary care spending on treatments for vitamin D deficiency rose from £28 million in 2004 to £76 million in 2011 (<u>Treating vitamin D</u>

<u>deficiency</u> GP, 13 February 2012; <u>Prescription cost analysis England 2011</u> Health and Social Care Information Centre). In 2006, it cost an estimated £2500 to treat each child identified with symptomatic vitamin D deficiency (Zipitis et al. 2006).

### How to get vitamin D supplements

Supplements containing vitamin D are available on prescription or for sale from pharmacies or shops. However, there is wide variation in the content and price and some supplements may not be suitable for particular at-risk groups. (For example many multivitamins contain vitamin A, which pregnant women should avoid during pregnancy.)

Healthy Start vitamins tend to be available from health clinics, children's centres, Sure Start centres, outreach programmes or GP surgeries, although there have been national and local supply problems. Manufacturers have not made them directly available to pharmacies.

In 2013, the Chief Medical Officer for England recommended a review of the cost effectiveness of extending the provision of free Healthy Start vitamins to every child. This was due to concerns that 'providing free vitamins to targeted groups has not led to high enough levels of uptake' (<u>CMO's annual report 2012</u>: our children deserve better Department of Health).

Up to April 2013, people not eligible for Healthy Start were able to buy the supplements at a much lower cost than commercial preparations. However, this option was encouraged in only a limited number of areas (<u>Help pregnant women, new mothers and children get their free healthy start vitamins</u> Department of Health). Since April 2013, following a change in health and social care legislation, these supplements can no longer be sold.

## 4 Considerations

The Public Health Advisory Committee (PHAC) took account of a number of factors and issues when developing the recommendations, as follows. Please note: this section does **not** contain recommendations. (See <u>recommendations</u>.)

## Background

- 4.1 The PHAC considered only the implementation of <u>existing</u> recommendations on vitamin D to prevent deficiency. The evidence base on which existing recommendations were made – and the contribution of dietary intake (including fortified foods) and sunlight exposure to <u>vitamin D</u> status – was outside its remit. Whether older adults should take vitamin D alone, or with calcium, was also outside its remit. Members were aware that the Scientific Advisory Committee on Nutrition (SACN) was considering many of these issues. Wherever possible, the guidance is consistent with SACN's advice and ongoing work in this area. NICE is also developing an associated guideline on the benefits and risks of sunlight exposure. It is hoped that these 3 pieces of work will provide the basis for clear, consistent advice to reduce the risk of <u>low vitamin D</u> <u>status</u> among all <u>specific population groups</u>.
- 4.2 A number of fundamental issues hinder the uptake of existing guidance among specific population groups. For example, many health professionals and the public may be unaware that the skin cannot synthesise vitamin D from sunlight during winter months in the UK. They may also be unaware that a balanced diet alone will not provide sufficient vitamin D. In addition, they do not know enough about the importance of vitamin D supplements for specific population groups. The availability of suitable low cost supplements may also be limited – and health professionals and the public may not know where they can get them locally. The PHAC decided that there will only be significant increases in uptake if all these issues are addressed. Members also discussed and made recommendations on other actions to prevent any further confusion about the existing guidance. This includes having a viable distribution policy to reach specific population groups before carrying out

further awareness-raising activities.

### Communications

Advice on the use of vitamin D supplements to maintain good bone 4.3 health has been available since 1991. (Dietary reference values for food energy and nutrients for the United Kingdom. Report of the panel on dietary reference values of the Committee on Medical Aspects of Food Policy Department of Health.) This includes existing recommendations on vitamin D from SACN, the 4 UK chief medical officers and NICE. However, awareness and implementation of the advice has been poor. The PHAC noted that, although existing recommendations are broadly consistent, the complexity of the advice and poor communications may have been the cause of confusion among both health professionals and the public. Members also noted the lack of clarity about who is 'at risk'. For example, health professionals and the public alike may question what constitutes 'a low exposure' to sunlight or 'dark' skin. Similarly, the disparity between those who are eligible for the Healthy Start scheme and the recommendations on vitamin D supplements for women and children appear to be another source of confusion.

## Availability of vitamin D supplements

4.4 The PHAC discussed the importance of increasing the availability of vitamin D supplements for all specific population groups. Members were unable to recommend free supplements for these groups, due to a lack of evidence on the effect that differential costs have on uptake. They did recognise that free provision had contributed to increased uptake in some areas. Members also noted the strong economic case for offering free or low cost supplements to specific population groups to prevent deficiency, when compared to the cost of widespread testing for vitamin D deficiency. They felt it was important to determine the effectiveness and cost effectiveness of providing free supplements to specific population for research on this. Allied to this, the PHAC discussed the potential for confusion among the public if free or low cost supplements were available in some areas but not others. Members agreed that this issue cannot be ignored by

areas considering such a policy.

