Vitamin D: implementation of existing guidance to prevent deficiency

What is this guideline about?

This guideline aims to improve the implementation of existing recommendations on vitamin D to prevent deficiency. It focuses, in particular, on advice for at-risk groups to take a vitamin D supplement.

Vitamin D is essential for skeletal growth and bone health. Severe vitamin D deficiency can result in rickets (among children) and osteomalacia (among children and adults). National surveys suggest that around a fifth of adults may have low vitamin D status. (See Context for more details.) Dietary sources of vitamin D are limited. The main natural source is from the action of sunlight on skin. The importance of safe sun exposure to prevent vitamin D deficiency is covered in a separate guideline (see related NICE guidance).

The focus of the guideline is on at-risk groups previously identified by the UK Health Departments (Vitamin D - advice on supplements for at risk groups - letter from UK Chief Medical Officers, Department of Health 2012), the Scientific Advisory Committee on Nutrition (Update on vitamin D 2007) and NICE (see antenatal care, NICE clinical guideline 62, and maternal and child nutrition, NICE public health guidance 11). The following groups are advised to take a vitamin D supplement:

- infants and children aged under 5
- pregnant and breastfeeding women
- older people
- people with darker skin
- people who have limited exposure to the sun.
SACN is currently reviewing the dietary reference values for vitamin D intake in the UK population. The recommendations here should be read in conjunction with any advice published by SACN.

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. (This includes people who may be hypersensitive to vitamin D.)

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 Who should take action?) In addition, it may be of interest to members of the public.

See About this guideline for details of how the guideline was developed and its current status.
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1 Draft recommendations

**Recommendation 1 Clarify existing guidance on, and which groups are at-risk of, vitamin D deficiency**

- Public Health England and the Department of Health should resolve any inconsistencies in the wording of existing recommendations on vitamin D. They should make it much clearer which at-risk groups need a daily vitamin D supplement. In particular, they should:
  - more clearly define the terms ‘housebound’ and ‘low sun exposure’
  - clarify guidance on vitamin D supplementation for children under 6 months of age (whether they are breast or formula fed)
  - make it clear whether children aged 4 to 5 years require a vitamin D supplement
  - make it clear that older adults with an adequate calcium intake from a balanced diet require vitamin D-only supplements, rather than a combined vitamin D and calcium supplement (which some people may find difficult to tolerate (for example, difficult to swallow).

**Recommendation 2 Increase access to vitamin D supplements**

- The Department of Health should work with manufacturers to ensure vitamin D supplements providing the reference nutrient intake, as recommended by SACN, are widely available for children and adults. Supplements should be safe and acceptable (for example, it is best if they do not contain peanut oil, are halal and are suitable for vegans).
- The Department of Health should work with manufacturers to ensure supplements containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
- The Department of Health should amend existing legislation to allow Healthy Start vitamins to be more widely distributed and sold. It should also renegotiate existing arrangements with the manufacturers to encourage them to provide the supplements direct to pharmacies.
• Pharmacies and other outlets selling food supplements (such as supermarkets) should stock affordable vitamin D supplements and promote them to at-risk groups. The supplements should provide the reference nutrient intake, as recommended by SACN.

• Manufacturers of multivitamin supplements for children and adults should include vitamin D in their preparations. Multivitamin supplements should provide the reference nutrient intake for vitamin D, as recommended by SACN.

**Recommendation 3 Develop a national campaign**

Public Health England should lead development of a national campaign to raise awareness of the importance of vitamin D, as soon as existing recommendations on vitamin D have been clarified and made consistent (see recommendation 1). The campaign should:

• emphasise the importance of vitamin D for good health
• emphasise the importance of a daily supplement for identified at-risk groups
• let people know where they can get vitamin D supplements.

Campaign resources should be easily adaptable for local use to minimise duplication of effort and ensure consistent, clear messages are communicated locally and nationally.

