NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate

Quality standards and indicators

Briefing paper

Quality standard topic: Osteoporosis

Output: Prioritised quality improvement areas for development.

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Contents

1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for osteoporosis. It provides the committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the committee in considering potential statements and measures.

1.2 Development sources

The key development sources referenced in this briefing paper are:

Osteoporosis: assessing the risk of fragility fracture NICE guideline CG146 (2012)

Note that in January 2015 NICE decided that CG146 should not undergo a regular surveillance review until after the completion of a new multiple technology appraisal to replace the following individual technology appraisal guidance that is relevant to osteoporosis:

- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women (2008) NICE technology appraisal guidance TA160
- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (2008) NICE technology appraisal guidance TA161
- Denosumab for the prevention of osteoporotic fractures in postmenopausal women (2010) NICE technology appraisal guidance TA204

Osteoporosis - prevention of fragility fractures NICE Clinical Knowledge Summaries (2016)

Management of osteoporosis and the prevention of fragility fractures Scottish Intercollegiate Guidelines Network guideline No.142 (2015)

2 Overview[1]

2.1 Focus of quality standard

This quality standard will cover management of osteoporosis in adults (aged 18 and over). This includes prevention and risk assessment of fragility fractures.

2.2 Definition

Osteoporosis is a disease characterised by low bone mass, with a consequent increase in bone fragility and susceptibility to fracture. Fragility fractures result from forces that would not ordinarily result in fracture, such as forces equivalent to a fall from a standing height or less.

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 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.

2.3 Incidence and prevalence

One in two women and one in five men in England and Wales break a bone after the age of 50. This amounts to over 500,000 fractures each year in the UK[2].

Reduced bone density is a major risk factor for fragility fracture. Other factors that may affect the risk 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.

2.4 Management

There are options available for the prevention of fragility fractures in people at risk, or to prevent further fractures in those who have already had them, including drug treatment and lifestyle interventions. However, identifying who will benefit from preventative treatment is imprecise. A number of risk assessment tools are available

[1] Unless referenced as from another source, the information in this section is from Osteoporosis: assessing the risk of fragility fracture NICE guideline CG146 (2012)
[2] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

to predict fracture incidence over a period of time, and these may be used to aid decision-making.

See appendix 1 for the risk assessment algorithm from NICE guideline CG146.

2.5 National outcome frameworks

Tables 1–3 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 NHS outcomes framework 2016–17

Domain	Overarching indicators and improvement areas
1 Preventing people from dying prematurely	***Overarching indicators*** 1b Life expectancy at 75 i Males ii Females
2 Enhancing quality of life for people with long-term conditions	***Overarching indicator*** 2 Health-related quality of life for people with long-term conditions** ***Improvement areas*** **Ensuring people feel supported to manage their condition** 2.1 Proportion of people feeling supported to manage their condition
3 Helping people to recover from episodes of ill health or following injury	***Overarching indicators*** 3b Emergency readmissions within 30 days of discharge from hospital* ***Improvement areas*** **Improving recovery from fragility fractures** 3.5 Proportion of patients recovering to their previous levels of mobility/walking ability at i 30 and ii 120 days
4 Ensuring that people have a positive experience of care	***Overarching indicators*** 4a Patient experience of primary care i GP services 4b Patient experience of hospital care ***Improvement areas*** **Improving people's experience of integrated care** *4.9 People's experience of integrated care***
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	***Overarching indicators*** *5a Deaths attributable to problems in healthcare* *5b Severe harm attributable to problems in healthcare* ***Improvement areas*** **Reducing the incidence of avoidable harm** *5.4 Hip fractures from falls during hospital care* **Improving the culture of safety reporting** 5.6 Patient safety incidents reported
Alignment with Adult Social Care Outcomes Framework and/or Public Health Outcomes Framework * Indicator is shared ** Indicator is complementary Indicators in italics in development	

Table 2 Public health outcomes framework for England, 2016–2019

Domain	Objectives and indicators
1 Improving the wider determinants of health	***Objective*** Improvements against wider factors which affect health and wellbeing and health inequalities ***Indicators*** 1.09 Sickness absence rate 1.16 Utilisation of outdoor space for exercise/health reasons
2 Health improvement	***Objective*** People are helped to live healthy lifestyles, make healthy choices and reduce health inequalities ***Indicators*** 2.13 Proportion of physically active and inactive adults 2.23 Self-reported well-being 2.24 Injuries due to falls in people aged 65 and over
4 Healthcare public health and preventing premature mortality	***Objective*** Reduced numbers of people living with preventable ill health and people dying prematurely, whilst reducing the gap between communities ***Indicators*** 4.11 Emergency readmissions within 30 days of discharge from hospital* 4.13 Health-related quality of life for older people 4.14 Hip fractures in people aged 65 and over
Alignment with Adult Social Care Outcomes Framework and/or NHS Outcomes Framework * Indicator is shared Indicators in italics in development	

Table 3 Adult social care outcomes framework 2015–16

Domain	Overarching and outcome measures
2 Delaying and reducing the need for care and support	***Overarching measure*** 2A Permanent admissions to residential and nursing care homes, per 100,000 population ***Outcome measures*** **Everybody has the opportunity to have the best health and wellbeing throughout their life, and can access support and information to help them manage their care needs** **Earlier diagnosis, intervention and reablement means that people and their carers are less dependent on intensive services** 2B Proportion of older people (65 and over) who were still at home 91 days after discharge from hospital into reablement/rehabilitation services*
Alignment with NHS Outcomes Framework and/or Public Health Outcomes Framework * Indicator is shared	

3 Summary of suggestions

3.1 Responses

In total 13 stakeholders responded to the 2-week engagement exercise between 3 - 16 August 2016, including 3 who made no comment.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 4 for further consideration by the committee.

Full details of all suggestions received are in appendix 3.

NHS Improvement's patient safety division submitted comments during stakeholder engagement, which are summarised in this paper and can be found in full in appendix 3 in the table of suggestions from stakeholders.

Table 4 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders
Who to assess for fragility fracture risk	• BNMS, BTS, NHS IPS, NOS, PCRS, RCP, SCM 1, SCM 2, SCM 3, SE
How to assess for fragility fracture risk • Use of DXA scanning	• NOS, PCRS, RCP
Management for people at risk of fragility fracture • Lifestyle advice • Drug treatment • Follow up	• SCM 3 • BTS, NOS, RCP, SCM 1 • NGC, NOS, PCRS, RCP, SCM 1, SCM 2, SCM 3
Additional areas • Quality of bone density reporting • Screening for coeliac disease • Access to treatments for vertebral compression fractures • Patient information • Falls: assessing risk and prevention • Indicators and implementation support	• BNMS • CUK • ML • NOS, SCM 3 • NHS IPS, SCM 3, SCM 4 • NHS IPS

BNMS, British Nuclear Medicine Society
BTS, British Thoracic Society
CUK, Coeliac UK
ML, Medtronic Ltd.
NGC, National Guideline Centre
NHS IPS, NHS Improvement: patient safety
NOS, National Osteoporosis Society
PCRS, Primary Care Rheumatology Society
RCP, Royal College of Physicians
SCM, Specialist Committee Member
SE, Society for Endocrinology

3.2 Identification of current practice evidence

Bibliographic databases were searched to identify examples of current practice in UK health and social care settings; 719 papers were identified for osteoporosis. In addition, 14 papers were suggested by stakeholders at topic engagement and 16 papers internally at project scoping.

Of these papers, 4 have been included in this report and are included in the current practice sections where relevant. Appendix 2 outlines the search process.