4.5 Until recently, low cost vitamin D-only supplements containing 100% of the <u>reference nutrient intake</u> were not widely available for sale. The PHAC noted that many vitamin D supplements also contain calcium (which may be poorly tolerated) and that some people may be deterred by the cost of supplements. Members agreed that there is unlikely to be a significant increase in the number of people in specific populations taking a vitamin supplement unless a free or low cost vitamin D-only supplement is widely available. This may be particularly true for lower income groups. The PHAC also noted that there is little point in awareness-raising activities to promote vitamin D supplements if affordable supplements are not widely available.

## Evidence

- 4.6 The evidence reviews identified very little data on how existing guidance on vitamin D supplements has been implemented. The evidence available tends to be relatively poor and usually focuses on groups targeted by the Healthy Start initiative. No evidence was identified for interventions aimed at increasing the uptake of vitamin D supplements among: people aged 65 or older, people who have low or no exposure to the sun, or people who have dark skin. In addition, only very limited information was available on the views of those taking supplements or in specific population groups. The effectiveness of specific interventions was also difficult to determine. For example, it was difficult to quantify the relative impact of: training for health professionals; making vitamin D or Healthy Start supplements more widely available (including the impact of cost); and activities to increase awareness of the importance of taking them among specific population groups.
- 4.7 The evidence on the implementation of existing vitamin D guidance was very limited. As a result, following discussion with PHAC, NICE commissioned an additional review of reviews on effective implementation of a range of public health and clinical guidelines. Several key themes emerged. For example, the PHAC noted that implementation of any health intervention is likely to be more effective if health professionals are made aware of the issue and are prompted to raise it.

Other 'effectiveness' factors include consistent guidance and advice and simple, inexpensive interventions.

4.8 The PHAC noted the importance of ongoing monitoring and evaluation of the availability and uptake of vitamin D supplements among specific population groups, at a national and local level. Members were also aware that data collection may involve using limited resources. Nevertheless, monitoring and evaluation appears to have been insufficient and inconsistent to date and there has been little opportunity to learn from good practice.

## Healthy Start

- 4.9 The limited evidence available points to extremely low uptake of Healthy Start supplements among eligible pregnant and breastfeeding women and children younger than 4 years. One study of 13 primary care trusts across all regions of England reported uptake to be below 10% (Jessiman et al. 2013). Another reported it to be less than 3% (Moonan et al. 2012). Variation between areas suggests that action can be taken to improve uptake. (For example, members discussed increasing the number of outlets providing the supplement and providing training for health professionals.)
- 4.10 The PHAC was aware that uptake of Healthy Start vouchers for infant formula, cow's milk and fruit and vegetables was good (at around 77% of those eligible) (Jessiman et al. 2013). Members noted that this could be because the voucher can be used at a variety of outlets as part of everyday shopping.
- 4.11 The PHAC discussed the need to give people eligible for Healthy Start support a clear explanation of the different benefits gained by taking Healthy Start supplements and consuming the milk, fruit and vegetables provided. Members were concerned that users of the scheme may be unaware of the importance of taking the supplement.
- 4.12 The PHAC was aware that numerous aspects of the system for distributing Healthy Start vitamins may hinder implementation. For example a report commissioned by the <u>Department of Health's Policy</u>

<u>Research Programme Healthy start: understanding the use of vouchers</u> <u>and vitamins</u> identified that senior public health practitioners may spend considerable time administering the scheme. In addition, the order and reimbursement processes are slow and complex, and there are ongoing concerns about shelf-life and storage. The study's authors also reported that the voucher format and the process for getting supplements are confusing for the public.

- 4.13 The PHAC discussed the fact that universal free provision of Healthy Start vitamins can improve uptake, but that without wider action the impact may be limited. One study suggests uptake may almost treble with universal free provision, but only to around 4% for children's drops and 7.7% for women's tablets. Another study showed a year-on-year increase in uptake to 23% for women's tablets and 20% for children's drops when universal free supplementation was supported by action to increase awareness (McGee and Shaw 2013). No studies were identified that compared universal free provision of vitamin D supplements with universal provision of supplements that have to be paid for (albeit at a low cost). This prevented the committee from commenting on the relative benefits of these approaches and members felt that this is an important area for future research.
- 4.14 The PHAC was concerned that most mothers and children at risk of vitamin D deficiency are not eligible for the Healthy Start scheme. The lack of a similar alternative, or the cost of commercial supplements, may deter them from taking a supplement (particularly those from lower income groups). Some areas had made local arrangements to sell Healthy Start vitamins. But health and social care legislation, introduced in April 2013, means this is no longer possible. Furthermore, the Department of Health's existing arrangements with manufacturers mean it is not possible to get Healthy Start supplements from many places where people might expect to find them. (For example, they are not available in high street or supermarket pharmacies.)

## Training

4.15 The PHAC agreed that health, social care and other practitioners in contact with specific population groups need training to provide robust,

consistent advice – and that this is essential if vitamin D supplementation is to increase. But members also recognised that this would have limited impact if the availability of supplements and inconsistencies in current guidelines are not resolved.