**Recommendation 4 Co-ordinate local action to increase use of vitamin D supplements in line with existing guidance**

Council leaders, commissioners and senior managers in local authorities and the NHS, elected members, directors of public health and their teams, and voluntary and community organisations should:

• Work in partnership to ensure there is a consistent multiagency approach to improve awareness of the importance of vitamin D and increase the availability and uptake of supplements. This should:
  – address local needs, as identified by the joint strategic needs assessment and other local data
- target at-risk groups
- target health, social care and other professionals in contact with at-risk groups
- work with relevant community and voluntary groups
- ensure mechanisms are in place to increase the availability and uptake of supplements (see recommendation 2)
- ensure action is culturally appropriate (for example, involve community organisations, 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 at-risk groups**

Local authorities should:

- Ensure vitamin D supplements are widely available for all at-risk groups. For example, consider using the NHS minor ailments scheme, or establishing other arrangements with local pharmacies, to promote and distribute supplements.
- Consider providing free supplements for at-risk groups.
- Ensure improvements in the availability of vitamin D supplements are supported by awareness-raising activities. These should be aimed at health and social care professionals (see recommendation 8) and at-risk groups (see recommendation 9).

**Recommendation 6: Improve access to Healthy Start supplements**

Local authorities should:

- Review current accessibility, availability and uptake of Healthy Start supplements.
- Consider how accessibility, availability and uptake could be improved. For example:
Consider offering free Healthy Start supplements to all pregnant and breastfeeding women and children aged under 4 years.

Use a range of outlets, in particular, high street or supermarket pharmacies, children’s centres and clinics.

Use outlets with different opening times that are accessible by public transport and are frequently visited by pregnant and breastfeeding women, and families and carers of children aged under 4 years.

Set up a central hub 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 hub, rather than holding their own licence and managing their own stock.

**Recommendation 7 Ensure health and social care professionals recommend vitamin D supplements**

Health and social care professionals should recommend a daily vitamin D supplement to people from at-risk groups at every available opportunity. They should avoid vitamin D testing in people who do not have symptoms of deficiency (see the National Osteoporosis Society’s guideline [Vitamin D and bone health: a practical clinical guideline](https://osteoporosis.org.uk/for-professionals/guidelines/vitamin-d-and-bone-health) 2013).

- Local authorities and primary and community healthcare commissioning groups should ensure computerised prompts on vitamin D are integrated into health and social care systems to recommend and record vitamin D supplement use among at-risk groups. This may include:
  - registration appointments with new patients in general practice
  - flu and other vaccine appointments
  - statutory health visitor appointments for infants and children
  - screening services
  - health checks
  - diabetes check-ups.

- Developers of standardised handheld maternity notes should add specific questions about vitamin D supplement use to the booking section.
• Developers of personal child health records (the ‘red book’) should add specific questions about the use of vitamin D supplements.

**Recommendation 8 Raise awareness among health, social care and other relevant professionals of the importance of vitamin D**

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

• Ensure health and social care professionals receive information on the following as part of their registration and post-registration training or continuing professional development:
  – the importance of vitamin D for good health
  – sources of vitamin D in the UK (from safe sun exposure, supplements and limited dietary sources)
  – groups at risk of low vitamin D status
  – supplement recommendations for different groups
  – how to improve adherence to taking supplements (see NICE’s guideline on medicines adherence).

• Ensure health and social care professionals in contact with at-risk groups are made aware of the following:
  – local policies and procedures in relation to vitamin D
  – local sources of vitamin D supplements
  – local sources of Healthy Start supplements
  – voluntary and community groups working with at-risk groups.

**Recommendation 9 Raise awareness of the importance of vitamin D supplements among the local population**

Local public health teams, health and social care professionals and voluntary and community groups working with at-risk groups (see Who should take action?) should:
Implementing vitamin D guidance consultation draft

- Undertake activities to increase awareness of the latest recommendations on vitamin D from Public Health England, the Department of Health and SACN. Adapt any national resources for local use to minimise the risk of inconsistent advice (see recommendations 1 and 3).

- Ensure messages and information are disseminated locally to groups at higher risk. Use local newspapers, social media and local radio channels targeted at these groups. Also make use of local shops and businesses, community workers and groups, social establishments, nurseries and educational institutions, workplaces, places of worship and local health care establishments, for example, hospitals.

- 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)
  - groups at risk of vitamin D deficiency and the importance of a daily vitamin D supplement for these groups
  - local sources of vitamin D supplements
  - local sources of Healthy Start supplements
  - sources of further information.

- Ensure awareness-raising activities meet the needs of all at-risk 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 culturally appropriate.