4 Suggested improvement areas

4.1 Who to assess for fragility fracture risk

4.1.1 Summary of suggestions

Who to assess for fragility fracture risk

Stakeholders felt that at-risk groups of people should be assessed for fragility fracture risk. Specific groups mentioned include people taking long term steroids, postmenopausal women, older people who have had a fall and people presenting with fragility and vertebral fractures. The difficulties in detecting vertebral fractures and variation in the numbers of risk assessments being carried out in primary care were highlighted. Targeted prevention through systematic identification of people at risk was also raised.

Stakeholders also suggested that Fracture Liaison Services (FLS) are effective at identifying who to assess, and ensuring people are assessed and receive interventions, but FLS are not universally available. This area focusses more on the service delivery model rather than on who to assess.

4.1.2 Selected recommendations from development sources

Table 5 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. Note that some of the recommendations use 'consider' wording, such as 'should be considered' or 'may be considered'. These are presented in full after table 5 to help inform the committee's discussion.

Table 5 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Who to assess for fragility fracture risk	**Targeting risk assessment** NICE CG146 Recommendation 1.1 NICE CG146 Recommendation 1.2 **Who to assess** NICE Osteoporosis CKS, Scenario: Assessment - Who to Assess: whole section **Risk Factors: non-modifiable risk factors** SIGN 142 Recommendations in sections 3.2.5 and 3.2.6

	Risk Factors: modifiable risk factors SIGN 142 Recommendations in sections 3.3.2 (first recommendation), 3.3.3 (second recommendation) and 3.3.4 (first recommendation) **Risk Factors: coexisting diseases** SIGN 142 Recommendations in sections 3.4.1, 3.4.2, 3.4.3, 3.4.5, 3.4.7, 3.4.8, 3.4.9, 3.4.11 and 3.4.12 **Risk Factors: pharmacological risk factors** SIGN 142 Recommendations in sections 3.5.2, 3.5.3, 3.5.5, 3.5.9, 3.5.11, 3.5.13 and 3.5.14 **Systems of care: Multifaceted interventions** SIGN 142 Recommendation in section 8.3

Targeting risk assessment

NICE CG146 – Recommendation 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[3]
  - 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.

NICE CG146 – Recommendation 1.2

[3] 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).

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.

Who to assess

NICE Osteoporosis CKS, Scenario: Assessment – Who to assess

Who should I assess for fragility fracture risk?

Identify high-risk groups of people to assess fragility fracture risk. These groups should include:

- All women aged 65 years and over, and all men aged 75 years and over.
- All women aged 50-64 years and all men aged 50-74 years who have any of the following risk factors:
  - A previous osteoporotic fragility fracture.
  - Current use or frequent recent use of oral corticosteroids.
  - History of falls.
  - Low body mass index (less than 18.5 kg/m²
  - Smoker.
  - Alcohol intake of more than 14 units per week.
  - A secondary cause of osteoporosis, including:
    - Hypogonadism in either sex, including untreated premature menopause (menopause before 40 years of age), treatment with aromatase inhibitors (such as exemastane) or gonadotrophin-releasing hormone agonists (such as goserelin).
    - Endocrine conditions, including diabetes mellitus, Cushing's disease, hyperthyroidism, hyperparathyroidism, and hyperprolactinaemia.
    - Conditions associated with malabsorption including inflammatory bowel disease, coeliac disease, and chronic pancreatitis.
    - Rheumatoid arthritis and other inflammatory arthropathies.
    - Haematological conditions such as multiple myeloma and haemoglobinopathies.
    - Chronic obstructive pulmonary disease.
    - Chronic liver failure.
    - Chronic kidney disease.
    - Immobility.
- People younger than 50 years of age with any of the following risk factors:
  - Current or frequent use of oral corticosteroids.
  - Untreated premature menopause.
  - A previous fragility fracture.
- People younger than 40 years of age with any of the following risk factors:

- Current or recent use of high-dose oral corticosteroids equivalent to, or more than, 7.5 mg prednisolone daily for 3 months or more.
- Previous fragility fracture of the spine, hip, forearm, or proximal humerus.
- History of multiple fragility fractures.

Consider assessing fracture risk for people taking the following medication, especially in the presence of other risk factors:

- Selective serotonin reuptake inhibitors.
- Antiepileptic medication - particularly enzyme-inducing drugs, such as carbamazepine.
- Aromatase inhibitors, such as exemastane.
- Gonadotropin-releasing hormone agonists, such as goserelin.
- Proton pump inhibitors.
- Thiazolidinediones, such as pioglitazone.

Risk Factors: non-modifiable risk factors

SIGN 142 – Family history 3.2.5

People with a parental history of osteoporosis, particularly those over the age of 50, should be considered for fracture-risk assessment.

SIGN 142 – Reproductive factors 3.2.6

Women over the age of 50 with a history of previously untreated early menopause should be considered for fracture-risk assessment, particularly in the presence of other risk factors.

Risk Factors: modifiable risk factors

SIGN 142 – Alcohol intake 3.3.2, first recommendation

People over the age of 50 who consume more than 3.5 units of alcohol per day should be considered for fracture-risk assessment.

SIGN 142 – Weight 3.3.3, second recommendation

People over the age of 50 with a low BMI (<20 kg/m2) may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Smoking 3.3.4, first recommendation

Smokers over the age of 50 should be considered for fracture-risk assessment, particularly in the presence of other risk factors.

Risk Factors: coexisting diseases

SIGN 142 – Diabetes 3.4.1

People over the age of 50 with diabetes may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Inflammatory rheumatic diseases 3.4.2

People over the age of 50 with rheumatoid arthritis or systemic lupus erythematosus may be considered for fracture-risk assessment particularly in the presence of other risk factors.

SIGN 142 – Gastrointestinal diseases 3.4.3

People over the age of 50 with inflammatory bowel disease or malabsorption may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Epilepsy 3.4.5

Institutionalised patients with epilepsy over the age of 50 are at an increased risk of fracture and may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Primary hyperparathyroidism and other endocrine diseases 3.4.7

People over the age of 50 with hyperparathyroidism or other endocrine diseases may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Chronic liver disease 3.4.8

People over the age of 50 with chronic liver disease may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Neurological disorders 3.4.9

People over the age of 50 with neurological disease (including Alzheimer's disease, Parkinson's disease, multiple sclerosis and stroke) may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Chronic kidney disease 3.4.11

People over the age of 50 with moderate to severe chronic kidney disease (eGFR <60 ml/min/1.73 m^2) may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Asthma 3.4.12

People over the age of 50 with asthma may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

Risk Factors: pharmacological risk factors

SIGN 142 – Antidepressants 3.5.2

People over the age of 50 on long-term antidepressant therapy (in particular SSRIs) may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Anticonvulsants 3.5.2

People with epilepsy over the age of 50 who are taking antiepileptic medication, in particular enzyme-inducing antiepileptic agents, may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Aromatase inhibitors and tamoxifen 3.5.5

Women over the age of 50 taking aromatase inhibitors may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Gonadotropin-releasing hormone agonists 3.5.9

Men over the age of 50 with prostate cancer, who are taking GnRH agonists may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Acid-suppressive drugs 3.5.11

People over the age of 50 taking PPIs may be considered for fracture-risk assessment, particularly in the presence of other risk factors.

SIGN 142 – Glucocorticoids 3.5.13

Patients taking oral glucocorticoids should be considered for fracture-risk assessment.

SIGN 142 – Antidiabetic agents 3.5.14

People aged over 50 using TZDs are at higher fracture risk than people with diabetes who are treated with other agents and should be considered for fracture-risk assessment, particularly in the presence of other risk factors.

