NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

PUBLIC HEALTH GUIDANCE

SCOPE

1 Guidance title

Vitamin D: implementation of existing guidance to prevent deficiency

2 Background

a) The National Institute for Health and Clinical Excellence (NICE) has been asked by the Department of Health (DH) to develop guidance to help safely implement existing evidence-based recommendations on the prevention of vitamin D deficiency. It will focus on at-risk groups including infants and children aged under 5, pregnant and breastfeeding women, older people, people with dark skin and those who have limited exposure to the sun.

b) This guidance will support a number of related policy and guidance documents including:

- 'Delivering a healthy start for pregnant women, new mums, babies and young children' (DH 2011a)
- 'Healthy lives, healthy people: our strategy for public health in England' (DH 2010)
- 'Public health outcomes framework for England 2013–2016' (DH 2012)
- 'Vitamin D – advice on supplements for at risk groups' (Chief Medical Officers 2012).

c) This guidance will provide recommendations for good practice, based on the best available evidence of effectiveness, including cost effectiveness. It is aimed at 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.

d) The guidance will support NICE guidance on antenatal care, maternal and child nutrition and skin cancer. For further details, see section 6.

This guidance will be developed using the NICE public health guidance process and methods guides.

3 The need for guidance

a) Vitamin D is essential for skeletal growth and bone health. Dietary sources are limited (they include oily fish, egg yolk and fortified foods such as margarines, breakfast cereals and infant formulae). The major natural source of vitamin D is from skin synthesis following exposure to sunlight. Existing evidence suggests that from October to April in the UK, there is no ambient ultraviolet sunlight of the appropriate wavelength. During this time, the population relies on body stores (from sun exposure in the summer) and dietary sources to maintain vitamin D levels (Scientific Advisory Committee on Nutrition 2007).

b) Severe vitamin D deficiency can result in rickets (among children) and osteomalacia (among children and adults). It has also been associated with some diseases and long-term conditions, such as osteoporosis, diabetes and some cancers (Scientific Advisory Committee on Nutrition 2007). There have been reports that rickets is re-emerging among children in the UK (Pearce and Cheetham 2010). The national diet and nutrition survey of British adults (Ruston et al. 2004) suggests that about a quarter of British women aged 19–24, and a sixth of those aged 25–34, are at risk of vitamin D deficiency[1].

c) 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. Infants who are exclusively breastfed, particularly for more than 6 months, are at increased risk because the amount of vitamin D in breast milk will not meet their requirements. (See NICE guidance on antenatal care and maternal and child nutrition.) People of

[1] Low vitamin D status is defined by the Department of Health as a plasma concentration of 25 hydroxyvitamin D (25[OH]D, the main circulating form of the vitamin) of below 25 nmol/l (equal to 10 ng/ml).

South Asian, African, Caribbean and Middle Eastern descent, and those who remain covered when outside, are at particular risk. Older people are also at increased risk because their skin cannot synthesise vitamin D efficiently, they are likely to spend more time indoors and may not have enough dietary vitamin D. Limited sun exposure all year round – for example, because people are house bound or are in prison –also increases the risk (Scientific Advisory Committee on Nutrition 2007).

d) In 1991, the Committee on Medical Aspects of food policy (COMA) set reference nutrient intakes (RNI) for vitamin D (DH 1991). Some population groups can only achieve the RNI for vitamin D by taking a supplement. The Scientific Advisory Committee on Nutrition is currently in the process of reviewing this advice. All UK health departments (Chief Medical Officers 2012) and NICE (see 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 (which contain vitamin D) to eligible families.

e) The 4 UK Chief Medical Officers have 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 (Chief Medical Officers 2012). They also stress the need to ensure people who may be eligible for the Healthy Start scheme know how they can apply. (Note: The Healthy Start scheme includes free formula milk and fruit and vegetables, as well as vitamin supplements.) Evidence suggests implementation of these recommendations has been limited and there has been concern about how clear and consistent the recommendations are (Chief Medical Officers 2012; Feeding for Life Foundation 2012;

