NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Osteoporosis: assessment of fracture risk and the prevention of osteoporotic fractures in individuals at high risk.

1.1 Short title

Osteoporosis

2 Background

a) The National Institute for Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Nursing and Supportive Care to develop a clinical guideline on the assessment of fracture risk and prevention of osteoporotic fractures in individuals at high risk for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health and Welsh Assembly Government (see Appendix). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

b) The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework. This guideline will refer to the NSF for Older People and the Institute's clinical guideline on the assessment and prevention of falls in older people, due for publication in April 2004.

3 Clinical need for the guideline

a) Osteoporosis is a progressive systemic skeletal disease characterised by low bone mass and micro-architectural deterioration of skeletal tissue. It results in compromised bone strength and an increased susceptibility to fracture. Osteoporosis literally means ‘porous bones’. Bones are made of a thick outer shell and a strong inner mesh filled with a protein called collagen, calcium and other minerals. This inner portion looks like a honeycomb with blood vessels and bone marrow in the spaces between bone. Osteoporosis occurs when the holes within the bone become bigger, making it more likely to break. Osteoporosis is known as a silent disease because the deterioration of skeletal tissue proceeds with no outward sign until fracture occurs. It is these fractures, and the concomitant pain, that give osteoporosis its clinical significance. The whole skeleton is affected, but the sites most prone to fracture are the wrist, spine and hip. One in three women and one in twelve men older than 50 years will sustain an osteoporotic fracture at one of these sites. An estimated 3 million people in the UK suffer from osteoporosis and more than 310,000 osteoporotic fractures are sustained each year. This annual total is projected to increase, primarily as a result of the ageing of the UK population. The combined social care and acute costs for treating the current level of osteoporotic fractures in the UK have been estimated at more than £1.7 billion annually.

b) It is the resultant fractures, rather than osteoporosis per se, that cause individuals to suffer severe pain, disability, significant reductions in quality of life and premature death. For example, following an osteoporotic hip fracture around 50% of patients lose the ability to live independently and 20% die within a year. Vertebral fractures have equally debilitating consequences for the individual, often at an earlier age than hip fracture. Vertebral fractures may cause curvature of the spine (kyphosis) resulting in pain and physical limitations, including hindered breathing and digestion. The psychological consequences of

these changes in body shape also have a profound impact. Regardless of fracture site, individuals who have sustained one osteoporotic fracture are at a significantly increased risk of sustaining further fracture. About 90% of osteoporotic hip fractures in both sexes result from a simple fall from standing height or less, while vertebral fractures are often triggered by routine daily activities such as bending or lifting light objects. The fact that osteoporotic fractures, also known as fragility fractures, are sustained so easily often imparts an intense fear of falling into individuals who, as a consequence, greatly restrict their daily activities to prevent a further fracture.

c) A clinical diagnosis of osteoporosis is made on the basis of a bone mineral density (BMD) measurement. The World Health Organization defines the BMD threshold for osteoporosis as 2.5 or more standard deviations below the young adult mean. The significance of this is that the risk of fracture approximately doubles for each standard deviation decrease in BMD. Although low bone mass is an important component of fracture risk it does not by itself predict in absolute terms whether or not an individual will sustain a fracture. Various other skeletal characteristics (including bone turnover, hip axis length and femoral neck shaft angle) and numerous non-skeletal factors, for example advanced age and propensity to fall, also contribute to fracture risk. Clinicians are increasingly attempting to encompass all these aspects in an overall assessment of risk to guide decisions about which individuals would benefit from interventions aimed at preventing fracture. For this reason there is a distinction between a diagnosis of osteoporosis based on bone mineral density and risk thresholds for fracture that would indicate intervention.