Systems of care: Multifaceted interventions

SIGN 142 - Multifaceted interventions

Patients over the age of 50 who have experienced a fragility fracture should be managed within a formal integrated system of care that incorporates a fracture liaison service.

4.1.3 Current UK practice

The Quality and Outcomes Framework (QOF)[4] is the annual reward and incentive programme detailing GP practice achievement results. The 2014/15 QOF indicators show that:

- 34,992 patients aged 50 – 74 with a record of a fragility fracture on or after 1 April 2012 and a diagnosis of osteoporosis confirmed on DXA scan, and aged 75 or over with a record of a fragility fracture on or after 1 April 2014, were on QOF registers for incentivised interventions. This compares with 65,000 hip fractures per year[5] and an estimated 500,000 fragility fractures[6], of which 50% would be expected to be on therapy[7].

The Fracture Liaison Service Database facilities audit (FLS-DBA)[8] reports on service provision for secondary fracture prevention within the NHS in England and Wales. Data from this report tells us that in 2014:

- 73% of FLSs in England routinely include a fracture risk assessment with a scoring tool (such as FRAX®) as part of their investigation pathway.

- Most FLSs did not see as many patients as expected compared to an estimated local fragility fracture caseload:
  - 24% (10/42) of FLSs in England and Wales identified at least 80% of their estimated caseload
  - 59% (23/39) of FLSs in England identified less than 50% of their estimated caseload
  - 23% (9/39) in England saw at least 20% of their estimated caseload

- Who is being missed:

[4] NHS Digital (2015) Quality and Outcomes Framework (QOF) - 2014-15
[5] Royal College of Physicians and Falls and Fragility Fracture Audit Programme (2015) National Hip Fracture Database (NHFD) annual report 2015
[6] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture
[7] Information provided by Royal College of Physicians at stakeholder engagement
[8] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

- 23% (12/52) of FLSs in England and Wales were identifying all the major fracture types
- 71% of FLSs in England routinely identified hip fracture patients
- 63% in England routinely identified patients presenting with a clinical vertebral fracture
- 31% in England routinely identified incidental radiological vertebral fracture

The National Audit of Falls and Bone Health in Older People 2010[9] is a combined audit that examines services and clinical care provided to older people for falls prevention, bone health and fractures. Data from this audit shows that in 2010:

- Only 32% (1933/6083) of non-hip fracture and 67% (2324/3484) of hip fracture patients had a clinical assessment for osteoporosis/fracture risk. This has improved significantly since the clinical audit in 2007 (19% for non-hips and 35% for hips).
- Under half of sites (44%) report that older people with a history of falls or mobility problems are assessed for fracture risk.
- 50% of the organisations that provide fracture clinic services have procedures that ensure the assessment or referral for further management of bone health.
- 88% of hip fracture services have hospital procedures to ensure that older people with hip fracture receive routine specialist assessment of bone health.
- Neither emergency departments (EDs) nor fracture clinics are assessing falls and bone health risk in most patients. Only 15% of fallers who attend ED or minor injury unit (MIU) are screened for osteoporosis. This has not improved significantly since 2008.

Current practice on service provisions tells us that:

- 65% of participating sites in England (48/74) had a dedicated FLS in 2014 (FLS-DBA)[10].
- Only 37% of local health services provide any kind of FLS and not all of these can demonstrate reliable assessment of all fracture patients in 2010 (National Audit of Falls and Bone Health in Older People 2010)[11].

[9] Royal College of Physicians (2010) Falling standards, broken promises. Report of the national audit of falls and bone health in older people 2010

[10] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

[11] Royal College of Physicians (2010) Falling standards, broken promises. Report of the national audit of falls and bone health in older people 2010

4.1.4 Resource impact assessment

The costing report for NICE guideline CG146 reported that there may be a resource impact associated with an increase in the number of fragility fracture risk assessments carried out, mainly in relation to extra clinical time needed to perform the assessments.

The guideline committee estimated that an additional 10 minutes of time may be required to perform a FRAX or QFracture risk assessment. However it is anticipated that many of these extra risk assessments could be undertaken opportunistically, as part of a consultation with a healthcare professional that the person is attending for other reasons. This would reduce the resource impact of carrying out fragility fracture risk assessments.

There are no costs to use the risk assessment tools.

Strategies which reduce the number of osteoporotic fractures should improve quality of life for people with osteoporosis and reduce costs associated with treating these fractures.

4.2 How to assess for fragility fracture risk

4.2.1 Summary of suggestions

Use of DXA scanning

Stakeholders raised the importance of including DXA scanning in fracture risk assessments and local access to scanning. Stakeholders suggested there is variation in which patients receive a scan and some areas are reducing numbers of scans undertaken because of financial constraints.

4.2.2 Selected recommendations from development sources

Table 6 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 6 to help inform the committee's discussion.

Table 6 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Use of DXA scanning	**Methods of risk assessment** NICE CG146 Recommendations 1.7, 1.8 and 1.9 **How to assess** NICE Osteoporosis CKS, Scenario: Assessment – How to assess: Bullets 2, 3 and 4 **Interpretation of fracture risk scores** NICE Osteoporosis CKS, Scenario: Assessment – Interpretation of fracture risk scores: Bullet 1 **How should I manage fragility fracture risk scores?** NICE Osteoporosis CKS, Scenario: Management – How should I manage fragility fracture risk scores?: Bullets 1 and 2 **Risk Factors: non-modifiable risk factors** SIGN 142 Recommendation in section 3.2.4 **Quantifying the risk of fracture: bone mineral density measurement** SIGN 142 Recommendation in section 4.3 **Targeting treatment: targeting treatment on the basis of age and previous non-hip fracture or non-vertebral fracture** SIGN 142 Recommendation in section 5.3 **Targeting treatment: targeting treatment on the basis of vertebral fractures** SIGN 142 Recommendation in section 5.4

Use of DXA Scanning

Methods of risk assessment

NICE CG146 – Recommendation 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[12] for a proposed treatment, and recalculate absolute risk using FRAX with the BMD value.

NICE CG146 – Recommendation 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).

NICE CG146 – Recommendation 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).

How to assess

NICE Osteoporosis CKS, Scenario: Assessment – How to assess: bullets 2, 3 and 4

- Offer a dual-energy X-ray absorptiometry (DXA) scan to measure bone mineral density (BMD) without calculating the fragility fracture risk in people:
  - Over 50 years of age with a history of fragility fracture.
  - Younger than 40 years of age who have a major risk factor for fragility fracture (see the section What are the risk factors?) - depending on the BMD T-score (see the section on What are osteoporosis and osteoporotic fractures?), refer to a specialist experienced in the treatment of osteoporosis.
- Consider starting drug treatment in people with vertebral or hip fractures without undertaking DXA if this is considered inappropriate or impractical (see the section on Drug treatments).
- For all other people with risk factors for osteoporosis, calculate the 10-year fragility fracture risk prior to arranging a DXA scan to measure BMD.
  - Consider using the online risk calculators QFracture® (preferred) or FRAX®, which predict the absolute risk of hip fracture and major osteoporotic fractures (spine, wrist, hip, or shoulder) over 10 years.
    - Measure the BMD with DXA (at the spine and hip) in people found to be at high risk of fragility fracture.

[12] 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.

        - Measure the BMD with DXA in people whose fracture risk is close to the recommended threshold, who have risk factors that may be underestimated by FRAX®. For more information, see the section How should I interpret a fragility fracture risk score?

