NICE National Institute for Health and Care Excellence

Osteoporosis: assessing the risk of fragility fracture

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Introduction

Osteoporosis is a disease characterised by low bone mass and structural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture. Osteoporosis leads to nearly 9 million fractures annually worldwide[1], and over 300,000 patients present with fragility fractures to hospitals in the UK each year[2].

Fragility fractures are fractures that result from mechanical forces that would not ordinarily result in fracture, known as low-level (or 'low energy') trauma[3]. 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 fracture. Other factors that may affect the risk of fragility fracture include the use of oral or systemic glucocorticoids, age, sex, previous fractures and family history of osteoporosis. Because of increased bone loss after the menopause in women, and age-related bone loss in both women and men, the prevalence of osteoporosis increases markedly with age, from 2% at 50 years to more than 25% at 80 years in women. As the longevity of the population increases, so will the incidence of osteoporosis and fragility fracture.

Fragility fractures occur most commonly in the spine (vertebrae), hip (proximal femur) and wrist (distal radius). They may also occur in the arm (humerus), pelvis, ribs and other bones. Osteoporotic fractures are defined as fractures associated with low bone mineral density (BMD) and include clinical spine, forearm, hip and shoulder fractures. Osteoporotic fragility fractures can cause substantial pain and severe disability, often leading to a reduced quality of life, and hip and vertebral fractures are associated with decreased life expectancy. Hip fracture nearly always requires hospitalisation, is fatal in 20% of cases and permanently disables 50% of those affected; only 30% of patients fully recover[4]. Projections suggest that, in the UK, hip fracture incidence will rise from 70,000 per year in 2006 to 91,500 in 2015 and 101,000 in 2020[5].

Direct medical costs from fragility fractures to the UK healthcare economy were estimated at £1.8 billion in 2000, with the potential to increase to £2.2 billion by 2025, and with most of these costs relating to hip fracture care[6].

There are a number of therapies and treatments available for the prevention of fragility fractures in people who are thought to be at risk, or to prevent further fractures in those who have already had one or more fragility fractures. However, identifying who will benefit from preventative treatment is imprecise. A number of risk assessment tools are available to predict fracture incidence over a period of time, and these may be used to aid decision-making. These tools are

limited in that they may not include all risk factors, or may lack details of some risk factors. Tools are dependent on the accuracy of the epidemiological data used to derive them and tools validated in other populations may not apply to the UK. Two tools, FRAX and QFracture, are available for use in the UK. It is not clear whether these tools are equally accurate and whether choice of tool should depend on circumstances. This short clinical guideline aims to provide guidance on the selection and use of risk assessment tools in the care of people who may be at risk of fragility fractures in all settings in which NHS care is received.

[1] Johnell O, Kanis JA (2006) An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporosis International 17: 1726–33.

[2] British Orthopaedic Association (2007). The care of patients with fragility fracture.

[3] Kanis JA, Oden A, Johnell O et al. (2001) The burden of osteoporotic fractures: a method for setting intervention thresholds. Osteoporosis International 12: 417–27.

[4] Sernbo I, Johnell O (1993). Consequences of a hip fracture: a prospective study over 1 year. Osteoporosis International 3: 148–53.

[5] Department of Health. Hospital episode statistics (England) 2006.

[6] Burge RT, Worley D, Johansen A, et al. The cost of osteoporotic fractures in the UK: projections for 2000–2020. Journal of Medical Economics 4: 51–52.

Patient-centred care

This guideline offers best practice advice on the assessment of fragility fracture risk in adults.

Treatment and care should take into account patients' needs and preferences. People at risk of fragility fracture should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the code of practice that accompanies the Mental Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

1 Guidance

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance.

Targeting risk assessment

1.1 Consider assessment of fracture risk:

- In all women aged 65 years and over and all men aged 75 years and over
- in women aged under 65 years and men aged under 75 years in the presence of risk factors, for example:
  - previous fragility fracture
  - current use or frequent recent use of oral or systemic glucocorticoids
  - history of falls
  - family history of hip fracture
  - other causes of secondary osteoporosis[7]
  - low body mass index (BMI) (less than 18.5 kg/m^2)
  - smoking
  - alcohol intake of more than 14 units per week for women and more than 21 units per week for men.

1.2 Do not routinely assess fracture risk in people aged under 50 years unless they have major risk factors (for example, current or frequent recent use of oral or systemic glucocorticoids, untreated premature menopause or previous fragility fracture), because they are unlikely to be at high risk.