4 The guideline

a) The guideline development process is described in detail in three booklets that are available from the NICE website (see ‘Further information’). *The Guideline Development Process – Information for*

Stakeholders describes how organisations can become involved in the development of a guideline.

b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health and Welsh Assembly Government (see Appendix).

c) The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

This guideline will consider the following.

a) Individuals with low bone mineral density (a diagnosis of osteoporosis by bone densitometry).

b) Individuals with radiographic evidence of osteopenia and/or vertebral deformity.

c) Individuals with previous osteoporotic fragility fracture (resulting from low trauma).

d) Individuals receiving prolonged oral corticosteroid therapy.

e) Individuals with secondary causes of osteoporosis. These include coeliac disease, chronic liver disease, chronic renal failure, hyperparathyroidism, hypercortisolism, hyperthyroidism and transplant recipients. This category also includes individuals with compromised physical function resulting from factors such as rheumatoid arthritis, neurological conditions or spinal paralysis from various causes.

f) Women with untreated hypogonadism, including post-menopause, primary hypogonadism, premature menopause, secondary amenorrhoea (for example, following anorexia nervosa, or associated

with extreme levels of exercise or certain forms of oral contraceptives), and early hysterectomy.

g) Men with primary or secondary hypogonadism.

h) Individuals with other risk factors including advancing age, maternal history of osteoporotic hip fracture, family history of osteoporosis, or low body mass index. Propensity to fall is a recognised risk factor for osteoporotic fracture that is being examined within the remit of the falls guideline and cross-reference will be made to this guideline.

4.1.2 Groups that will not be covered

a) No groups recognised to be at high risk for osteoporotic fracture will specifically be excluded from the guideline.

4.1.3 Groups/clinical aspects that will not be covered

a) Population-wide primary prevention strategies in the general population not considered to be at high risk for the condition do not fall within the remit of this guideline. For example, this might include health promotion activities within schools.

b) Post-fracture management, such as surgical procedures and post-operative nutrition, will not be covered within the remit of this guideline.

4.2 Healthcare setting

a) The guideline will cover the care received from primary and secondary NHS healthcare professionals who have direct contact with and make decisions concerning the care of individuals at high risk of osteoporosis and osteoporotic fracture.

b) The guideline will address areas that require collaboration between primary and secondary NHS services.

c) This is an NHS guideline and therefore it will not make specific recommendations regarding services outside the NHS. It will, however,

be relevant to practice within non-NHS residential and nursing homes, social services and the voluntary sector,

4.3 Clinical management

The guideline will examine interventions used to prevent an initial osteoporotic fracture in individuals at high risk, and also to prevent subsequent fractures where fracture has already been sustained. The following aspects of clinical management will be covered.

a) **Assessment of fracture risk.** In order to identify individuals most likely to benefit from intervention to prevent an osteoporotic fracture it is important to assess all factors contributing to an individual's risk. This will incorporate skeletal and non-skeletal factors. The guideline will review evidence on the following.

- *Measures of bone mass or bone mineral density (BMD).* Bone mass measured by dual-energy X-ray absorptiometry (DXA), quantitative computed tomography (QCT) and quantitative ultrasound (QUS) will be considered. All methods and sites will be considered with regard to their ability to predict fracture.

- *Biochemical indices of bone turnover*. The principal markers of resorption (hydroxyproline, pyridinium crosslinks and associated peptides) and formation (total alkaline phosphatase, bone-specific alkaline phosphatase, osteocalcin and the procollagen propeptides of type I collagen) will be assessed for their utility to predict fracture risk.

- *Clinical risk factors*. The main independent clinical risk factors previously listed within the groups covered (Section 4.1.1) will be assessed for their utility in predicting fracture risk.

The guideline will assess the evidence for recommending a threshold for intervention based upon assessments of fracture risk. It will also consider methods of identifying these individuals in practice.

b) **Interventions**. Several pharmacological and non-pharmacological interventions are available for reducing fracture risk. At this time, however, no hierarchy of effectiveness has been established.

Pharmacological interventions. This guideline will take into account recommendations identified by the technology appraisals currently under way and listed in this scope. Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only where clearly supported by the evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use the Summary of Product Characteristics to inform their decisions for individual patients. The following pharmacological interventions will be examined.

- Interventions currently licensed for osteoporosis: anabolic steroids (nandrolone); bisphosphonates (alendronate, etidronate and risedronate); calcitonin; calcitriol; calcium, calcium and vitamin D, and vitamin D alone; and hormone-replacement therapy (HRT) including tibolone, selective oestrogen-receptor modulators (SERMs, that is, raloxifene), and testosterone (licensed for men).