Interpretation of fracture risk scores

NICE Osteoporosis CKS, Scenario: Assessment – Interpretation of fracture risk scores: bullet 1

- A 10-year fracture risk of 10% is considered to be the threshold for arranging a dual-energy X-ray absorptiometry (DXA) scan in men and women. However, a pragmatic approach is advised and clinical judgement and local pathways should be considered.
    - When using the QFracture® calculator, be aware that women are considered to be at high risk if their 10-year risk is more than 11.1%, and men are considered to be at high risk if their 10-year risk is more than 2.6%.

How should I manage fragility fracture risk scores?

NICE Osteoporosis CKS, Scenario: Management – How should I manage fragility fracture risk scores?: Bullets 1 and 2

- For people at high risk of fragility fracture
    - For people whose fracture risk is above the recommended threshold, offer a dual-energy x-ray absorptiometry (DXA) scan, then bone-sparing drug treatment if the T-score is -2.5 or less.
    - If the T-score is greater than -2.5, modify risk factors where possible (see the section on Risk factors), treat any underlying conditions (see the section on What causes osteoporosis and osteoporotic fractures?), and repeat the DXA at an interval appropriate for the person based on their risk profile, using clinical judgement (but usually within 2 years). For more information, see the section on How should I follow up a person at risk of fragility fracture?
- For people at intermediate risk of fragility fracture
    - For people whose fracture risk is close to the recommended threshold and who have risk factors that may be underestimated by FRAX® (see the section How should I interpret a fragility fracture risk score?), arrange a DXA scan to measure their bone mineral density (BMD) and offer drug treatment if the T-score is -2.5 or less.

Risk Factors: non-modifiable risk factors

SIGN 142 – Previous fractures 3.2.4

People with a history of fragility fractures over the age of 50 should be offered DXA scanning to evaluate the need for antiosteoporosis therapy.

Quantifying the risk of fracture: bone mineral density measurement

SIGN 142 – Bone mineral density 4.3

Measurement of bone mineral density by DXA at the spine and hip should be carried out following fracture-risk assessment in patients in whom antiosteoporosis treatment is being considered.

Targeting treatment: targeting treatment on the basis of age and previous non-hip fracture or non-vertebral fracture

SIGN 142 – Targeting treatment on the basis of age and previous non-hip fracture or non-vertebral fracture 5.3

Postmenopausal women aged 75 and above who have suffered a previous non-hip or non-vertebral fragility fracture should not be initiated on bone-sparing drug treatments unless they are shown to have osteoporosis on DXA examination.

Targeting treatment: targeting treatment on the basis of vertebral fractures

SIGN 142 – Targeting treatment on the basis of vertebral fractures 5.4

Measurements of BMD by DXA should normally be performed prior to starting osteoporosis drug treatment, but therapy can be commenced in patients with prevalent vertebral fractures without undertaking BMD measurements if these are felt to be inappropriate or impractical.

4.2.3 Current UK practice

Current practice dating relating to who is receiving DXA scans tells us that:

- In 2014 90% of FLSs include DXA at hip and/or spine routinely in post-fracture assessments, 25% include vertebral fracture assessment by DXA (VFA or instant vertebral assessment (IVA)) and 10% include peripheral DXA (FLS-DBA)[13]
- In 2010 a small proportion of patients aged under 75 had a clinical decision not to request DXA: 4% of non-hip and 22% of hip fracture patients. Only a further 25% (non-hip) and 29% (hip) fracture patients received a DXA scan in this age group (National Audit of Falls and Bone Health in Older People 2010)[14]

Information on access to DXA scans shows that:

- In 2014 63% (30/48) of FLSs had DXA available on site. 21% refer to another DXA provider (FLS-DBA)[15]
- In 2010 71% (96/135) of organisations said they commission direct access to DXA services by GPs (without the need to refer to a specialist service. 63% (203/321) said they provide direct access to DXA services by GPs (National Audit of Falls and Bone Health in Older People 2010)[16]

4.2.4 Resource impact assessment

The guideline committee considered that implementing NICE guideline CG146 may result in more appropriate use of DXA scanning because the use of DXA should be directed to those most at risk of fragility fracture, identified by risk assessment tools.

The cost payable by commissioners for a DXA scan is £62 (RA15Z, National Tariff 2016-17).

[13] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

[14] Royal College of Physicians (2010) Falling standards, broken promises. Report of the national audit of falls and bone health in older people 2010

[15] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

[16] Royal College of Physicians (2010) Falling standards, broken promises. Report of the national audit of falls and bone health in older people 2010

4.3 Management for people at risk of fragility fracture

4.3.1 Summary of suggestions

Lifestyle advice

A stakeholder suggested the number of people undertaking regular exercise as a quality improvement area, as this decreases the number of fragility fractures.

Drug treatment

In developing the quality standard we will not consider a quality statement with reference to drugs that are included in technology appraisal guidance TA160, TA161 and TA204. Technology appraisal guidance is generally not considered as a source for quality standards because the NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisal guidance. If this area is progressed to statement development:

- it is unlikely that named drugs will be covered as these will fall under the scope of the forthcoming multiple technology appraisal (MTA)
- intervention thresholds may also be considered by the forthcoming MTA, including the scope for aligning the thresholds in the clinical guideline (CG146) and technology appraisal guidance.

Stakeholders suggested that initiating bone protective therapy is key for reducing fracture risk. There is variation in the thresholds for initiating therapy, and who is considered appropriate for treatment.

Follow up

Stakeholders raised the importance of reviewing osteoporosis treatment, including the duration of, and need to continue, treatment; adherence; and checking for any adverse effects. Stakeholders suggested that guidance on duration of treatment and monitoring is lacking, and that not enough people are receiving reviews.

4.3.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. Note that some of the recommendations from the SIGN guideline use ‘consider’ wording, such as ‘should be considered’ or ‘may be considered’. These are presented in full after table 7 to help inform the committee’s discussion.

Table 7 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Lifestyle advice	**Lifestyle information and advice** NICE Osteoporosis CKS, Scenario: Management – Lifestyle information and advice: Bullet 1 **Management of osteoporosis in postmenopausal women: exercise interventions** SIGN 142 Recommendations in section 6.2.7 **Management of osteoporosis in other groups: exercise interventions on premenopausal women** SIGN 142 Recommendations in section 7.4
Drug treatment	**How should I manage fragility fracture risk scores?** NICE Osteoporosis CKS, Scenario: Management - How should I manage fragility fracture risk scores?: bullets 1 – 3 **Drug treatment** NICE Osteoporosis CKS, Scenario: Management – Drug treatment: all bullets **Targeting treatment: Targeting treatment on the basis of age and previous non-hip fracture or non-vertebral fracture** SIGN 142 Recommendation in section 5.3 **Targeting treatment: Targeting treatment on the basis of hip fracture** SIGN 142 Recommendation in section 5.5 **Management of osteoporosis in postmenopausal women: The role of diet** SIGN 142 Recommendation in section 6.3.6 **Management of osteoporosis in postmenopausal women: Pharmacological management**

	SIGN 142 Recommendations in sections 6.4.1, 6.4.2, 6.4.3, 6.4.4, 6.4.5, 6.4.7, 6.4.8, 6.4.10, 6.4.11, 6.4.12, 6.4.13 and 6.4.14 **Management of osteoporosis in other groups: Glucocorticoid-induced osteoporosis** SIGN 142 Recommendations in sections 7.5.1, 7.5.2 and 7.5.4 **Oral therapy** NICE CG 101 Recommendation 1.2.3.2 **Assessment and treatment of bone loss** NICE CG80 Recommendation 1.10.3
Follow up	**Follow up** NICE Osteoporosis CKS, Scenario: Management – Follow up: All bullets **Management of osteoporosis in postmenopausal women: pharmacological management** SIGN 142 Recommendation in section 6.4.6 (second recommendation) **Management of osteoporosis in postmenopausal women: Monitoring of pharmacological effect** SIGN 142 Recommendations in section 6.6.1 and 6.6.2 **Management of osteoporosis in postmenopausal women: Adherence, compliance and concordance** SIGN 142 Recommendation in section 6.7.3

Lifestyle advice

Lifestyle information and advice

NICE Osteoporosis CKS, Scenario: Management – Lifestyle information and advice: Bullet 1

- Advise the person to:

- Take regular exercise (tailored to the person) to improve muscle strength. Encourage:
  - Walking, especially outdoors, as this will increase exposure to sunlight, increasing vitamin D production.
  - Strength training (such as weight training) of different muscle groups (for example hip, wrist, and spine).
  - A combination of exercise types, for example balance, flexibility, stretching, endurance, and progressive strengthening exercises.