Methods of risk assessment

1.3 Estimate absolute risk when assessing risk of fracture (for example, the predicted risk of major osteoporotic or hip fracture over 10 years, expressed as a percentage).

1.4 Use either FRAX[8] (without a bone mineral density [BMD] value if a dual-energy X-ray absorptiometry [DXA] scan has not previously been undertaken) or QFracture[9], within their allowed age ranges, to estimate 10-year predicted absolute fracture risk when assessing risk of fracture. Above the upper age limits defined by the tools, consider people to be at high risk.

1.5 Interpret the estimated absolute risk of fracture in people aged over 80 years with caution, because predicted 10-year fracture risk may underestimate their short-term fracture risk.

1.6 Do not routinely measure BMD to assess fracture risk without prior assessment using FRAX (without a BMD value) or QFracture.

1.7 Following risk assessment with FRAX (without a BMD value) or QFracture, consider measuring BMD with DXA in people whose fracture risk is in the region of an intervention threshold[10] for a proposed treatment, and recalculate absolute risk using FRAX with the BMD value.

1.8 Consider measuring BMD with DXA before starting treatments that may have a rapid adverse effect on bone density (for example, sex hormone deprivation for treatment for breast or prostate cancer).

1.9 Measure BMD to assess fracture risk in people aged under 40 years who have a major risk factor, such as history of multiple fragility fracture, major osteoporotic fracture, or current or recent use of high-dose oral or high-dose systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer).

1.10 Consider recalculating fracture risk in the future:

- if the original calculated risk was in the region of the intervention threshold[11] for a proposed treatment and only after a minimum of 2 years, **or**
- when there has been a change in the person's risk factors.

1.11 Take into account that risk assessment tools may underestimate fracture risk in certain circumstances, for example if a person:

- has a history of multiple fractures
- has had previous vertebral fracture(s)
- has a high alcohol intake
- is taking high-dose oral or high-dose systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer)
- has other causes of secondary osteoporosis[7].

1.12 Take into account that fracture risk can be affected by factors that may not be included in the risk tool, for example living in a care home or taking drugs that may impair bone metabolism (such as anti-convulsants, selective serotonin reuptake inhibitors, thiazolidinediones, proton pump inhibitors and anti-retroviral drugs).

[7] Causes of secondary osteoporosis include endocrine (hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; diabetes), gastrointestinal (coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption), rheumatological (rheumatoid arthritis; other inflammatory arthropathies), haematological (multiple myeloma; haemoglobinopathies; systemic mastocytosis), respiratory (cystic fibrosis; chronic obstructive pulmonary disease), metabolic (homocystinuria), chronic renal disease and immobility(due for example to neurological injury or disease).

[8] FRAX, the WHO fracture risk assessment tool, can be used for people aged between 40 and 90 years, either with or without BMD values, as specified.

[9] QFracture can be used for people aged between 30 and 84 years. BMD values cannot be incorporated into the risk algorithm.

[10] An intervention threshold is the level of risk at which an intervention is recommended. People whose risk is in the region from just below to just above the threshold may be reclassified if BMD is added to assessment. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

[11] An intervention threshold is the level of risk at which an intervention is recommended. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover.

How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations.

There is more information about how NICE clinical guidelines are developed on the NICE website. A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' is available.

3 Implementation

NICE has developed tools to help organisations implement this guidance.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline.

4.1 Using GP practice lists to identify people at high risk

What is the clinical and cost effectiveness of using GP practice lists to identify people at high risk of fracture, leading to formal risk assessment and possible treatment?

Why this is important

Fracture risk is currently assessed opportunistically. GP records are now universally computerised and contain information that may be useful in identifying patients at high risk of fracture (for example, age, record of prescriptions, major diagnoses and previous fracture). A study is needed to assess whether people at higher risk can be identified by using risk assessment tools to obtain an estimate of risk based on pre-existing information and inviting people at highest risk for a clinical assessment and risk-factor estimation. This could result in a more effective and efficient use of staff time and health service resources than an opportunistic approach.

4.2 FRAX and QFracture in adults receiving bone protective therapy

What is the utility of FRAX and QFracture in adults receiving bone protective therapy?