### **Cost effectiveness**

- The main question asked in the economic model was: 'What is the most 4.16 cost-effective way of providing vitamin D supplements to specific population groups?'. Because of the focus of the guideline, 'What is the cost effectiveness of vitamin D supplementation among specific population groups?' was a subsidiary question for pregnant and breastfeeding women, and for children under 5 years. Modelling was based on 4 specific population groups: pregnant women and breastfeeding women, children aged under 5 years, people aged 65 or over and people whose skin is darker. There were not enough data to model this question for 'people whose skin is not sufficiently exposed to the sun'. (We do not know how many people in the population this affects, nor the extent of the deficiency among this group.) The cost of giving everyone in each group a daily supplement was compared with the cost of testing everyone and giving vitamin D supplements only to those with an identified deficiency. The model included estimated costs of intervention administration and delivery, based on an intervention in Birmingham (McGee and Shaw 2013).
- 4.17 The economic model found that it is cost saving to give everyone in each group a daily vitamin D supplement, rather than testing them all and supplementing only those who are deficient. It was assumed that the cost of a test is fixed at £16.50.
- 4.18 A potential limitation of the modelling analysis is that it assumes everyone is given a prophylactic supplement without being tested. This may mean that less emphasis is given to finding people who are severely deficient and who may need a higher dose of vitamin D. However, people showing the symptoms of severe deficiency may well be tested. Aspects of this situation are explored in a sensitivity analysis in the <u>cost</u> <u>effectiveness report</u>. The model did not consider any risks associated with taking a supplement containing the reference nutrient intake for

vitamin D. The PHAC agreed that there is a negligible risk associated with taking the prophylactic dose.

- 4.19 The subsidiary analysis looked at increasing the uptake of vitamin D supplements among pregnant and breastfeeding women and children aged 5 years and younger. The estimated cost of supplementation for each additional woman who is pregnant or breastfeeding was £10.15. This resulted in an estimated cost per deficiency averted of £2859. For children aged 5 or younger, the estimated cost of supplementation per additional child was £4.62. This resulted in an estimated cost per deficiency averted of per deficiency averted of £2859.
- 4.20 A limitation of the subsidiary analysis (see 4.19) is that people with a vitamin D deficiency are defined in the model in terms of the symptoms of deficiency, rather than by their vitamin D status. So if someone had a low vitamin D status but did not show any symptoms of deficiency, the model assumed they would not benefit from a supplement. Because people with symptoms of deficiency are likely to be a relatively small subset of those defined as having a low vitamin D status, the model almost certainly overstates the cost of averting a 'deficiency'.

## 5 Recommendations for research

The Public Health Advisory Committee (PHAC) recommends that the following research questions should be addressed. It notes that 'effectiveness' in this context relates not only to the size of the effect, but also to cost effectiveness and duration of effect. It also takes into account any harmful or negative side effects.

All the research should aim to identify differences in effectiveness among groups, based on characteristics such as socioeconomic status, age, gender and ethnicity.

Outcomes for all the questions below may include <u>vitamin D</u> status, user adherence or any unintentional consequences. The recommendations apply to all <u>specific population groups</u>, but there is a particular need for research in people over 65, people with dark skin and people living in institutions.

- 5.1 How effective and cost effective are interventions to increase vitamin D access, uptake, adherence or status among identified specific population groups? Does effectiveness vary by age, gender, ethnicity, socioeconomic or other specific population characteristics (such as depression or a disability)? The following could be considered:
  - availability and uptake of supplements (including the impact of the cost of supplements)
  - type of supplements provided and how that impacts on adherence
  - knowledge and attitudes (of both the public and health and social care practitioners).
- 5.2 How cost effective are preventive approaches to vitamin D deficiency among all specific population groups, compared with the cost of testing and treatment? This should include a comparison of universal provision of free supplements with the provision of low or standard cost supplements for different specific population groups. (If there is any new legislation allowing for the sale of Healthy Start supplements, this would provide an opportunity to test this question.)
- 5.3 How can a multiagency approach to improving awareness, availability

and uptake of vitamin D supplements best be established, improved and sustained? For example, what are the key components, who are the key partners and how does the local context affect effectiveness? The latter may include local population characteristics (such as age, ethnicity or levels of deprivation), setting and the approach to commissioning. Research should be conceived, developed and implemented as a collaboration between academics and local practitioners or the local community.

- 5.4 What type of training and awareness-raising can improve how health and social care practitioners:
  - promote vitamin D supplements among specific population groups
  - improve the local population's awareness of, and attitudes towards, vitamin D supplements
  - uptake of vitamin D supplements?
- 5.5 What is the best way of monitoring the local system for distributing vitamin D supplements? Assessments of methods that enable robust data collection such as computerised data capture systems would be particularly useful. (The aim would be to use that data to improve the service.)

More detail identified during development of this guideline is provided in gaps in the <u>evidence</u>.