Management of osteoporosis in postmenopausal women: exercise interventions

SIGN142 – Exercise interventions 6.2.7

- Combinations of exercise types including balance training, flexibility or stretching exercises, endurance exercise and progressive strengthening exercises should be considered to reduce risk of fractures caused by falls.

- Static weight-bearing exercise, for example, single-leg standing should be considered to slow decline of hip BMD.

- Progressive resistance strength training exercise (such as weight training) should be considered to slow decline of femoral neck BMD, either alone or in combination with impact exercise training (such as jogging, walking or aerobics).

Management of osteoporosis in other groups: exercise interventions on premenopausal women

SIGN 142 – Exercise interventions on premenopausal women 7.4

- High-impact exercise (such as jogging) and combining impact exercise (such as stair climbing) with progressive-resistance strength training (such as weight training) should be considered to slow decline of femoral neck BMD.

- Progressive-resistance strength training (such as weight training) alone, or in combination with impact exercise (such as stair climbing or jogging), should be considered to slow decline of lumbar spine BMD.

Drug treatment

How should I manage fragility fracture risk scores?

NICE Osteoporosis CKS, Scenario: Management - How should I manage fragility fracture risk scores?: bullets 1 – 3

- For people at high risk of fragility fracture
    - For people whose fracture risk is above the recommended threshold, offer a dual-energy x-ray absorptiometry (DXA) scan, then bone-sparing drug treatment if the T-score is -2.5 or less.
- For people at intermediate risk of fragility fracture
    - For people whose fracture risk is close to the recommended threshold and who have risk factors that may be underestimated by FRAX® (see the section How should I interpret a fragility fracture risk score?), arrange a DXA scan to measure their bone mineral density (BMD) and offer drug treatment if the T-score is -2.5 or less.
- For people at low risk of fragility fracture
    - For people whose fracture risk is below the recommended threshold, do not offer drug treatment, offer lifestyle advice and follow up within 5 years. See the section on Lifestyle information and advice.

Drug treatment

NICE Osteoporosis CKS, Scenario: Management – Drug treatment: all bullets

- If bone-sparing treatment is recommended, prescribe a bisphosphonate (alendronate 10 mg once daily or 70 mg once weekly, or risedronate 5 mg once daily or 35 mg once weekly), if there are no contraindications and after appropriate counselling to:
    - Postmenopausal women and men over 50 years of age who have been confirmed by dual-energy X-ray absorptiometry (DXA) scan to have osteoporosis (bone mineral density [BMD] T-score of -2.5 or less).
    - Consider prescribing to:
        - People who are taking high doses of oral corticosteroids (more than or equivalent to prednisolone 7.5 mg daily for 3 months or longer).
    - All the bisphosphonates are licensed for use in postmenopausal women. However, only alendronate (once-daily tablets) and risedronate (once-weekly tablets) are licensed for use in men.
    - Counsel people on the use of bisphosphonates (for more information, see the section on What advice should I give a person taking a bisphosphonate?) and explain about possible adverse effects (for more information, see the section on What are the adverse effects of bisphosphonates?).
    - If an oral bisphosphonate is not tolerated or is contraindicated, consider specialist referral. Specialist treatment options include zoledronic acid, strontium ranelate, raloxifene, denosumab, and teriparatide.
- If the person's calcium intake is adequate (700 mg/day), prescribe 10 micrograms (400 international units) of vitamin D (without calcium) for people not exposed to much sunlight. See the section on How should I assess a person for fragility fracture risk?).
- If calcium intake is inadequate:

    - Prescribe 10 micrograms (400 international units) of vitamin D with at least 1000 mg of calcium daily.
    - Prescribe 20 micrograms (800 international units) of vitamin D with at least 1000 mg of calcium daily for elderly people who are housebound or living in a nursing home.
- Consider prescribing hormone replacement therapy (HRT) to women who have a premature menopause (menopause before 40 years of age) to reduce the risk of fragility fractures and for the relief of menopausal symptoms. For further information on prescribing HRT, see the CKS topic on Menopause.

Targeting treatment: targeting treatment on the basis of age and previous non-hip fracture or non-vertebral fracture

SIGN 142 – Targeting treatment on the basis of age and previous non-hip fracture or non-vertebral fracture 5.3

Postmenopausal women aged 75 and above who have suffered a previous non-hip or non-vertebral fragility fracture should not be initiated on bone-sparing drug treatments unless they are shown to have osteoporosis on DXA examination.

Targeting treatment: targeting treatment on the basis of hip fracture

SIGN 142 – Targeting treatment on the basis of hip fracture 5.5

Zoledronic acid is recommended to prevent further fractures in postmenopausal women with hip fracture who are unable or unwilling to take oral osteoporosis treatments, without undertaking BMD measurements if these are felt to be inappropriate or impractical.

Management of osteoporosis in postmenopausal women: The role of diet

SIGN 142 – Vitamin K 6.3.6

High-dose vitamin K_2 supplements are not recommended for the treatment of osteoporosis or prevention of fragility fractures.

Management of osteoporosis in postmenopausal women: Pharmacological management

SIGN 142 – Alendronic acid 6.4.1

Alendronic acid is recommended to prevent vertebral fractures, non-vertebral fractures and hip fractures in postmenopausal women with pre-existing vertebral fractures and/or DXA-proven osteoporosis.

SIGN 142 – Risedronate 6.4.2

Risedronate is recommended to prevent vertebral fractures, non-vertebral fractures and hip fractures in postmenopausal women with pre-existing vertebral fractures and/or DXA-proven osteoporosis.

SIGN 142 – Zoledronic acid 6.4.3

- Zoledronic acid is recommended to prevent vertebral, non-vertebral and hip fractures in postmenopausal women with pre-existing vertebral fractures or DXA-proven osteoporosis. It should be considered in those who are intolerant of oral therapy and those in whom adherence with oral therapy may be difficult.

- Zoledronic acid may be considered to prevent clinical fractures and reduce mortality in selected postmenopausal women who have suffered a hip fracture. It should be considered in those who are intolerant of oral therapy and those in whom adherence with oral therapy may be difficult.

SIGN 142 – Ibandronic acid 6.4.4

- Oral ibandronic acid (150 mg monthly) may be considered to prevent vertebral fractures in postmenopausal women with DXA-proven osteoporosis.

- Intravenous ibandronic acid (3 mg every three months) may be considered to prevent vertebral fractures in postmenopausal women with DXA-proven osteoporosis who are intolerant of oral therapy or those in whom adherence to oral therapy may be difficult.

SIGN 142 – Cyclical etidronate 6.4.5

Cyclical etidronate may be considered to prevent vertebral fractures in postmenopausal women when other drugs are poorly tolerated or contraindicated.

SIGN 142 – Strontium ranelate 6.4.7

Strontium ranelate may be considered for the treatment of severe postmenopausal osteoporosis to reduce the risk of vertebral and non-vertebral fractures in patients without established cardiovascular disease when other treatments are contraindicated.