DH: personal communication 2012). The cost effectiveness of implementing existing guidance on vitamin D also remains unclear.

f) Supplements containing vitamin D are available on prescription or for sale from pharmacies or shops. However, there is wide variation in the content and cost 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 local supply problems. Manufacturers have not made them directly available to pharmacies, although this can be arranged locally. Those not eligible for Healthy Start can buy Healthy Start supplements (at a much lower cost than commercial preparations) and this has been encouraged in some areas (DH 2011b). Primary care spending on treatments for vitamin D deficiency rose from £28 million in 2004 to £76 million in 2011 (Robinson 2012; Health and Social Care Information Centre 2012).

4 The guidance

Public health guidance will be developed according to NICE processes and methods. For details see section 5.

This document defines exactly what this guidance will (and will not) examine, and what the guidance developers will consider. The scope is based on a referral from the DH (see appendix A).

4.1 Who is the focus?

4.1.1 Groups that will be covered

Population groups highlighted in existing guidance as being at increased risk of vitamin D deficiency:

- All pregnant and breastfeeding women.
- Infants and young children aged under 5 years.

- Older people aged 65 and over.
- People who have low (or no exposure) to the sun. For example, those who cover their skin for cultural reasons, and those who are housebound or confined indoors all year round (such as people in care homes or in prison).
- People with dark skin, for example, people of African, African-Caribbean, Middle Eastern and South Asian origin (because their bodies cannot make as much vitamin D as those with paler skins).

4.1.2 Groups that will not be covered

- People being treated for vitamin D deficiency.
- People with diseases or conditions which may be associated with an increased risk of vitamin D deficiency.

4.2 Activities

4.2.1 Activities that will be covered

a) Activities to increase awareness or uptake of vitamin D supplements among at-risk groups in a range of settings, in line with existing evidence-based guidance for England. This includes guidance issued by the Committee on Medical Aspects of food policy, the Scientific Advisory Committee on Nutrition, the DH and NICE.

b) Activities to increase provision of vitamin D supplements in a range of settings, in line with existing guidance for England (see above).

c) Activities to increase uptake of Healthy Start vitamins in a range of settings among eligible groups in England.

4.2.2 Activities/measures that will not be covered[2]

Activities that will not be covered include:

- Management of vitamin D deficiency.
- Management of conditions that may increase the risk of vitamin D deficiency.
- Fortification of food and drinks with vitamin D.
- Recommendations on the intake of vitamin D for different population groups.
- Legislative issues relating to vitamin D supplements.

Measures that will not be covered include:

- Indicators of vitamin D status.
- The relative contribution of dietary and cutaneous vitamin D synthesis to the vitamin D status of the UK population.
- The association between vitamin D status and health outcomes.
- Length and intensity of sun exposure for different population groups.

4.3 Key questions and outcomes

Below are the overarching questions that will be addressed, along with some of the outcomes that would be considered as evidence of effectiveness:

Question 1: How effective and cost effective are interventions to increase awareness and implementation of existing guidance on vitamin D among

[2] The Scientific Advisory Committee on Nutrition (SACN) is due to publish a report in 2014. It will cover: biochemical indicators of vitamin D status; the association between vitamin D status and various health outcomes; the risks of skin damage and other adverse effects associated with sunlight exposure; potential adverse effects of high vitamin D intakes; and the relative contributions of diet and vitamin D synthesis to vitamin D status in the UK. SACN is a stakeholder for the development of this guidance

health professionals or others working with at-risk populations? What are the implications for professional training and practice?

Question 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)?

Question 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?

Question 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)?

