NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Prevention, assessment and treatment of osteoporosis and osteoporotic fractures.

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 prevention, assessment and treatment of osteoporosis and osteoporotic fractures 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.

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 bone fragility and an increased susceptibility to fracture. It is a silent disease, such that the deterioration of skeletal tissue occurs with no outward sign until fracture occurs. This is what gives osteoporosis its clinical significance. The whole skeleton is affected but fractures occur most often at three sites, the wrist, spine and hip. One in 3 women and 1 in 12 men over the age of 50 years will sustain a fracture at one of these sites (NOS 2002). The total number of osteoporotic fractures in the UK is increasing each year primarily as a result of the ageing of the population (Cummings and Melton 2002).

b) Osteoporotic fractures have major debilitating consequences on the quality of life of an individual in terms of pain and disability. Around 50% of hip fracture patients lose the ability to live independently (Eddy et al 1998). Furthermore 20% die within a year following their fracture (Cummings and Melton 2002). Each year the estimated 86,000 hip fractures sustained in the UK cost health and social services £1.7 billion (Torgerson et al. 2001). About 90% of osteoporotic hip fractures in both sexes result from a simple fall from standing height or less (Youm et al 1999) while vertebral fractures are often triggered by no more than routine daily activities.

c) A clinical diagnosis of osteoporosis is made on the basis of a bone mineral density (BMD) measurement. The World Health Organisation (WHO 1994) defines the BMD threshold for osteoporosis as 2.5 or more standard deviations (SD) below the young adult mean. The significance of this is that the risk of fracture approximately doubles for each standard deviation (SD) decrease in BMD (RCP 1999). While low bone mass is an important component of fracture risk it alone cannot predict in absolute terms whether or not an individual will fracture. Various other skeletal characteristics that cannot be measured and

numerous non-skeletal factors such as age also contribute to fracture risk. Clinicians are increasingly attempting to encompass all these aspects in an assessment of risk to guide decisions regarding which individuals would benefit from interventions aimed at preventing fracture (Kanis 2002). For this reason there is a distinction between diagnosis of osteoporosis and risk thresholds for 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) Men and women with low bone mineral density (a diagnosis of osteoporosis by bone densitometry).

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

c) Men and women with previous osteoporotic fragility fracture.

d) Men and women receiving prolonged oral corticosteroid therapy.

e) Men and women with secondary causes of osteoporosis including gastrointestinal disorders resulting in chronic malabsorption, chronic liver disease, hyperparathyroidism, hypercortisolism, hyperthyroidism.

f) Women with untreated hypogonadism including post-menopause, primary hypogonadism, premature menopause, secondary amenorrhoea such as following anorexia nervosa, and early hysterectomy.

g) Men with primary or secondary hypogonadism.

h) Other risk factors including advancing age, maternal history of osteoporotic fracture, low body mass index.

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

4.1.2 Groups/clinical aspects that will not be covered

a)

b) Population-wide primary prevention strategies for reducing the incidence of osteoporosis and osteoporotic fractures do not fall within the remit of this guideline.

c) Mass screening strategies with the aim of reducing osteoporosis and osteoporotic fractures do not fall 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 people at high risk of osteoporosis and osteoporotic fracture.

b) The guideline will consider areas where there needs to be collaboration between primary and secondary NHS services.

c) This is an NHS guideline and although it will also be relevant to practice within residential and nursing homes, social services and the voluntary sector, it will not make recommendations regarding services exclusive to these sectors.

4.3 Clinical Management

The emphasis of this guideline is on the prevention and treatment of osteoporosis and osteoporotic fracture. It will examine interventions used to prevent an initial osteoporotic fracture in individuals at highest 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. The guideline will review evidence on the following;

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.

Biochemical indices of bone turnover: the principal markers of resorption (hydroxyproline, pyridinium crosslinks and associated peptides) and formation (total 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 will be assessed for their utility in predicting fracture risk.

The guideline will assess available evidence for recommending a threshold for intervention based upon assessments of fracture risk.

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: Where available, this guideline will take into account recommendations identified by the technology appraisals currently underway 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;

Licensed for osteoporosis or as an adjunct to treatment: anabolic steroids (nandrolone), bisphosphonates (alendronate, etidronate (cyclic) and risedronate), calcitonin, calcitriol, calcium, calcium and vitamin D or vitamin D alone, hormone replacement therapy (HRT) including tibolone, selective oestrogen receptor modulators (SERMs ie, raloxifene), and testosterone (licensed for men).

License pending: parathyroid hormone (PTH)(Teriparatide).

Other pharmaceutical interventions (under development or used in specialist clinics): bisphosphonates (clodronate, ibandronate, pamidronate, zoledronate), fluoride, other SERMs, strontium.

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 to include calcium and vitamin D, reduced alcohol consumption and physical 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 currently underway. Recommendations regarding the use of hip protectors will be cross-referenced with the falls guideline.

Interventions to prevent falls are being examined by the Institute's guideline on falls currently underway. Recommendations regarding interventions to prevent falls will be cross-referenced with the falls guideline.

This guideline will refer to the work, update and extend the evidence base of previously published UK guidelines and technology appraisals and those currently under development where appropriate. The following will be considered 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. *Glucocorticoid-induced osteoporosis: guidelines for prevention and treatment* (December 2002).

Scottish Intercollegiate Guidelines Network (SIGN). *Osteoporosis.* (due for publication 2003).

Department of Health. Health Technology Appraisals (HTA).

HTA 95/11/04. *Treatment of Established Osteoporosis.* (due for publication Spring 2003).

HTA 01/06/02. *Cost-effectiveness of different strategies for the management of steroid-induced osteoporosis.* (due for publication mid 2004).

NICE Technology Appraisal. *Prevention and Treatment of Osteoporosis.* (due for publication Sept 2003).

NICE Clinical Guidelines. *The assessment and prevention of falls in older people.* (due for publication April 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 also including the NSF for Older People.

4.5 Status

4.5.1 Scope

This is the consultation draft version of the scope. The consultation period is 10th February 2003 to 10th March 2003.

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.

6 References

Cummings SR and Melton III LJ (2002). Epidemiology and outcomes of osteoporotic fractures. *The Lancet* ;359:1761-1767.

Eddy DM, Johnson CC, Cummings SR, Dawson-Hughes B, Lindsay R, Melton LJ and Slemenda CW. (1998) Osteoporosis: review of the evidence for

prevention, diagnosis, treatment and cost-effectiveness analysis. *Osteoporosis International*;8 (Suppl 4):S7-80

Kanis JA. (2002). Diagnosis of osteoporosis and assessment of fracture risk. *The Lancet*;359:1929-36.

National Osteoporosis Society (NOS) (2002). *Primary Care Strategy for Osteoporosis and Falls.*

Royal College of Physicians and Bone and Tooth Society of Great Britain. (RCP) (1999). *Osteoporosis: Clinical guidelines for prevention and treatment.* And *Update on pharmacological interventions and an algorithm for management* (2000).

Torgerson DJ, Iglesias CP and Reid DM. (2001) Chapter 9. The economics of fracture prevention. In *The Effective Management of Osteoporosis*;111-21.

World Health Organization (WHO) (1994). Assessment of fracture risk and its application to screening for post-menopausal osteoporosis. Technical Report Series 843. Geneva:WHO.

Youm T, Koval KJ, Kummer FJ, Zuckerman JD (1999). Do all hip fractures result from a fall? *American Journal of Orthopaedics*;28:190-194.

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 7th 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."