SIGN 142 – Parathyroid hormone 6.4.8

Teriparatide (parathyroid hormone 1-34) is recommended to prevent vertebral and non-vertebral fractures in postmenopausal women with severe osteoporosis and may be of particular value in patients at high risk of vertebral fracture.

SIGN 142 – Denosumab 6.4.10

Denosumab is recommended to prevent vertebral, non-vertebral and hip fractures in postmenopausal women with DXA-proven osteoporosis for whom oral bisphosphonates are unsuitable due to contraindication, intolerance or inability to comply with the special administration instructions.

SIGN 142 – Hormone replacement therapy 6.4.11

Hormone replacement therapy may be considered for the prevention of vertebral, non-vertebral and hip fractures in younger postmenopausal women.

SIGN 142 – Tibolone 6.4.12

Tibolone may be considered to prevent vertebral and non-vertebral fractures in younger postmenopausal women, particularly those with menopausal symptoms.

SIGN 142 – Raloxifene 6.4.13

Raloxifene may be considered as a treatment option for the prevention of vertebral fractures in postmenopausal women when other treatments are contraindicated or unsuitable.

SIGN 142 – Calcium and vitamin D supplementation 6.4.14

Calcium and vitamin D supplements may be considered to reduce the risk of non-vertebral fractures in patients who are at risk of deficiency due to insufficient dietary intake or limited sunlight exposure.

Management of osteoporosis in other groups: Glucocorticoid-induced osteoporosis

SIGN 142 – Alendronic acid 7.5.1

Alendronic acid may be considered to prevent vertebral fractures in men and women on prednisolone doses of 7.5 mg daily or greater (or an equivalent dose of glucocorticoids) for three months or more.

SIGN 142 – Risedronate 7.5.2

Risedronate should be considered to prevent vertebral fracture in men and women on prednisolone doses of 7.5 mg daily or greater (or an equivalent dose of glucocorticoids) for three months or more.

SIGN 142 – Zoledronic acid 7.5.4

Zoledronic acid should be considered to prevent vertebral fracture in men and women on prednisolone doses of 7.5 mg daily or greater (or an equivalent dose of glucocorticoids) for three months or more. The treatment should be considered in

patients who are intolerant of oral bisphosphonates and those in whom adherence to oral therapy may be difficult.

The following recommendations are included for information:

Oral therapy

NICE CG101 – Recommendation 1.2.3.2

Patients treated with long-term oral corticosteroid therapy should be monitored for the development of osteoporosis and given appropriate prophylaxis. Patients over the age of 65 should be started on prophylactic treatment, without monitoring.

Assessment and treatment of bone loss

NICE CG80 – Recommendation 1.10.3

Offer bisphosphonates to patients identified by algorithms 1 and 2 in 'Guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK expert group' (2008)17

Follow up

Follow up

NICE Osteoporosis CKS, Scenario: Management – Follow up: All bullets

- After starting bone-sparing treatment (see the section What drug treatments are recommended for people at high risk of osteoporotic fracture?), and at routine medication review:
  - Ask about adverse effects of bisphosphonate treatment, if appropriate, in particular:
    - Upper gastrointestinal adverse effects such as dyspepsia or reflux. These are common in the first month of treatment and often improve with continuing use. They are less likely if the recommended method of taking bisphosphonates is followed. See the section on What advice should I give someone taking bisphosphonates?
    - Symptoms of atypical fracture including new onset hip, groin, or thigh pain. If this occurs, stop treatment and arrange an X-ray of the femur.
  - Ask about adherence to treatment
    - See the section on Drug treatment for recommended alternative treatments if adverse effects are unacceptable.

[17] Reid DM, Doughty J, Eastell R et al (2008) Guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK Expert Group. Cancer Treatment Reviews 34: S3–S18.

        - Consider prescribing a weekly dose of bisphosphonates for people who have difficulty adhering to daily treatment. For further information, see the section on Prescribing information .
- People taking oral corticosteroids
    - Continue treatment with bisphosphonates and/or calcium and vitamin D until treatment with oral corticosteroids has stopped, then reassess the osteoporotic fragility fracture risk to determine the need for continuing treatment with a bisphosphonate and calcium and vitamin D. See the section on How should I assess a person for fragility fracture risk? for more information.
- For all other people, review the need for continuing treatment with bisphosphonates after 3-5 years.
    - For people who remain at high risk of an osteoporotic fragility fracture, continue treatment with alendronic acid for up to 10 years, and risedronate for up to 7 years. This includes people with any of the following risk factors:
        - Age over 75 years.
        - A previous hip or vertebral fracture.
    - In other people, arrange a dual-energy X-ray absorptiometry (DXA) scan and consider:
        - Continuing treatment if the T-score is less than -2.5. Reassess their fracture risk and bone mineral density (BMD) every 3-5 years.
        - Stopping treatment if the BMD T-score is greater than -2.5. Reassess their fracture risk and re-measure BMD after 2 years.
- For people who sustain an osteoporotic fracture while on bone-sparing treatment - check adherence to treatment and exclude secondary causes for osteoporosis (see the section on What investigations should I consider to exclude an underlying cause for fragility fracture and osteoporosis?). If other underlying causes are excluded, consider referral to a specialist for advice on drug treatment. Drug treatment is recommended for at least 5 years to reduce the risk of further fractures.
- For people whose fracture risk was intermediate the last time they were assessed, reassess after a minimum of 2 years. See the section on How should I assess a person for fragility fracture risk? for more information.

Management of osteoporosis in postmenopausal women: pharmacological management

<u>SIGN 142 General harms associated with bisphosphonates 6.4.6 (second recommendation)</u>

Bisphosphonate therapy should be evaluated every five years to determine if the benefits in continuing therapy outweigh potential risks.

Management of osteoporosis in postmenopausal women: Monitoring of pharmacological effect

SIGN 142 Monitoring treatment response by DXA 6.6.1

Repeat BMD measurements by DXA after an interval of three years may be considered to assess response to treatment in postmenopausal women on alendronic acid, ibandronic acid, zolendronic acid or denosumab therapy.

SIGN 142 Monitoring treatment response by bone turnover markers 6.6.2

Measurement of BTMs may be considered to assess response to treatment in patients treated with selected antiosteoporosis drug therapies.

Management of osteoporosis in postmenopausal women: Adherence, compliance and concordance

SIGN 142 General and mixed interventions 6.7.3

Interventions by healthcare professionals, with or without feedback of biomarker results, aimed at improving adherence are recommended in patients who are being given drug treatment for osteoporosis.

4.3.3 Current UK practice

Lifestyle advice

The National Audit of Falls and Bone Health in Older People 2010[18] reports that:

- 53% (170/321) of services routinely give written lifestyle advice on maintaining bone health in respect of smoking, diet, physical activity and alcohol use to patients with, or at risk of, osteoporosis.
- Only 19% (965/5109) of non-hip fracture and 44% (1346/3038) of hip fracture patients participated in any form of exercise for falls prevention within 12 weeks of the fracture.

The following current practice information relates to guidance on strength and balance training for falls prevention (NICE clinical guideline 161), but is presented here as it may be indicative of access to exercise and lifestyle advice:

[18] Royal College of Physicians (2010) Falling standards, broken promises. Report of the national audit of falls and bone health in older people 2010

- Only 4 sites were confident that the services they referred to could provide the best-evidenced intensity of 50 hours of strength and balance exercise training needed to reduce falls (FLS-DBA)[19].
- 69% of FLSs in England (that provided a falls assessment) could refer patients to some form of exercise programme. Most (91%) of these programmes included strength and balance training, and most (94%) were delivered by appropriately trained professionals (OTAgo, FaMe, HELP) (FLS-DBA)[20].
- 86% (277/321) of services provide supervised strength and balance exercise training (National Audit of Falls and Bone Health in Older People 2010)[21].