**Recommendation 10 Monitor and evaluate the provision and uptake of vitamin D supplements**

The Department of Health, Public Health England and local authority commissioners should:
- Work together at national and local level to monitor the uptake of vitamin D supplements among different at-risk groups. Use consistent criteria. Develop a standardised tool to monitor local awareness of, access to and uptake of, vitamin D supplements among all at-risk groups (including those covered by Healthy Start).
- Use a range of sources to assess implementation, for example, orders for supplements and information collected in personal child health records, maternal antenatal notes and computerised prompts (see recommendation 7).
- Make monitoring data widely available.
- Ensure monitoring data are used to improve how people are encouraged to take vitamin D supplements on an ongoing basis.

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 do what at a glance

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Who should take action in detail

Recommendation 1
Public Health England, the Department of Health

Recommendation 2
Department of Health; pharmacies and other outlets selling food supplements (such as supermarkets); manufacturers of supplements

Recommendation 3
Public Heath England

Recommendation 4
Council leaders; elected members; directors of public health and their 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
Developers of standardised medical notes; developers of personal child health records; health and social care professionals; local authorities; primary and community healthcare commissioning groups

Recommendation 8
Public Health England; Health Education England; clinical commissioning groups; health and wellbeing boards; local authorities

Recommendation 9
Local public health teams; voluntary and community groups; health, social care and other professionals working with at-risk groups. This includes: dietitians, district nurses, GPs, health visitors, midwives, nursing assistants, pharmacists, physiotherapists, practice nurses. It also includes people working in nursing homes, nurseries, schools, children’s centres, prisons and residential care.

Recommendation 10
Department of Health; Public Health England; local authority commissioners

3 Context

Background

Vitamin D 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 some breakfast cereals and fat spreads (margarine). In addition, infant formula milk has to be fortified with vitamin D (this is voluntary for formula milks for toddlers). Breast milk contains very little vitamin D and is not a significant
source. The major natural source is from skin synthesis following exposure to sunlight.

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

The National Diet and Nutrition Survey 2001 (Office for National Statistics 2001) showed that only 6% of women had low vitamin D status in the summer months, compared with 24% in the winter.

In 1991, the Committee on Medical Aspects of food policy (COMA) set reference nutrient intakes for vitamin D (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). COMA did not set a reference nutrient intake for vitamin D for most children and adults, as it assumed that they obtain enough vitamin D from sun exposure. The SACN is currently reviewing this advice.

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 (among children and adults) and hypocalaemia 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 (Update on vitamin D, Scientific Advisory Committee on Nutrition 2007).

**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 active form of vitamin D in their body – 25 hydroxy vitamin

Vitamin D deficiency can occur at any age but is more likely during periods of rapid growth (for example, during childhood), during pregnancy and while breastfeeding. A newborn baby's vitamin D status is largely determined by the mother’s level of vitamin D during pregnancy.

Infants who are exclusively breastfed, particularly for more than 6 months, or have an infant formula intake less than 500ml, are at increased risk because the amount of vitamin D in their milk will not meet their needs. The same is true of infants who are given less than 500ml of infant formula (See NICE guidance on antenatal care and maternal and child nutrition.) The Asian Feeding Survey (Infant feeding in Asian families, 1994–1996, Office for National Statistics 1997) found that up to a third of Indian, Bangladeshi or Pakistani children had low vitamin D status at age 2.

People with darker (pigmented) 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, less pigmented skin. People of South Asian, African-Caribbean and Middle Eastern 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 expert paper in What evidence is the guidance based on?)

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 (Update on vitamin D, Scientific Advisory Committee on Nutrition 2007). 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 [Health Survey for England](https://www.nhi.gov.uk/healthsurvey) (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 expert paper in *What evidence is the guidance based on?*). This probably reflects the higher number of people from 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 Chief Medical Officers’ report *Vitamin D – advice on supplements for at risk groups* 2012) and NICE (see our guidance on *antenatal care* and *maternal and child nutrition*) have issued evidence-based guidance on vitamin D supplements for various at-risk groups. They have also provided guidance on how to distribute free Healthy Start 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*, Chief Medical Officers 2012).

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 and there has been concern about how clear and consistent the recommendations are (*Vitamin D – advice on supplements for at risk groups*, Chief Medical Officers 2012; *Mind the gap – are the current vitamin*...
recommendations meeting the needs of the under 5s in the UK? Feeding for Life Foundation 2012).

