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 fragility fractures in people with or at risk of 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 and/or osteoporosis.

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 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

(DXA). 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), and fracture of the head (skull and face) 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 £2.3 billion in 2011, with the potential to increase to more than £6 billion by 2036. 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 33% within 12 months. Of those who fracture their hips, about 50% are permanently disabled, and only 30% fully recover. Projections show that, if current trends continue, by 2036 there could be as many as 140,000 hospital admissions for hip fracture a year in the UK – this would be an increase of 57% on 2008 admissions.

f) Osteoporosis is defined by a T-score1 of −2.5 standard deviations or below on dual-energy X-ray absorptiometry (DXA) scanning.

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; Women's Health Initiative (WHI) hip fracture risk calculator; and Foundation for Osteoporosis Research and Education (FORE) 10-year fracture risk calculator.

c) Other tools are available for predicting bone mineral density, for example: osteoporosis risk estimation score for men (OST); osteoporosis risk assessment instrument (ORAI); simple calculated osteoporosis risk estimation score (SCORE); and osteoporosis index of risk (OSIRIS).

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
- people who have received treatment for breast or prostate cancer
- people currently receiving treatment for osteoporosis.

4.1.2 Groups that will not be covered

a) Children and young people (younger than 18).

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 for risk assessment, for example: previous fracture (including vertebral fracture), age and use of steroids.

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

- bone mineral density measured by DXA
- 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 final scope.

4.6.2 Timing

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

5 Related NICE guidance

5.1 Published guidance

- The management of hip fracture in adults. NICE clinical guideline 124 (2011). Available from www.nice.org.uk/CG124

- 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
- Denosumab for the prevention of osteoporotic fractures in postmenopausal women. NICE technology appraisal guidance TA204 (2010). Available from www.nice.org.uk/guidance/TA204
- 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), and recommendations from it will be cross referenced in the osteoporosis fragility fracture risk guideline.

- Patient experience in generic terms. NICE clinical guideline. Publication expected October 2011.

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).