Expected outcomes

- Awareness of vitamin D guidance among at-risk groups (including any differences between socioeconomic groups).
- Awareness of vitamin D guidance among health professionals, commissioners and providers.
- Uptake of Healthy Start vitamins.
- Adherence to vitamin D guidance among at-risk groups (including any differences between socioeconomic groups).
- Adherence to vitamin D guidance among health professionals, commissioners and providers.
- Reported barriers and facilitators to implementing vitamin D guidance among at-risk groups, health professionals, commissioners and providers.
- Indicators of supplement availability.

Economic outcomes

- For economic modelling, estimates of length and quality of life, with and without an intervention, will be needed to estimate quality-adjusted life years (QALYs) gained.
- An economic analysis will be conducted from several perspectives – the NHS, local government, public sector and societal (as appropriate).
- Disaggregated information on health and non-health related costs and benefits may be captured in cost–consequences analyses. Return on investment (ROI) may also be considered.
- The main time horizon for cost effectiveness will be lifetime, but shorter timescales will be required for ROI analyses.

More information about these terms is available at the NICE glossary.

4.4 Status of this document

This is the final scope, incorporating comments from a 4-week consultation.

5 Further information

The public health guidance development process and methods are described in Methods for development of NICE public health guidance (third edition) (2012) and The NICE public health guidance development process (third edition) (2012).

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)

Maternal and child nutrition. NICE public health guidance 11 (2008)

Antenatal care. NICE clinical guideline 62 (2008)

Postnatal care. NICE clinical guideline 37 (2006)

Under development

Sunlight exposure: benefits and safety. NICE public health guidance (publication date to be confirmed)

Prisons: physical conditions and diseases. NICE public health guidance (publication date to be confirmed)

Appendix A Referral from the Department of Health

The Department of Health asked NICE to develop public health guidance on:

'The safe implementation of existing evidence-based guidance on prevention of vitamin D deficiency, to include recommendations relating to infants, children, older people, pregnant and lactating women and those with limited sun exposure'.

Appendix B Potential considerations

It is anticipated that the Public Health Advisory Committee (PHAC) will consider the following issues:

- The target audience, actions taken and by whom, context, frequency and duration.
- Critical elements. For example, whether effectiveness and cost effectiveness varies according to:
    - the diversity of the population (for example, in terms of the user's age, gender or ethnicity)
    - the status of the person delivering it and the way it is delivered
    - its frequency, length and duration, where it takes place and whether it is transferable to other settings
    - its intensity.
- Any trade-offs between equity and efficiency.
- Any factors that prevent – or support – effective implementation.
- Any adverse or unintended effects.
- Current practice.
- Availability and accessibility for different groups.

Appendix C References

Chief Medical Officers (2012) Vitamin D - advice on supplements for at risk groups [online].

Department of Health (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. London: HMSO

Department of Health (2010) Healthy lives, healthy people: our strategy for public health in England. London: Department of Health

Department of Health (2011a) Delivering a healthy start for pregnant women, new mums, babies and young children. London: Department of Health

Department of Health (2011b) Help pregnant women, new mothers and children get their free healthy start vitamins. London: Department of Health

Department of Health (2012) Public health outcomes framework for England 2013–2016 [online]

Feeding for Life Foundation (2012) Mind the gap – are the current vitamin recommendations meeting the needs of the under 5s in the UK? London: Feeding for Life Foundation

Health and Social Care Information Centre, Prescribing and Primary Care Services (2012) Prescription cost analysis England 2011. London: Health and Social Care Information Centre

Pearce SHS, Cheetham TD (2010) Diagnosis and management of vitamin D deficiency [online]

Robinson S (2012) Treating vitamin D deficiency [online]

Ruston D, Hoare J, Henderson L et al. (2004) The national diet and nutrition survey: adults aged 19 to 64 years. Nutritional status (anthropometry and

blood analytes), blood pressure and physical activity. London: The Stationery Office

Scientific Advisory Committee on Nutrition (2007) Update on vitamin D. Position statement by the Scientific Advisory Committee on Nutrition. London: The Stationery Office