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 (Treating vitamin D deficiency GP, 13 February 2012; Prescription cost analysis England 2011 Health and Social Care Information Centre 2012).

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 products may not be suitable for particular at-risk groups.

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’ (CMO’s annual report 2012: our children deserve better, Department of Health 2013).

Up to April 2013, people not eligible for Healthy Start were entitled to buy the supplements at a much lower cost than commercial preparations. However, this option was only encouraged in a limited number of areas (Help pregnant women, new mothers and children get their free healthy start vitamins, Department of Health 2011). 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 Recommendations.)

Background

4.1 The PHAC considered only the implementation of existing 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 vitamin D 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 safe sunlight exposure. It is hoped that these 3 pieces of work will provide the basis for clear, consistent advice to reduce the risk of low vitamin D status among all at-risk groups.

4.2 A number of fundamental issues hinder the uptake of existing guidance among at-risk groups. Many health professionals and the public are 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 at-risk groups. Also, the availability of suitable low cost supplements is limited – and health professionals and the public may not know where they can get them locally. The PHAC decided that there will be significant increases in uptake only if all these issues are addressed. The recommendations stress the order in which action should be taken. Members also discussed and made recommendations on other
actions that are needed to prevent any further confusion about existing guidance. This includes having a viable distribution policy to reach at-risk groups before carrying out further awareness-raising activities.

**Communications**

4.3 Advice on the use of vitamin D supplements to maintain good bone 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](http://www.gov.uk/government/publications/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)) This includes existing recommendations 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, small differences in wording may be a source of confusion among both health professionals and the public. This may hinder implementation of the advice. 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 how many hours spent indoors equates to being ‘housebound’.

**Availability of vitamin D supplements**

4.4 The PHAC discussed the importance of increasing the availability of vitamin D supplements for all at-risk 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 at-risk 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 at-risk groups and made a recommendation 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 Commercial low cost vitamin D-only supplements containing 100% of the reference nutrient intake have not been widely available for sale. The PHAC noted that many vitamin D supplements also contain calcium (which may be poorly tolerated) and that commercially available supplements may be prohibitively expensive. Members agreed that there is unlikely to be a significant increase in the number of at-risk people 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 darker skin. In addition, only very limited information was available on the views of those taking supplements or in at-risk 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 at-risk groups.
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.

The PHAC noted the importance of ongoing monitoring and evaluation of the availability and uptake of vitamin D supplements among at-risk groups, at a national and local level. Members were also aware that data collection can cut into 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**

The limited evidence available points to extremely low uptake of Healthy Start supplements among eligible pregnant and breastfeeding women and children under the age of 4 years. One recent study reported uptake to be below 10% (Jessiman 2013) and another less than 3% (Moonan 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.)

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 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. They were also concerned that the voucher format and process for obtaining supplements may add to any confusion.

4.12 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 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.

4.13 The PHAC was concerned that most mothers and children at risk of vitamin D deficiency are not eligible for the Healthy Start scheme. For those who are not eligible, supplements containing vitamin D may be prohibitively expensive or unsuitable. 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 means that it is not possible to obtain Healthy Start supplements from many places where people might expect to find them, such as high street or supermarket pharmacies.
**Training**

4.14 PHAC agreed that health, social care and other professionals need training to provide robust, consistent advice to at-risk groups – 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**

4.15 Because of the focus of this guideline, the economic model did not address the question: ‘What is the cost effectiveness of vitamin D supplementation among at-risk groups?’. The question asked was: ‘What is the most cost-effective way of providing vitamin D supplements to at-risk groups?’ Modelling was based on 4 at-risk 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.

4.16 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. Economies of scale mean the greater the number of people tested, the more likely the cost effectiveness of testing would improve. However, this was not subjected to a sensitivity analysis.

4.17 A limitation of the modelling analysis is that it assumes everyone is given a prophylactic supplement without being tested. This means
that people who are severely deficient and who need a higher treatment dose of vitamin D may not be given it. Aspects of this situation are explored in a sensitivity analysis in the cost effectiveness report. This approach also ignores the possibility that some people may receive too much vitamin D from the supplement. However, the PHAC believed that a relatively low prophylactic dose would rarely cause such a problem.

4.18 A further 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 £8.90. This resulted in an estimated cost per deficiency averted of £2506. 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 £1229.