## 6 Related NICE guidance

- Physical health of people in prison NICE guideline 57 (2016)
- Sunlight exposure: risks and benefits NICE guideline 34 (2016)
- Falls: assessment and prevention of falls in older people NICE guideline CG161 (2013).
- <u>Behaviour change individual approaches</u> NICE guideline PH49 (2014).
- <u>Skin cancer prevention: information, resources and environmental changes</u> NICE guideline PH32 (2010).
- Weight management before, during and after pregnancy NICE guideline PH27 (2010).
- Maternal and child nutrition NICE guideline PH11 (2008).
- Antenatal care NICE guideline CG62 (2008).
- <u>Postnatal care</u> NICE guideline CG37 (2006).

## 7 Glossary

## At-risk groups

Although the entire UK population is at risk of having a low vitamin D status, these population groups are at higher risk:

- People who have low or no exposure to the sun. For example, those who cover their skin for cultural reasons, who are housebound or confided indoors for long periods.
- People who have dark skin, for example, people of African, African-Caribbean and South Asian origin.

## Culturally appropriate

Culturally appropriate interventions take account of the community's cultural or religious beliefs and language and literacy skills by:

- Using community resources to improve awareness of, and increase access to, interventions. For example, they involve community organisations and leaders early in the development stage, use media, plan events or make use of community-specific festivals.
- Understanding the target community and the messages that resonate with them.
- Identifying and addressing barriers to access and participation, for example, keeping costs low to ensure affordability and taking account of working patterns and education levels.
- Developing communication strategies that are sensitive to language use and information needs. For example, involve staff who can speak the languages used by the community, and provide information in different languages and for varying levels of literacy (for example, using colour-coded visual aids and spoken rather than written information).

- Taking account of cultural or religious values, for example, in relation to body image, separate physical activity sessions for men and women, beliefs and practices about hospitality and food, or dates, days, settings, or timings considered unsuitable for community events or interventions.
- Providing opportunities to discuss how interventions would work in the context of people's lives.
- Considering how closely aligned people are to their ethnic group or religion and whether they are exposed to influences from both the mainstream and their community in relation to diet and physical activity.

### **Dietary reference values**

Dietary reference values is a collective term for reference nutrient intake, estimated average requirement and lower reference nutrient intakes. Dietary reference values reflect the amount of energy and nutrients needed by healthy people according to their age and gender. For certain nutrients, set increments reflect the increased demands associated with pregnancy and lactation.

### Existing recommendations on vitamin D

The <u>UK Health Departments</u>, the <u>Scientific Advisory Committee on Nutrition</u> and NICE have all issued evidence-based guidance on vitamin D supplements for various specific population groups. (See the <u>NICE guideline on antenatal care</u> and <u>maternal and child</u> <u>nutrition</u>.) They have also provided advice on how to distribute free Healthy Start supplements (containing vitamin D) to eligible families.

### Halal

Halal refers to foods or non-food items such as cosmetics or pharmaceuticals permitted by and prepared according to Islamic law.

### Healthy Start

Healthy Start is a UK-wide government scheme that provides a 'nutritional safety net' for pregnant women and families on benefits and tax credits. Women who are at least

10 weeks pregnant and families with children younger than 4 years qualify if the family receives the relevant benefits:

- pregnant women get 1 Healthy Start voucher a week worth £3.10
- babies younger than 1 year get 2 vouchers a week worth £6.20
- children over 1 and under 4 years of age get 1 voucher a week worth £3.10.

Vouchers are posted every 4 weeks. They can be spent on plain cow's milk, plain fresh or frozen fruit and vegetables, or infant formula milk at retail outlets registered to accept them. These include supermarkets, grocery stores, chemists and milk rounds.

Every 8 weeks, beneficiaries get vitamin coupons to swap for Healthy Start vitamins. It is the responsibility of NHS England until October 2015 – and from then on, local areas – to provide or arrange the provision of Healthy Start vitamins. The vitamin tablets for mothers contain folic acid and vitamins C and D. Healthy start vitamin drops for children contain vitamins A, C and D.

### Kosher

Kosher refers to food (or premises where food is sold, cooked or eaten), cosmetics and pharmaceuticals that comply with Jewish law.

#### Low vitamin D status

Low vitamin D status (sometimes called vitamin D deficiency) is defined by the Department of Health as a plasma concentration of 25 hydroxyvitamin D (the main circulating form of the vitamin) of below 25 nmol/litre (equal to 10 ng/ml).

### **Reference nutrient intake**

Reference nutrient intake is the amount of a nutrient needed to meet the needs of 97.5% of individuals in a group. Reference nutrient intake for a given nutrient may vary by gender, age and physiological status (for example during pregnancy and lactation). The reference nutrient intake is not a minimum target that all people need to achieve, but the risk of deficiency is minimised if the average population intake exceeds it.

The current reference nutrient intakes ( $\mu$ g/day) for vitamin D are:

- 10 micrograms of vitamin D per day, throughout the year, for everyone in the general population aged 4 years and older
- 10 micrograms of vitamin D per day for pregnant and lactating women and population groups at increased risk of vitamin D deficiency.

