BONE HEALTH PATHWAY

Management of patients with Osteoporosis
Or at risk of Osteoporosis

Guidelines for Primary Care

This guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient.

If patients fall outside the scope of this guideline, seek specialist advice or consider a referral to secondary care. The Integrated Falls and Bone Health Service or Fracture Liaison Nurse may provide further advice.
Background:
The Falls and Bone Health Needs Assessment and Strategy (2010) for Wandsworth clearly identified that there were significant unmet needs for both falls prevention services and services to address poor bone health.

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. Fragility fractures are fractures that result from mechanical forces that would not ordinarily result in fracture, known as low-level (or 'low energy') trauma.

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. 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.

Osteoprototic fractures are defined as fractures associated with low bone mineral density (BMD) and include clinical spine, forearm, hip and shoulder fractures.

Diagnosis of osteoporosis
The diagnosis of osteoporosis relies on the quantitative assessment of bone mineral density (BMD), usually by axial dual energy X-ray absorptiometry (DXA). BMD at the femoral neck provides the reference site. Osteoporosis is defined as a value for BMD 2.5 SD or more below the young female adult mean (T-score ≤ –2.5 SD).

However, the diagnosis may be assumed in women aged 75 years or older if the responsible clinician considers a DXA scan to be clinically inappropriate or unfeasible.

Assessment tools:
Use either FRAX (40-90 years) or QFracture (30-84 years) to estimate 10-year predicted absolute fracture risk when assessing risk of fracture. Use the EMIS Read Codes, once a FRAX score is obtained.

Outside of the age ranges, clinical judgment should be used to assess fracture risk or seek advice from a specialist. 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.

These assessment tools have limitations and may underestimate fracture risk. For example multiple versus single fractures or variable steroid doses do not calculate different risk scores.

FRAX may underestimate fracture probability in users of high dose inhaled glucocorticoids. Also 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 antiretroviral drugs).

Therefore, clinical judgment should be used to interpret the results.

Both assessment tools are valid only in osteoporosis treatment naïve patients.

Consider measuring BMD in patients on treatments that cause rapid bone loss e.g. sex hormone deprivation treatments for breast and prostate cancer.

Prevention & Treatment of osteoporosis:
General management includes lifestyle measures, calcium and vitamin D supplementation and pharmacological interventions.

MHRA Advice:
- Bisphosphonates: The optimal duration of bisphosphonate treatment for osteoporosis has not been established. The need for continued treatment should be re-evaluated periodically based on the benefits and potential risks of bisphosphonates on an individual patient basis, particularly after 5 or more years of use. Be aware of the risk of atypical stress fractures of the femur and the rare adverse effect of osteonecrosis of the jaw, with bisphosphonates. [http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON120213]
- Strontium: There are cardiovascular safety concerns. Use of strontium is now restricted to treatment of severe osteoporosis in postmenopausal women at high risk of fracture and in men at increased risk of fracture. [http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON266148]

Reassess osteoporosis risk and treatment if clinical conditions or risk factors change.

Adherence with bone protection treatments:
The key factors that affect adherence to treatment are adverse events, lack of understanding of the condition/ disease being treated, lack of information about the treatment (including potential side effects) and lack of follow up. Compliance is poor with bone protection treatments and the prescriber may need to discuss benefits and risks with the patient.

EMIS Read Codes:
Fragility fracture - N331N Osteoporosis - N330 Osteopenia – NyuBC Referral for DXA - 8HLz
Osteoporosis risk assessment - 9OdA FRAX Score - various
Refer to Integrated falls/bone health service - 8Hk1 Declined referral to Integrated falls/bone health service - 9Og4
Management of Men and Women at risk of Osteoporosis

Primary Prevention (No Previous Fragility Fracture)
Fracture risk should be assessed in these patients:
• All women aged 65 years and over and all men aged 75 years and over
• Patients at any age with ≥ 1 Risk Factors, which are:
  Parental history of hip fracture, high alcohol intake, rheumatoid arthritis, oestrogen deficiency, early menopause, low BMI (<19kg/m2), hypogonadism in men, osteomalacia, thyrotoxicosis, hyperparathyroidism, liver disease, growth hormone treatment, malabsorption, kidney dialysis, prolonged immobility (> 6 months bedridden).

Assess fracture risk* using FRAX Tool (validated for 40-90yrs only) (Read Code 9OdA)
http://www.shef.ac.uk/FRAX/tool.jsp?country=1
*QFRACTURE is an alternative tool for assessing fracture risk. http://www.qfracture.org

Secondary Prevention
Previous Fragility Fracture
(Read code N331N)

Offer Treatment
See Appendix 1

General Measures
• Recommend good nutrition especially with adequate calcium and vitamin D (Calcium 1–1.2g & Vitamin D 20micrograms (800units) daily).
• Assess falls risk and give advice.
• Refer to Integrated Falls and Bone Health Service for Bone Boost classes (Read code 8Hk1), where appropriate. [If patient declines referral, Read code 9Og4]
Management of Glucocorticoid-Induced Osteoporosis in Adults

**Primary Prevention**
- No previous fragility fracture

**Secondary Prevention**
- Previous Fragility Fracture

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**Glucocorticoid therapy**
(expected to be ≥ 3 months or cumulative dose equivalent to 1.5 g per year for patients prescribed repeated short courses)

**Assess fracture risk** * using FRAX Tool (validated for 40-90 yrs only) (Read Code 9OdA)
http://www.shef.ac.uk/FRAX/tool.jsp?country=1
Note: Fracture probability using FRAX is most accurate for prednisolone doses of 2.5-7.5 mg / day or its equivalent. For doses outside this range, FRAX can under or over-estimate risk.