4.19 A limitation of the further 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’.

This section will be completed in the final document.

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 should include vitamin D status, user adherence and any unintentional consequences.

5.1 How effective and cost effective are interventions to increase vitamin D awareness and uptake on a continuing basis among identified at-risk groups (in particular, people over 65, minority ethnic groups and people living in institutions)? What is the impact on health outcomes? Does effectiveness vary by age, gender, ethnic, socioeconomic or other specific population characteristics (such as depression or a disability)?

5.2 For interventions aimed at improving long-term vitamin D supplement use among all ages of at-risk groups, what is the relative contribution of actions to increase:

- availability and uptake of supplements (including the impact of supplement costs on people)
- people’s knowledge and attitudes
- knowledge and attitudes among health and social care professionals
- consistent supplement use.

5.3 How cost effective are preventive approaches to vitamin D deficiency among all at-risk 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 at-risk groups.

5.4 How can a multiagency approach to improving awareness, availability and uptake of vitamin D supplements best be established, improved and sustained? What are the key components, for example, 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 not:

- be conceived, developed and implemented by academics with limited consultation with local practitioners or the local community
- be limited in terms of the number of situations where the approach could be implemented
- focus on interventions in 1 setting or target group.

5.5 How does training and awareness-raising affect the practice of health and social care professionals in relation to:

- promoting vitamin D supplements among at risk groups
- improving the local population’s awareness of vitamin D
- uptake of vitamin D supplements and improving health outcomes among different at-risk groups?

More detail identified during development of this guideline is provided in Gaps in the evidence.

6 Related NICE guidance

Published

- Skin cancer prevention: information, resources and environmental changes NICE public health guidance 32 (2010).
- Weight management before, during and after pregnancy NICE public health guidance 27 (2010).
**Under development**

- **Prisons: physical conditions and diseases** NICE public health guidance. Publication date to be confirmed.

## 7 Glossary

### At-risk groups
Population groups at higher risk of having a low vitamin D status include:

- All pregnant and breastfeeding women, especially teenagers and young women.
- Infants and young children under 5 years.
- Older people aged 65 and older.
- People who have low or no exposure to the sun. For example, people who cover their skin for cultural reasons, or who are housebound or confined indoors for long periods.
- People who have darker skin because their bodies are not able to make as much vitamin D. For example, people of African, African–Caribbean and South Asian origin.

At-risk groups are currently advised to take a supplement that meets 100% of the reference nutrient intake for their age group. This is 8.5 micrograms/day for infants aged 0–6 months, 7 micrograms/day for older infants and children up to their 4th birthday and 10 micrograms/day for adults ([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 1991)).

### 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 requirements. 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 UK Health Departments, the Scientific Advisory Committee on Nutrition and NICE have all issued evidence-based guidance on vitamin D supplements for various at-risk groups. (See NICE’s guidance on antenatal care and maternal and child nutrition.) They have also provided advice on how to distribute free Healthy Start supplements (containing vitamin D) to eligible families.

Halal

Halal means permitted or lawful according to Islamic law. Muslims are only allowed to eat Halal foods. Halal specifies which foods (or non-food items such as cosmetics or pharmaceuticals) are allowed and how they are prepared.

Healthy Start

Healthy Start is a UK-wide government scheme to improve the health of 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 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 between 1 and 4 years old 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 in local shops and supermarkets and with registered milk delivery companies.

Every 8 weeks, beneficiaries get green vitamin coupons that they can swap for Healthy Start vitamins. It is the responsibility of primary care and health trusts and health boards to make these vitamins available locally. Healthy Start vitamin tablets for mothers contain folic acid and vitamins C and D. Healthy start vitamin drops for children contain vitamins A, C and D.
Reference nutrient intake

Reference nutrient intake is the amount of a nutrient needed to meet the needs of around 97% 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 (µg/day) for vitamin D are:

- 8.5 for infants up to 6 months
- 7 for children between 6 months and 3 years
- 10 for older adults (65 years and older), and during pregnancy and lactation.

Currently there is no reference nutrient intake for people aged between 4 and 65 years. It is assumed that the action of sunlight on skin will provide adequate vitamin D, except for specific at-risk groups, such as women whose clothing conceals them fully or those confined indoors. The reference nutrient intake for at-risk groups is 10 micrograms/day.