### Safe intake

Safe intakes are different to RNIs. A <u>safe intake</u> is used where there is insufficient evidence to set a RNI. The safe intake is the amount judged to be enough for almost everyone, but below a level that could have undesirable effects.

- a 'safe intake' of 8.5 to 10 micrograms per day for all infants from birth to 1 year of age
- a 'safe intake' of 10 micrograms per day for children aged 1 to 4 years.

All population groups are currently advised to take a supplement that meets 100% of the reference nutrient intake for their age group (as above). The reference nutrient intake for population groups is 10 micrograms/day (1 microgram=40 international units, so 10 micrograms=400 IU).

### Specific population groups

Although the entire population of the UK are at risk of having a low vitamin D status, evidence was only considered in regard to increasing the supplement use for these specific population groups:

- All pregnant and breastfeeding women, particularly teenagers and young women.
- Infants and children under 4 years (breast fed, non-breast fed and mixed fed).
- People over 65.
- People who have low or no exposure to the sun. For example, those who cover their skin for cultural reasons, who are housebound or confined indoors for long periods.
- People who have dark skin, for example, people of African, African–Caribbean and South Asian origin.

All population groups are currently advised to take a supplement that meets 100% of the reference nutrient intake for their age group. The reference nutrient intake levels are noted above.

All infants and young children aged 6 months to 3 years are advised to take a daily supplement containing vitamin D in the form of vitamin drops. But infants who are fed infant formula will not need them until they have less than 500 ml of infant formula a day, because these products are fortified with vitamin D. Breastfed infants may need drops containing vitamin D from 1 month of age if their mother has not taken vitamin D supplements throughout pregnancy. ('Vitamin D – advice for supplements for at risk groups – letter from the UK Chief Medical Officers' Department of Health).

### Vegan

People who follow a vegan diet consume only plant products. They avoid all food, drink and non-food items, such as pharmaceuticals that contain any animal products.

### Vitamin D

Vitamin D is a fat soluble pro-hormone. It is obtained through the action of sunlight on skin and from dietary sources. The action of sunlight (ultraviolet radiation of wavelength 290–310 nm) on skin converts 7-dehydrocholesterol to previtamin D3, which is then metabolised to vitamin D3.

Dietary vitamin D exists as either ergocalciferol (vitamin D2) or cholecalciferol (vitamin D3).

The liver 25-hydroxylase enzymes convert vitamin D2 and D3 (from diet or from the action of sunlight on skin) to the main circulating form of the vitamin, 25 hydroxyvitamin D – also known as 25(OH)D. This is then converted by the kidney and other tissues to the active form of the vitamin 1,25-dihydroxyvitamin D.

# 8 References

Jessiman T, Cameron A, Wiggins M et al. (2013) <u>A qualitative study of uptake of free</u> <u>vitamins in England</u>. Archives of Disease in Childhood 98: 587–91

McGee E, Shaw N (2013) <u>Vitamin D supplementation: Putting recommendations into</u> <u>practice</u>. Journal of Health Visiting 1 (3): 138–43

Moonan M, Hanratty B, Whitehead M (2012) <u>Which is more effective, a universal or</u> <u>targeted approach, to implementing the National Healthy Start Programme? A mixed</u> <u>methods study</u>. Journal of Epidemiology and Community Health 66: A44–5

Pearce SHS, Cheetham TD (2010) <u>Diagnosis and management of vitamin D deficiency</u>. BMJ 340: b5664

Sattar N, Welsh P, Panarelli M et al. (2012) <u>Increasing requests for vitamin D measurement:</u> <u>costly, confusing, and without credibility</u> The Lancet 379 (9811): 95–6

Zipitis CS, Markides GA, Swann IL (2006) <u>Vitamin D deficiency: prevention or treatment?</u> Archives of Disease in Childhood 91: 1011–4

# 9 Summary of the methods used to develop this guideline

### Introduction

The review and economic modelling report include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the Public Health Advisory Committee (PHAC) meetings provide further detail about the Committee's interpretation of the evidence and development of the recommendations.

# Guideline development

The stages involved in developing public health guidelines are outlined in the box below.

- 1. Draft scope released for consultation
- 2. Stakeholder meeting about the draft scope
- 3. Stakeholder comments used to revise the scope
- 4. Final scope and responses to comments published on website
- 5. Effectiveness reviews and economic modelling undertaken and submitted to PHAC
- 6. PHAC produces draft recommendations
- 7. Draft guideline (and evidence) released for consultation
- 8. PHAC amends recommendations
- 9. Final guideline published on website
- 10. Responses to comments published on website

### Key questions

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and were used by the PHAC to help develop the recommendations. The overarching questions were:

1. How effective and cost effective are interventions to increase awareness and implementation of existing guidance on vitamin D among health professionals or others working with specific population groups? What are the implications for professional training and practice?

2. How effective and cost effective are interventions to increase awareness and uptake of existing guidance on vitamin D among specific population groups (with special consideration given to those eligible for the <u>Healthy Start</u> scheme)?

3. What helps or hinders the implementation of existing guidance on vitamin D by

commissioners, providers, practitioners, those working with specific population groups and people in specific population groups?