*QFRACTURE is an alternative tool for assessing fracture risk http://www.qfracture.org

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**General Measures**
- Reduce dose of glucocorticoid when possible. Consider glucocorticoid sparing therapy if appropriate or consider alternative route of administration.
- Recommend good nutrition especially with adequate calcium and vitamin D (Calcium 1–1.2 g & Vitamin D 20 micrograms (800 units) daily).
- Assess falls risk and give advice.
- Refer to Integrated Falls and Bone Health Service for Bone Boost classes (Read code 8Hk1), where appropriate. If patient declines referral, Read code 9Oq4

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**Investigations**
- ** Investigations**: FBC, Bone, Serum 25 OH Vit.D, LFT, U&E, TFT
- **Additional tests if indicated**: ESR (myeloma), serum testosterone in men <60 yrs, PTH

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**Measure BMD** (Read code 8HLz)
(DXA scan hip + spine + wrist)

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**Low Risk**
- Advise on General Measures (and seek specialist advice if T-score is < -1.5)

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**Intermediate Risk**
- Measure BMD (Read code 8HLz) (DXA scan hip + spine + wrist)
- **Low Risk** T score > 0
- **Intermediate Risk** T score 0 to -1.5
- **High Risk** T Score < -1.5

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**High Risk**
- Refer to Integrated Falls and Bone Health Service for Bone Boost classes (Read code 8Hk1), where appropriate. If patient declines referral, Read code 9Oq4

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Offer Treatment
See Appendix 1
Prevention and Treatment of Osteoporosis

Secondary prevention of osteoporotic fragility fractures in postmenopausal women and men

1st Line
Alendronate 70mg once weekly (unlicensed for men)
or
Risedronate 35mg once weekly

Patients with history of upper GI structural abnormality e.g. oesophageal stricture
or
Patients unable to adhere to bisphosphonate administration advice

2nd Line
Strontium 2g at bedtime (MHRA safety advice)
or
Raloxifene 60mg daily in postmenopausal women (no evidence for hip fracture prevention)

Patient intolerant of bisphosphonates

Patient unable to tolerate therapy or unsatisfactory response in women*

*NICE definition - “when a woman has another fragility fracture despite adhering fully to treatment for one year and there is also evidence of a decline in BMD below her pre-treatment baseline”

*Refer to secondary care
Hospital-Only drugs: IV bisphosphonates, teriparatide, denosumab

Primary prevention of osteoporotic fragility fracture in postmenopausal women & men

1st Line
Alendronate 70mg once weekly (unlicensed for men)
or
Risedronate 35mg once weekly

2nd Line
Strontium 2g at bedtime (MHRA safety advice)
or
Raloxifene 60mg daily in postmenopausal women (no evidence for hip fracture prevention)

Prevention and treatment of Corticosteroid-induced osteoporosis

Men & Postmenopausal women NOT receiving hormone replacement therapy

Postmenopausal women receiving hormone replacement therapy

1st Line
Alendronate 70mg once weekly (unlicensed)
or
Risedronate 35mg once weekly

2nd Line:
Strontium 2g at bedtime (unlicensed)
(MHRA safety advice)
or
Raloxifene 60mg daily in postmenopausal women (no evidence for hip fracture prevention)

1st line
Alendronate 10mg alternate days (unlicensed)
or
Risedronate 5mg alternate days (unlicensed)
Appendix 2: FRAX risk assessment tool.

After calculation, click to NOGG site:

![FRAX risk assessment tool](image)

### Calculation Tool

Please answer the questions below to calculate the ten year probability of fracture with BMD.

**Questionnaire:**

1. Age (between 40-89 years) or Date of birth:
   - Age: [ ]
   - Date of birth: [ ]
2. Sex: [ ] Male  [ ] Female
3. Weight (kg):
4. Height (cm):
5. Previous fracture: [ ] No  [ ] Yes
6. Parental fractured hip: [ ] No  [ ] Yes
7. Current smoking: [ ] No  [ ] Yes
8. Glucocorticoids: [ ] No  [ ] Yes
9. Rheumatoid arthritis: [ ] No  [ ] Yes
10. Secondary osteoporosis: [ ] No  [ ] Yes
11. Alcohol Drinking units per day: [ ] No  [ ] Yes
12. Femoral neck BMD (g/cm²): [ ]
   - Select DXA: [ ]

[Clear]  [Calculate]

### Weight Conversion

- Pounds  [ ] kg

### Height Conversion

- Inches  [ ] cm

**00692709**

Individuals with fracture risk assessed since 1st June 2011

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**Graphs**

Assessment threshold - Major fracture

10 year probability of major osteoporotic fracture (%)

- Treat
- Measure BMD
- Lifestyle advice and reassure

[Graph image]

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**Risk factors**

For the clinical risk factors a yes or no response is asked for. If the field is left blank, then a "no" response is assumed.