Drug treatment

The Quality and Outcomes Framework (QOF)[22] has 2 indicators on patients on GP registers for osteoporosis currently treated with an appropriate bone-sparing agent. The 2014/15 indicators show:

- 83% receiving intervention (92% underlying achievement net of exception-reporting), for patients aged 50 – 74, with a fragility fracture on or after 1 April 2012, in whom osteoporosis is confirmed on DXA scan. This ranged from 77.8% in the Arden, Herefordshire and Worcestershire Area Team to 87.4% in the London North West region.
- 79% receiving intervention (93% underlying achievement net of exception-reporting), for patients aged 75 or over with a record of a fragility fracture on or after 1 April 2014 and a diagnosis of osteoporosis. This ranged from 73.4% in the North Yorkshire and Humber Area Team to 89.5% in the London North West region.

The Fracture Liaison Service Database facilities audit (FLS-DBA)[23] reports that:

- 91% of FLSs in England were able to recommend or prescribe at least one bone-specific therapy
- 56% of FLSs in England could directly recommend or prescribe denosumab
- 92% of FLSs in England could recommend or initiate oral bisphosphonates, 53% intravenous bisphosphonates and 31% strontium ranelate

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[19] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

[20] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

[21] Royal College of Physicians (2010) Falling standards, broken promises. Report of the national audit of falls and bone health in older people 2010

[22] NHS Digital (2015) Quality and Outcomes Framework (QOF) - 2014-15

[23] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

- 31% (16/52) of all FLSs (in England and Wales) were able to recommend the initiation of teriparatide (a form of PTH therapy)

The National Hip Fracture Database (NHFD) is a clinically-led, web-based audit of hip fracture care and secondary prevention. All 177 eligible hospitals in England, Wales and Northern Ireland are now regularly uploading data. Their annual report describes care provided to nearly 95% of all cases in England, Wales and Northern Ireland. The NHFD 2016 report states that[24] :

- In 2015 97% of patients had been assessed for the need for bone protection medication, compared with 80% in 2014.
- 79% of patients had been started on bone protection medication, or referred for DXA scan or bone clinic, or were already on appropriate medication.
- 18% of patients were recorded as having been assessed but not considered appropriate for treatment. This figure increased slightly from 16% in 2014.
- 6 sites report that more than 50% of patients are assessed as inappropriate for treatment.

The National Audit of Falls and Bone Health in Older People 2010[25] reports that:

- There has been some improvement in bone health treatment since 2007, but it remains substandard for the majority of patients. 33% (2037/6083) of non-hip fracture and 60% (2092/3484) of hip fracture patients received appropriate management for bone health
- Male fracture patients of all ages were less likely than women to receive adequate treatment for osteoporosis (54% males and 62% females with hip fracture, 22% males and 35% females with non-hip fracture).

Follow up

The Fracture Liaison Service Database facilities audit (FLS-DBA)[26] reports that:

- 79% of FLSs in England included monitoring of patients' medication adherence, persistence and adverse effects as part of their service scope. The responsibility for continued monitoring of patients is divided between FLSs and primary care.

- Most sites in England include medication adherence (82%, 23/28) and adverse effects of medication (82%, 23/28) in re-evaluation. Adherence is most commonly assessed or re-evaluated by telephone interview in England (82%, 23/28), with

[24] Royal College of Physicians and Falls and Fragility Fracture Audit Programme (2016) National Hip Fracture Database (NHFD) annual report 2016
[25] Royal College of Physicians (2010) Falling standards, broken promises. Report of the national audit of falls and bone health in older people 2010
[26] Royal College of Physicians Falls and Fragility Fracture Audit Programme (2016) Fracture Liaison Service Database (FLS-DB) facilities audit. FLS breakpoint: opportunities for improving patient care following a fragility fracture

some sites also using postal questionnaire (32%, 9/28), clinic review (29%, 8/28), DXA (14%, 4/28), other methods (14%, 4/28) and prescription review (7%, 2/28).

- Most FLSs performed 1 evaluation within 6 months of initiating treatment for secondary fracture prevention, with fewer performing a review at 12 months.
- 50% (14/28) monitored patients once, 39% (11/28) of services monitored twice and no services reported monitoring three or more times.

4.3.4 Resource impact assessment

Drug treatment

The weighted average drug cost of bone sparing agents appraised in NICE technology appraisal guidance TA161 (Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide) is £101.08 per year.

The estimated cost of a 10% increase in prescribing an appropriate bone-sparing agent (assumed to be about 6,385 additional people, after assuming 50% uptake) is £645,000. (Based on QOF indicators cost impact statement).

Lifestyle advice and follow up

There are no NICE recommendations underpinning these areas in respect of osteoporosis, so no NICE resource impact work is available.

4.4 Additional areas

Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise. However they were felt to be either unsuitable for development as quality statements, outside the remit of this particular quality standard referral or require further discussion by the committee to establish potential for statement development.

There will be an opportunity for the committee to discuss these areas at the end of the session on 28 September.

Quality of bone density reporting

A stakeholder suggested that bone density reporting is often done by radiographers and radiologists who are unfamiliar with the field. Doctors and GPs use these reports to guide decisions. There are no recommendations in the NICE or NICE accredited guidance on this area.

Screening for coeliac disease

A stakeholder suggested screening people with osteoporosis for coeliac disease, as osteoporosis can be a complication of undiagnosed coeliac disease. The NICE guideline on coeliac disease: recognition, assessment and management (NG20), recommendation 1.1.2, recommends considering serological testing for coeliac disease in people with metabolic bone disorder (reduced bone mineral density or osteomalacia). However, this is outside the scope for the quality standard on osteoporosis.

Access to treatments for vertebral compression fractures

A stakeholder raised improved access to percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. These treatment options are covered in NICE technology appraisal guidance TA279. Quality standards do not draw on technology appraisal guidance as development sources because the NHS is legally obliged to fund and resource treatments recommended by NICE's technology appraisal guidance.

Patient information

Stakeholders raised the provision of information on medication, including information on the risks and benefits of medication, as well as how to take it correctly. It was felt this will make people more likely to take it. Statement 5 in the patient experience in adult NHS services quality standard (QS15) already covers supporting patients to

“understand relevant treatment options, including benefits, risks and potential consequences”.