4. What local provision is made to ensure vitamin D supplements are available for different specific population groups (including Healthy Start, prescriptions and over-the-counter sales)?

These questions were made more specific for the effectiveness review 'Vitamin D: a systematic review of effectiveness and cost-effectiveness of activities to increase awareness, uptake and provision of vitamin D supplements in specific population groups'.

### **Reviewing the evidence**

#### **Effectiveness review**

One effectiveness review was conducted.

#### Identifying the evidence

Several databases were searched in June 2013 for evidence of any type published from 2000 onwards. See review 1: <u>Vitamin D: a systematic review of effectiveness and cost-effectiveness of activities to increase awareness, uptake and provision of vitamin D supplements in at-risk groups for details.</u>

Evidence was also identified through:

- citation searches of papers identified for inclusion
- a search for additional studies by authors of papers identified for inclusion
- a search of identified webpages
- a call for evidence issued by NICE in March 2013.

#### **Selection criteria**

Studies were included in the effectiveness review if they:

- were undertaken in the UK
- addressed at least 1 of the key questions.

Studies were excluded if they focused on:

- the management of vitamin D deficiency or conditions that may increase the risk
- fortification of food and drinks with vitamin D
- vitamin D for different population groups.

See review 1 for details.

#### Review of systematic review

One review of systematic reviews was conducted.

• Review 2 Review of systematic reviews exploring guideline uptake/implementation

#### Identifying the evidence

Several systematic review databases were searched in November 2013 for systematic reviews published from 2004 onwards.

#### **Selection criteria**

Studies were included if they were systematic reviews and addressed at least 1 of the key questions. Studies were excluded if they were not systematic reviews. See <u>review 2</u>.

#### Quality appraisal

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in <u>Methods for the development of NICE public health</u> <u>guidance</u>. A checklist developed by Cardiff University was used for the cross-sectional studies and survey reports. Systematic reviews were assessed using the AMSTAR checklist. Each study was graded (++, +, -) to reflect the risk of potential bias arising from its design and execution.

#### Study quality

++ All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very unlikely to alter.

+ Some of the checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are unlikely to alter the conclusions.

- Few or no checklist criteria have been fulfilled. The conclusions of the study are likely or very likely to alter.

#### Summarising the evidence and making evidence statements

The review data were summarised in evidence tables (see review 1 and review 2).

The findings from the review were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements were prepared by the external contractor (see <u>Supporting evidence</u>). The statements reflect their judgement of the strength (quality, quantity and consistency) of evidence and its applicability to the populations and settings in the scope.

### Cost effectiveness

There was a review of economic evaluations and an economic modelling exercise.

#### Review of economic evaluations

This was conducted as part of the effectiveness reviews (see above).

#### Economic modelling

An economic model was constructed, incorporating data from the reviews of effectiveness and cost effectiveness. The results are reported in: <u>An economic evaluation of</u> <u>interventions to improve the uptake of vitamin D supplements in England.</u>

### How the PHAC formulated the recommendations

At its meetings in September and October 2013, the Public Health Advisory Committee (PHAC) considered the evidence, expert testimony and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of strength and applicability) to form a judgement
- where relevant, whether (on balance) the evidence demonstrates that the intervention or programme or activity can be effective or is inconclusive
- where relevant, the typical size of effect
- whether the evidence is applicable to the target groups and context covered by the guideline.

The PHAC developed recommendations through informal consensus, based on the following criteria:

- Strength (type, quality, quantity and consistency) of the evidence.
- The applicability of the evidence to the populations/settings referred to in the scope.
- Effect size and potential impact on the target population's health.
- Impact on inequalities in health between different groups of the population.
- Equality and diversity legislation.
- Ethical issues and social value judgements.
- Cost effectiveness (for the NHS and other public sector organisations).
- Balance of harms and benefits.
- Ease of implementation and any anticipated changes in practice.

Where possible, recommendations were linked to an evidence statement (see <u>The</u> <u>evidence</u> for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

# 10 The evidence

### Introduction

The evidence statements from 1 review are provided by external contractors (see <u>Supporting evidence</u>).

This section lists how the evidence statements and expert papers link to the recommendations and sets out a brief summary of findings from the economic analysis.

### How the evidence links to the recommendations

The evidence statements are short summaries of evidence, in a <u>review</u>, <u>report or paper</u> (provided by an expert in the topic area). Each statement has a short code indicating which document the evidence has come from.

**Evidence statement number 1.1** indicates that the linked statement is numbered 1 in review 1.

**EM** indicates that the economic modelling report is linked to a recommendation.

Where a recommendation is not directly taken from the evidence statements, but is inferred from the evidence, this is indicated by IDE (inference derived from the evidence).

