NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Osteoporosis: assessing the risk of fragility fracture

1.1 Short title

Osteoporosis fragility fracture risk

2 The remit

The Department of Health has asked NICE: 'To produce a clinical guideline on the risk assessment of people with osteoporosis'.

3 Clinical need for the guideline

3.1 Definitions

a) Fragility fractures are fractures that result from low-level trauma, which means mechanical forces that would not ordinarily cause fracture. The World Health Organization (WHO) has quantified this as forces equivalent to a fall from a standing height or less. Reduced bone density is a major risk factor for fragility fractures. Other factors considered to predispose to fragility fractures include the use of glucocorticoids, age, sex, previous fractures, and family history of fracture.

b) Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue. The WHO defines osteoporosis as a bone mineral density (BMD) of 2.5 or more standard deviations below that of a normal young adult (t score of −2.5 or less) as measured by central dual energy X-ray

absorptiometry (DEXA). Bone mineral density is the major criterion used to diagnose and monitor osteoporosis.

c) Osteoporotic fragility fractures can cause substantial pain and severe disability, and are associated with decreased life expectancy. Osteoporotic fragility fractures occur most commonly in the spine (vertebrae), hip (proximal femur), and wrist (distal radius). They also occur in the arm (humerus), pelvis, ribs, and other bones. Fractures of the hands and feet (for example, metacarpal and metatarsal fractures) are not generally regarded as osteoporotic fragility fractures.

3.2 Epidemiology

d) Direct medical costs to the UK healthcare economy from fragility fractures have been estimated at £1.8 billion in 2000, with the potential to increase to £2.2 billion by 2025. Most of these costs relate to hip fracture care.

e) More than 300,000 patients present to hospitals in the UK with fragility fractures each year, with medical and social care costs – most of which relate to hip fracture care – at around £2 billion. Hip fracture nearly always requires hospitalisation, about 10% of people die within 1 month and about one third within 12 months. Hip fracture permanently disables a further 50%, and only 30% fully recover. Current projections suggest that hip fracture incidence in the UK will rise from the current figure of 70,000 per year to 91,500 in 2015 and 101,000 in 2020.

f) Bone mineral density assessment by DEXA is the current gold standard test for diagnosing osteoporosis.

3.3 Current practice

a) The aim of identifying people at risk is to offer preventive treatment. There are many treatments available for the prevention of fragility fractures but it is difficult to identify who will benefit from them.

b) A number of risk assessment tools are available to predict risk of fracture, including: WHO fracture risk assessment tool (FRAX); QFracture; osteoporosis risk estimation score for men (OST); osteoporosis risk assessment instrument (ORAI); simple calculated osteoporosis risk estimation score (SCORE); osteoporosis index of risk (OSIRIS); Women's Health Initiative (WHI) hip fracture risk calculator;; Foundation for Osteoporosis Research and Education (FORE) 10-year fracture risk calculator; and the Garvan Institute fracture risk calculator.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, ‘Further information’).

This scope defines what the 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.

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

a) Adults (18 and older), including those without osteoporosis or previous fracture.

b) Specific consideration will be given to the particular needs of:

- women with premature menopause
- men
- people who have frequent falls
- people using glucocorticoids long term (3 months or longer)
- people who have received treatment for breast and prostate cancer.

4.1.2 Groups that will not be covered

a) Children and young people (17 and younger).

4.2 Healthcare setting

a) All settings in which NHS care is received.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Utility of simple clinical measures as risk assessment tools, for example: previous fracture, age, height and strength of grip.

b) Evaluation of fracture risk assessment tools including, for example:

- BMD
- FRAX
- Qfracture.

4.3.2 Clinical issues that will not be covered

a) Drugs to prevent fractures.

b) Fracture and post-fracture management.

4.4 Main outcomes

a) Ability to predict fracture occurrence:

- vertebral
- hip
- forearm
- any fragility fracture.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence for risk estimation will be conducted. We will consider the resource cost of conducting risk assessment

from an NHS and personal social services (PSS) perspective, alongside estimates of diagnostic accuracy and other risk tool characteristics. However, because the guideline is not looking at treatment a formal cost-effectiveness analysis will not be conducted. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the consultation draft of the scope. The consultation dates are 16 June to 14 July 2011.

4.6.2 Timing

The development of the guideline recommendations will begin in August 2011.

5 Related NICE guidance

5.1 Published guidance

- Denosumab for the prevention of osteoporotic fractures in postmenopausal women. NICE technology appraisal guidance TA204 (2010). Available from www.nice.org.uk/guidance/TA204
- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal guidance TA161 (2011). Available from www.nice.org.uk/guidance/TA161
- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal guidance TA160 (2011). Available from www.nice.org.uk/guidance/TA160
- Falls. NICE clinical guideline 21 (2004). Available from www.nice.org.uk/guidance/CG21

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website).

- Hip fracture. NICE clinical guideline. Publication expected June 2011.
- Patient experience in generic terms. NICE clinical guideline. Publication expected October 2011. Recommendations from this will be incorporated into the osteoporosis fragility fracture risk guideline.

6 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).