Why this is important

Because of concerns about rare but serious side-effects of long-term anti-resorptive therapy, many physicians prescribe these drugs for a finite period of time, usually 3–5 years. Reassessment of fracture risk at the end of this treatment period is important, since some people remain at high risk of fracture and require continued treatment whereas others may benefit from a 'drug holiday' for 1 or more years. Neither FRAX nor QFracture has been examined in treated

patients, and it is not known whether the ability of clinical risk factors with or without measurement of BMD to predict fracture risk is similar in untreated and treated patients. There is therefore a need for prospective studies to investigate the predictive power of these tools to assess fracture risk in patients after a period of bone protective therapy.

4.3 FRAX and QFracture in adults with secondary causes of osteoporosis

What is the utility of FRAX and QFracture in detecting risk of fragility fracture in adults with secondary causes of osteoporosis?

Why this is important

If secondary osteoporosis is entered as a risk factor in FRAX, the algorithm assumes that the effect is mediated solely through effects on BMD. Input of BMD into the questionnaire in such patients will therefore generate the same fracture risk whether or not secondary osteoporosis is entered. However, it is likely that at least some causes of secondary osteoporosis (for example, inflammatory bowel disease) affect fracture risk by mechanisms that are partially independent of BMD and fracture risk may therefore be underestimated in such patients. There is therefore a need to investigate the accuracy of FRAX in predicting fracture risk in patients with causes of secondary osteoporosis other than rheumatoid arthritis and to establish whether their effect on fracture risk is mediated solely through effects on BMD.

4.4 BMD with FRAX

What is the added prognostic value of BMD in the assessment of fracture risk with FRAX?

Why this is important

The 10-year fracture risk as estimated by FRAX is calculated using clinical risk factors with or without BMD. The clinical risk factors are routinely available, making calculation of fracture risk possible at the time of consultation. However, refinement of a patient's 10-year fracture risk using BMD requires assessment using DXA scanning equipment.

Currently, there are no definitive studies in primary or secondary care evaluating whether the addition of BMD to FRAX improves the accuracy of the predicted fracture risk. There is a need

for studies to examine whether adding BMD to FRAX results in the correct reclassification of patients from low risk to high risk (and vice-versa). Furthermore, studies are also needed to evaluate the clinical usefulness (net benefit) of adding BMD to FRAX; that is, how many more patients are correctly classified as high risk (true positives) and low risk (true negatives).

4.5 FRAX and QFracture in adults living in residential care

What is the utility of FRAX and QFracture in detecting risk of fragility fracture in adults living in residential care?

Why this is important

Care home residents are at high risk of fragility fracture. This is probably related to increased age and frailty with multiple comorbidities, which increase fracture risk. There is also evidence that care home residents have lower BMD, with 70% assessed as having osteoporosis using densitometry criteria alone. However, tools such as FRAX and QFracture, which only estimate fracture risk up to the 9th decade and use 10-year fracture risk, may underestimate short-term risk in care home residents, who have a mean age of approximately 85 years and a life expectancy of less than 5 years.

A study is required to assess whether care home residents should have targeted fracture risk assessment and whether residents at higher risk of fracture can be identified, using FRAX or QFracture. This could result in a more effective and efficient strategy for fracture prevention, targeting health service resources on those at the very highest fracture risk.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, Osteoporosis: assessing the risk of fragility fracture, contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre.

5.2 NICE pathway

The recommendations from this guideline have been incorporated into a NICE pathway.

5.3 Information for the public

NICE has produced information for the public explaining this guideline.

We encourage NHS and voluntary sector organisations to use text from this information in their own materials about assessment of fragility fracture.

6 Related NICE guidance

- Patient experience in adult NHS services. NICE clinical guideline 138 (2012).
- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal guidance 161 (2011).
- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal guidance 160 (2011).
- The management of hip fracture in adults. NICE clinical guideline 124 (2011).
- Denosumab for the prevention of osteoporotic fractures in postmenopausal women. NICE technology appraisal guidance 204 (2010).
- Falls. NICE clinical guideline 21 (2004).

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Clinical Guideline Centre and NICE project team

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Changes after publication

November 2013: minor maintenance.

October 2012: minor maintenance.

About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

The guideline was developed by the National Clinical Guideline Centre, which is based at the Royal College of Physicians. The Collaborating Centre worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in The guidelines manual.

The recommendations from this guideline have been incorporated into a NICE pathway. We have produced information for the public explaining this guideline. Tools to help you put the guideline into practice and information about the evidence it is based on are also available.

Your responsibility
This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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