Recommendation 1: evidence statements 1.11, 1.14, 1.15, 1.16

Recommendation 2: evidence statements 1.10, 2.12; IDE

Recommendation 3: evidence statements 1.1, 1.10, 1.11; 2.12; IDE

Recommendation 4: evidence statements 1.1, 1.3, 1.10, 1.11, 1.14, 1.15, 2.10, 2.13

Recommendation 5: evidence statements 1.1, 1.3, 1.5, 1.7, 1.9, 1.11, 1.14, 1.15, 1.16, 2.10; EM

Recommendation 6: evidence statements 1.1, 1.3, 1.5, 1.7, 1.8, 1.9, 1.11, 1.12, 1.13, 1.14, 1.15,

1.16, 2.2; EM

Recommendation 7: evidence statements 1.7; EM; IDE

Recommendation 8: evidence statements 1.10, 1.11, 2.2, 2.9

**Recommendation 9**: evidence statements 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.10, 1.11, 2.3, 2.4, 2.5, 2.13

Recommendation 10: evidence statements 1.10, 1.11, 1.12, 2.14

Recommendation 11: evidence statement 2.6; IDE

### **Economic modelling**

The economic model addressed the question: 'What is the most cost-effective way of providing vitamin D to <u>specific population groups</u> (pregnant women, children under 5 years, people aged 65 or over and people whose skin is darker)?' There were not enough data to model this question for 'people whose skin is not sufficiently exposed to the sun'.

There were 2 sets of analysis. The first compared the cost of providing each group with a daily supplement (without testing for deficiency) with the cost of testing everyone and giving those with a deficiency a supplement.

The second analysis looked at increasing uptake of supplements among pregnant and breastfeeding women, and among children up to the age of 5.

See <u>An economic evaluation of interventions to improve the uptake of vitamin D</u> <u>supplements in England</u>.

# 11 Gaps in the evidence

The Public Health Advisory Committee (PHAC) identified a number of gaps in the evidence related to the programmes under examination, based on an assessment of the evidence, expert and stakeholder comment. These gaps are set out below.

1. There is a lack of good quality interventions aiming to increase Vitamin D supplement use among <u>specific population groups</u> in England.

2. There is a lack of good quality evidence on the relative impact of the following on the uptake of vitamin D supplements among specific population groups: awareness-raising activities, health professional training and supplement provision.

3. There is a lack of good quality evidence on whether making a free or low cost vitamin D-only supplement available affects uptake among specific population groups.

4. There is a lack of evidence on whether the following affect the effectiveness of interventions to increase vitamin D supplement use among specific population groups: sexual orientation, disability, religion, place of residence, occupation, education, socioeconomic position or a sense of community (or 'social capital').

5. There is a lack of evidence on what strategies may encourage people to take a vitamin D supplement on a regular basis.

6. There is a lack of evidence on whether health professional training leads to more effective interventions to improve uptake of vitamin D supplements among specific population groups.

#### (Source: review 1 and review 2)

The Committee made 5 recommendations for research into areas that it believes will be a priority for developing future guidelines. These are listed in <u>recommendations for research</u>.

# 12 Membership of the Public Health Advisory Committee and the NICE project team

### Public Health Advisory Committee A

NICE has set up several Public Health Advisory Committees (PHACs). These standing committees consider the evidence and develop public health guidelines. Membership is multidisciplinary, comprising academics, public health practitioners, topic experts and members of the public. They may come from the NHS, education, social care, environmental health, local government or the voluntary sector. The following are members of PHAC A:

**Susan Jebb** (Chair) Professor of Diet and Population Health, Department of Primary Care Health Sciences, University of Oxford

#### Core members

**Mireia Jofre Bonet** Professor of Health Economics, City University, London

Alison Lloyd Community Member

**Chris Packham** Associate Medical Director, Nottinghamshire Healthcare NHS Trust

**Toby Prevost** Professor of Medical Statistics, King's College, London

#### Joyce Rothschild

Independent Education Consultant

Vitamin D: supplement use in specific population groups (PH56)

#### Amanda Sowden

Deputy Director, National Institute for Health Research Centre for Reviews and Dissemination, University of York

#### Lucy Yardley

Professor of Health Psychology, University of Southampton

#### **Topic members**

#### Adrian Martineau

Professor of Respiratory Infection and Immunity, Queen Mary University, London

#### Eleanor McGee

Public Health Nutrition Lead, Birmingham Community Healthcare NHS Trust

#### **Colin Michie** Consultant Paediatrician, Ealing Hospital NHS Trust, London

**Judy More** Freelance Paediatric Dietitian and Honorary Lecturer, School of Health Professions, Plymouth University

#### Frances Quinn Community Member

#### Expert testimony to PHAC

Gillian Swan, Diet and Obesity Branch, Public Health England

#### NICE project team

Mike Kelly CPH Director

Jane Huntley Associate Director Vitamin D: supplement use in specific population groups (PH56)

Adrienne Cullum Lead Analyst

Caroline Mulvihill Analyst

Alastair Fischer Technical Adviser Health Economics

Victoria Axe Project Manager (up to June 2014)

Rupert Franklin Project Manager (from June 2014)

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# **Update information**

**August 2017:** The guideline was updated after publication of the <u>SACN vitamin D and</u> <u>health report 2016</u>. We have amended the definition of at-risk groups, updated links to the new report and updated reference nutrient intake details.