Vitamin D

Vitamin D is a fat soluble pro hormone. It is obtained either through the action of sunlight on skin or 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 enzyme 25-hydroxylase converts vitamin D2 and D3 (from diet or from the action of sunlight on skin) to the active form of the vitamin, 25 hydroxyvitamin D – also known as 25(OH)D.

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).
8 References


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.
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**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 at-risk populations? 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 at-risk groups (with special consideration given to those eligible for the Healthy Start scheme)?
3. What helps or hinders the implementation of existing guidance on vitamin D by commissioners, providers, practitioners, those working with at-risk groups and people in at-risk groups?

4. What local provision is made to ensure vitamin D supplements are available for different at-risk 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 at-risk 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: [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.

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
- legislative issues relating to vitamin D supplements.

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 review 2.

**Quality appraisal**

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in [Methods for the development of NICE public health guidance](#). 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 Supporting evidence). 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: An economic evaluation of interventions to improve the uptake of vitamin D supplements in England.

**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 The evidence 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 Supporting evidence).
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 [review, report or paper](#) (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.

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 1.8, 2.12; IDE

**Recommendation 2**: evidence statements 1.9, 1.11, 1.12

**Recommendation 3**: evidence statements 1.1, 1.8, 1.9

**Recommendation 4**: evidence statements 1.1, 1.2, 1.8, 1.9, 1.11, 1.12, 2.10, 2.13

**Recommendation 5**: evidence statements 1.1, 1.2, 1.4, 1.9, 1.11

**Recommendation 6**: evidence statements 1.1, 1.2, 1.4, 1.5, 1.6, 1.7, 1.9, 1.11, 1.22

**Recommendation 7**: evidence statements 1.9, 2.2, 2.9

**Recommendation 8**: evidence statements 1.2, 1.3, 1.4, 1.8, 1.9, 2.13

**Recommendation 9**: evidence statements 1.9, 1.10, 2.14

**Recommendation 10**: 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 at-risk groups (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 [An economic evaluation of interventions to improve the uptake of vitamin D supplements in England](#).

### 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. These gaps are set out below.

1. There is a lack of good quality interventions aiming to increase Vitamin D supplement use among at-risk groups 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 at-risk 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 at-risk groups.

4. There is a lack of evidence on whether the following affect the effectiveness of interventions to increase vitamin D supplement use among at-risk 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 at-risk groups.

(Source: review 1 and review 2)

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

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
Clinical Reader in 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

Judy More
Freelance Paediatric Dietitian

Frances Quinn
Community Member

Expert testimony to PHAC
Gillian Swan, Diet and Obesity Branch, Public Health England

NICE project team
Mike Kelly
CPH Director
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 implementing existing guidance on vitamin D (see the scope).

This guideline does not provide detail on levels of safe sun exposure or management of vitamin D deficiency. (See Related NICE guidance for other recommendations that may be relevant to the prevention or management of vitamin D deficiency.)
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:

- To add SACN report 2014

**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 [Membership of the Public Health Advisory Committee and the NICE project team](#).

For information on how NICE public health guidelines are developed, see the NICE [public health guidance process and methods guides](#).

**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.


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 Recommendations for research and Gaps in the evidence.

**Status of this guideline**

This is a draft guideline. The recommendations made in section 1 are provisional and may change after consultation with stakeholders.

This document does not include all sections that will appear in the final guideline. The stages NICE will follow after consultation (including fieldwork) are summarised below.

- The Committee will meet again to consider the comments, reports and any additional evidence that has been submitted.
- After that meeting, the Committee will produce a second draft of the guideline.
- The draft guideline will be signed off by the NICE Guidance Executive.

The key dates are:

- Closing date for comments: 24 June 2014
- Next PHAC meeting: 4 September 2014

The guideline will complement the NICE guideline on sunlight exposure. (For further details, see Related NICE guidance).
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*.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government and the Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

**Implementation**

NICE guidance can help:

- Commissioners and providers of NHS services to meet the requirements of the *NHS outcomes framework 2013–14*. 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 *Health and Social Care Act (2012)* and the *Public health outcomes framework for England 2013–16*.
- 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 will develop tools to help organisations put this guideline into practice. Details will be available on our website after the guideline has been issued.

**Updating the recommendations**

This section will be completed in the final document.