The risk factors used are the following:

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>The model accepts ages between 40 and 90 years. If ages below or above are entered, the programme will compute probabilities at 40 and 90 year, respectively.</td>
</tr>
<tr>
<td>Sex</td>
<td>Male or female. Enter as appropriate.</td>
</tr>
<tr>
<td>Weight</td>
<td>This should be entered in kg.</td>
</tr>
<tr>
<td>Height</td>
<td>This should be entered in cm.</td>
</tr>
<tr>
<td>Previous fracture</td>
<td>A previous fracture denotes more accurately a previous fracture in adult life occurring spontaneously, or a fracture arising from trauma which, in a healthy individual, would not have resulted in a fracture. Enter yes or no (see also notes on risk factors).</td>
</tr>
<tr>
<td>Parent fractured hip</td>
<td>This enquires for a history of hip fracture in the patient's mother or father. Enter yes or no.</td>
</tr>
<tr>
<td>Current smoking</td>
<td>Enter yes or no depending on whether the patient currently smokes tobacco (see also notes on risk factors).</td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>Enter yes if the patient is currently exposed to oral glucocorticoids or has been exposed to oral glucocorticoids for more than 3 months at a dose of prednisolone of 5mg daily or more (or equivalent doses of other glucocorticoids) (see also notes on risk factors).</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>Enter yes where the patient has a confirmed diagnosis of rheumatoid arthritis. Otherwise enter no (see also notes on risk factors).</td>
</tr>
<tr>
<td>Secondary osteoporosis</td>
<td>Enter yes if the patient has a disorder strongly associated with osteoporosis. These include type I (insulin dependent) diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (&lt;45 years), chronic malnutrition, or malabsorption and chronic liver disease</td>
</tr>
<tr>
<td>Alcohol 3 or more units/day</td>
<td>Enter yes if the patient takes 3 or more units of alcohol daily. A unit of alcohol varies slightly in different countries from 8-10g of alcohol. This is equivalent to a standard glass of beer (285ml), a single measure of spirits (30ml), a medium-sized glass of wine (120ml), or 1 measure of an aperitif (60ml) (see also notes on risk factors).</td>
</tr>
<tr>
<td>Bone mineral density (BMD)</td>
<td>(BMD) Please select the make of DXA scanning equipment used and then enter the actual femoral neck BMD (in g/cm²). Alternatively, enter the T-score based on the NHANES III female reference data. In patients without a BMD test, the field should be left blank (see also notes on risk factors) (provided by Oregon Osteoporosis Center).</td>
</tr>
</tbody>
</table>
Notes on risk factors

**Previous fracture**
A special situation pertains to a prior history of vertebral fracture. A fracture detected as a radiographic observation alone (a morphometric vertebral fracture) counts as a previous fracture. A prior clinical vertebral fracture or a hip fracture is an especially strong risk factor. The probability of fracture computed may therefore be underestimated. Fracture probability is also underestimated with multiple fractures.

**Smoking, alcohol, glucocorticoids**
These risk factors appear to have a dose-dependent effect, i.e. the higher the exposure, the greater the risk. This is not taken into account and the computations assume average exposure. Clinical judgment should be used for low or high exposures.

**Rheumatoid arthritis (RA)**
RA is a risk factor for fracture. However, osteoarthritis is, if anything, protective. For this reason reliance should not be placed on a patient's report of 'arthritis' unless there is clinical or laboratory evidence to support the diagnosis.

**Bone mineral density (BMD)**
The site and reference technology is DXA at the femoral neck. T-scores are based on the NHANES reference values for women aged 20-29 years. The same absolute values are used in men.
Appendix 3: QFracture risk assessment tool.

There is no generally agreed threshold, regarding the definition of high risk, equivalent to the 20% intervention threshold used for cardiovascular disease (which is a cost-effectiveness threshold set by NICE). Therefore, thresholds for QFracture have been defined based on the risks of patients within the QResearch database for men and women separately.

- For women, the cut off for the top 10% at highest risk is a 10 year risk of 11.1%.
- For men, the cut off for the top 10% at highest risk is 2.6%.

For further information, see [http://www.bmj.com/content/342/bmj.d3651.full](http://www.bmj.com/content/342/bmj.d3651.full)
References:

Osteoporosis: assessing the risk of fragility fracture. NICE clinical guideline 146 (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)


Acknowledgements:
WCCG Falls Prevention, Management and Bone Health Clinical Reference Group.

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