**May 2017:** The introduction, recommendations 1 and 6, the context section and the glossary have been updated after publication of the <u>SACN vitamin D and health report</u> <u>2016.</u> The changes have amended specific population age ranges, updated links to the new report and updated reference nutrient intake details.

#### Minor changes since publication

**December 2020:** We clarified in recommendation 10 that not all the specific population groups in the guideline are advised to have a daily vitamin D supplement. We also changed 'darker skin' to 'dark skin'. These changes are in line with the latest NHS guidance on vitamin D supplementation.

# About this guideline

### What does this guideline cover?

The Department of Health asked the National Institute for Health and Care Excellence (NICE) to produce a guideline on how to increase supplement use to prevent vitamin D deficiency among specific population groups. The guideline focuses on supplement use (see the <u>scope</u>).

This guideline is a partial update of <u>maternal and child nutrition</u>, NICE guideline PH11 (2008). The recommendations will replace recommendation 3 in 'Maternal and child nutrition'.

This guideline does not provide detail on the benefits and risks of sunlight exposure or management of vitamin D deficiency. (See <u>related NICE guidance</u> for other recommendations that may be relevant to the prevention or management of vitamin D deficiency.)

This guideline does not examine the cost effectiveness of extending the Healthy Start vitamin programme from the current targeted offering to a universal offering. NICE is working on a separate report on this issue. This will be forwarded to the Chief Medical Officer in 2015.

The absence of any recommendations on interventions that fall within the scope of this guideline is a result of lack of evidence. It should not be taken as a judgement on whether they are cost effective.

### Other guidance and policies

The guideline should be implemented alongside other guidance and regulations including:

• Scientific Advisory Committee on Nutrition report on vitamin D (expected 2015).

### How was this guideline developed?

The recommendations are based on the best available evidence. They were developed by the Public Health Advisory Committee (PHAC).

Members of the PHAC are listed in <u>membership of the Public Health Advisory Committee</u> and the NICE project team.

For information on how NICE public health guidelines are developed, see the <u>NICE public</u> <u>health guidance process and methods guides</u>.

### What evidence is the guideline based on?

The evidence that the PHAC considered included:

- Evidence reviews:
  - Review 1 'Vitamin D: a systematic review of effectiveness and cost-effectiveness of activities to increase awareness, uptake and provision of vitamin D supplements in at-risk groups', was carried out by York Health Economics Consortium. The principal authors were: Anne Morgan, Danielle Varley, Mick Arber, Maria Cikalo, Victoria Burley, Anita Fitzgerald and Julie Glanville.
  - Review 2 'Review of systematic reviews exploring guideline uptake/ implementation' was carried out by York Health Economics Consortium. The principal authors were: Anita Fitzgerald, Anne Lethaby, Maria Cikalo, Julie Glanville and Hannah Wood.
  - Economic modelling 'An economic evaluation of interventions to improve the uptake of vitamin D supplements in England' was carried out by York Health Economics Consortium. The principal authors were: Alexandra Filby, Lily Lewis and Matthew Taylor.
- Expert paper: 'Vitamin D intakes and status' by Gillian Swan, Public Health England.

Note: the views expressed in the expert papers above are the views of the authors and not those of NICE.

In some cases the evidence was insufficient and the PHAC has made recommendations

for future research. For the research recommendations and gaps in research, see <u>Recommendations for research</u> and <u>Gaps in the evidence</u>.

### Status of this guideline

The draft guideline, including the recommendations, was released for consultation in May and June 2014. At its meeting in September 2014, the PHAC amended the guideline in light of comments from stakeholders and experts and the fieldwork. The guideline was signed off by the NICE Guidance Executive in November 2014.

The guideline complements the NICE guideline on sunlight exposure and replaces recommendation 3 in the NICE guideline on maternal and child nutrition. (For further details, see <u>Related NICE guidance</u>).

The recommendations should be read in conjunction with existing NICE guidance unless explicitly stated otherwise. They should be implemented in light of duties set out in the Equality Act 2010.

The guideline is available on NICE's website. The recommendations are also available in the <u>NICE Pathway on vitamin D: supplement use for specific population groups</u>, for professionals whose remit includes public health and for interested members of the public.

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### Implementation

NICE guidance can help:

 Commissioners and providers of NHS services to meet the requirements of the <u>NHS</u> <u>outcomes framework 2013–14</u>. This includes helping them to deliver against domain 1: preventing people from dying prematurely. • Local health and wellbeing boards to meet the requirements of the <u>Health and Social</u> <u>Care Act (2012)</u> and the <u>Public health outcomes framework for England 2013–16</u>.

Local authorities, NHS services and local organisations determine how to improve health outcomes and reduce health inequalities during the joint strategic needs assessment process.

NICE has developed <u>tools</u> to help organisations put this guideline into practice. Details will be available on our website after the guideline has been issued.

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# Accreditation