- Interventions with licence pending: parathyroid hormone (PTH), that is, Teriparatide.

- Other pharmaceutical interventions (under development or used in specialist clinics): bisphosphonates (clodronate, ibandronate, pamidronate, zoledronate), fluoride, drugs acting on oestrogen receptors, strontium ranelate.

Where there is evidence, duration of therapy will be considered for pharmacological interventions.

Non-pharmacolgical interventions. The following will be considered in the context of adjuncts to therapy in those individuals identified for treatment: cessation of smoking, dietary factors (including calcium, calcium and vitamin D, and vitamin D), reduced alcohol consumption

and increased physical activity. For individuals with osteoporosis secondary to paralysis, physical activity would include artificially stimulated muscular activity.

Hip protectors to reduce the impact of a fall and consequently reduce hip fracture rates are being examined in the Institute's guideline on falls, which is currently under way. Recommendations regarding the use of hip protectors will be cross-referenced to the falls guideline.

Interventions to prevent falls are being examined by the Institute's guideline on falls, which is currently under way. Recommendations regarding interventions to prevent falls will be cross-referenced to the falls guideline.

How advice and information is made available to individuals at risk or suffering from the condition will be considered. This will include aspects relating to self-management of the condition.

This guideline will refer to, update and extend the evidence base of previously published UK guidelines and technology appraisals and those currently under development where appropriate. The following are the primary documents for incorporation in this guideline.

- Royal College of Physicians. *Osteoporosis. Clinical guidelines for prevention and treatment* (1999) and *update on pharmacological interventions and an algorithm for management* (July 2000).
- Royal College of Physicians (2002) *Glucocorticoid-induced Osteoporosis: Guidelines for Prevention and Treatment.*
- Scottish Intercollegiate Guidelines Network. *Management of Osteoporosis* (due for publication 2003).
- Kanis JA, Brazier JE, Stevenson M et al. (2002) Treatment of established osteoporosis: a systematic review and cost-utility analysis. *Health Technology Assessment* 6.

- Cost-effectiveness of different strategies for the management of steroid-induced osteoporosis. *Health Technology Assessment* (HTA 01/06/02, in preparation – due for publication mid 2004).

- National Institute for Clinical Excellence. The clinical effectiveness and cost effectiveness of prevention and treatment of osteoporosis (alendronate, etidronate, risedronate, raloxifene, teriparatide). *NICE Technology Appraisal Guidance* (in preparation, target publication month May 2004).

4.4 Audit support within guideline

The guideline will incorporate review criteria and audit advice.

The audit will complement other existing and proposed work of relevance listed above, in particular the NSF for Older People and the Institute's guideline on falls.

4.5 Status

4.5.1 Scope

This is the final version of the scope.

4.5.2 Guideline

The development of the guideline recommendations will begin in April 2003.

5 Further information

Information on the guideline development process is provided in:

- *The Guideline Development Process – Information for the Public and the NHS*
- *The Guideline Development Process – Information for Stakeholders*

- *The Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups.*

These booklets are available as PDF files from the NICE website (www.nice.org.uk). Information on the progress of the guideline will also be available from the website.

Appendix – Referral from the Department of Health and Welsh Assembly Government

The following remit was received from the Department of Health and Welsh Assembly Government in May 2002 as part of the Institute's seventh wave programme of work:

"To prepare clinical guidelines for the NHS in England and Wales for the targeted prevention, assessment and treatment of osteoporosis. The guideline should specifically include recommendations for reducing the risk of fracture in those groups at highest risk of osteoporosis, including postmenopausal women, people who have been anorexic, long-term users of corticosteroids and other men at risk of osteoporosis. It should be developed to support both primary and secondary care osteoporosis services, as well as the integrated falls service detailed in the NSF for Older People. The guideline should take account of NICE's clinical guidelines on the assessment and prevention of falls, and of NICE's technology appraisal guidance on new pharmaceutical treatments for the prevention and treatment of osteoporosis."