Falls: assessing risk and prevention

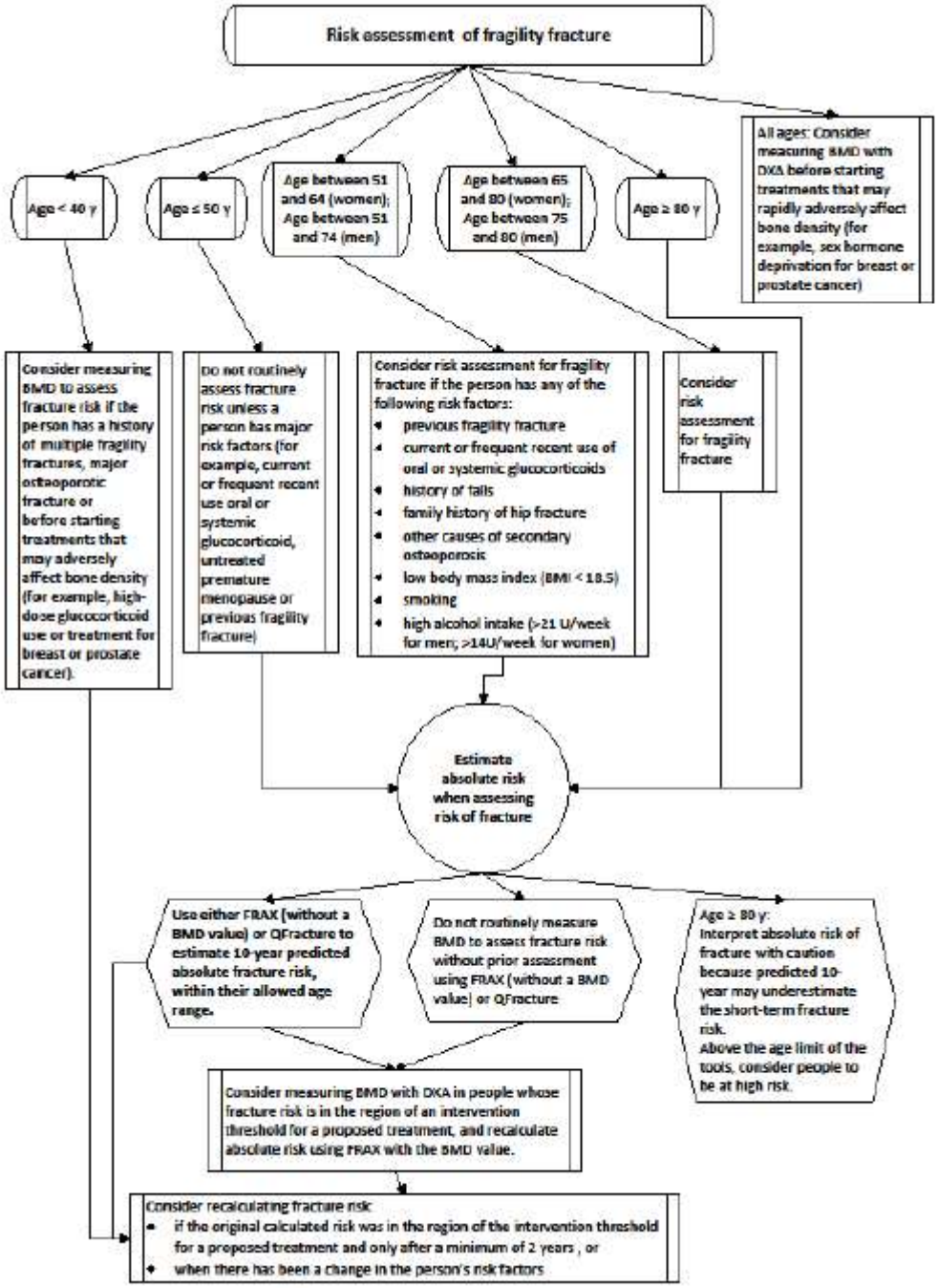
Stakeholders highlighted falls risk assessments and prevention as improvement areas. This is an area within the scope of the quality standard on falls prevention, which is due to publish in January 2017.

Indicators and implementation support

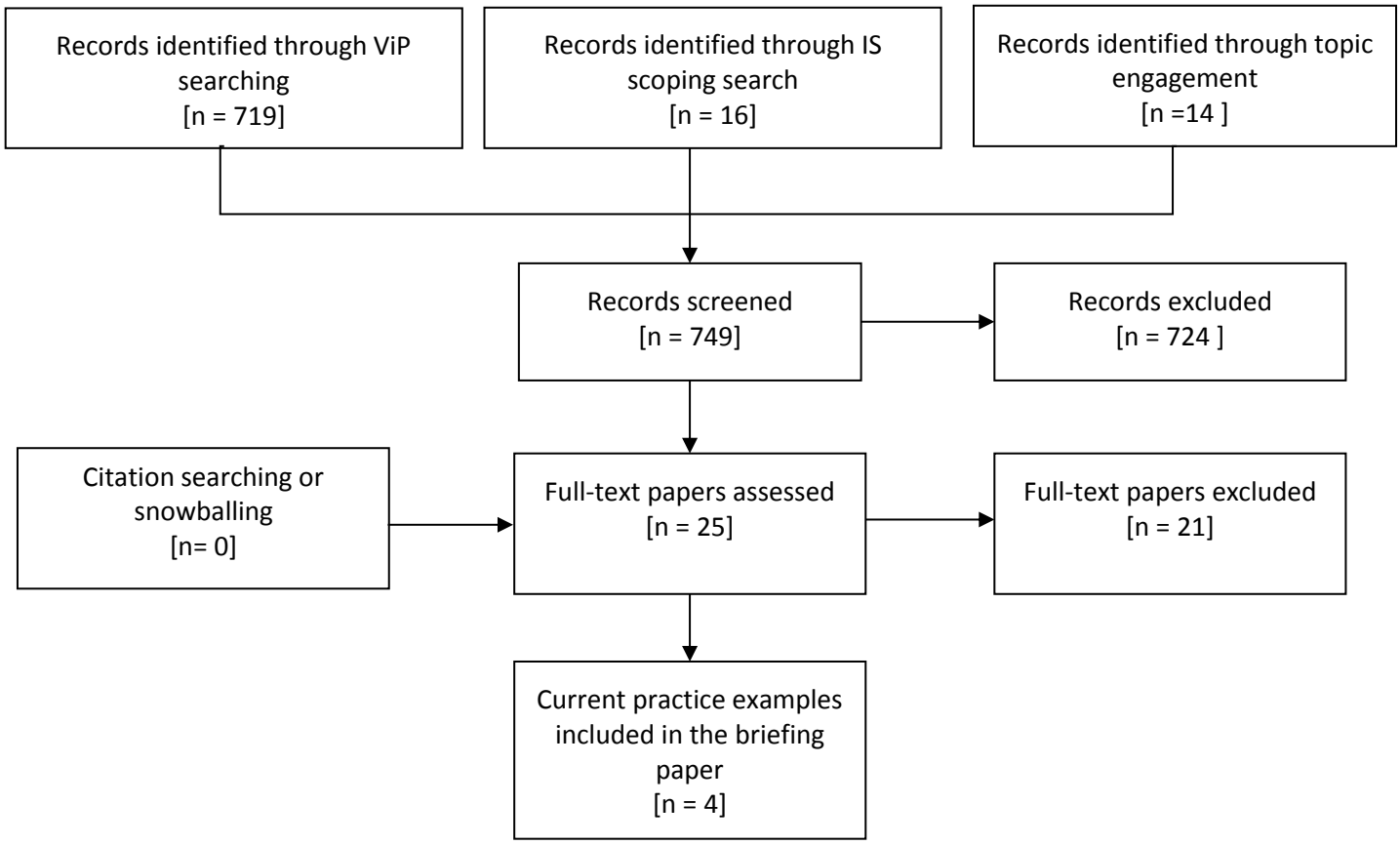
A stakeholder suggested linking in with indicators from Domain 5 of the NHS Outcomes Framework, and highlighted an eLearning tool on falls prevention to support implementation. The relevant indicators have been included in section 2.5 of this paper. The eLearning tool relates to falls, and falls are outside the scope of this quality standard as they are covered by separate quality standards.

Appendix 1: Algorithm for risk assessment of fragility fracture

Taken from the full NICE clinical guideline 146



Appendix 2: Review flowchart



Appendix 3: Suggestions from stakeholder engagement exercise – registered stakeholders

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
4.1 Who to assess for fragility fracture risk					
1	British Nuclear Medicine Society	The importance of detection of vertebral fracture	Patients often have incidental vertebral fracture noted on x-ray, CT or MRI not reported on or not followed up, sometimes because significance is not appreciated or because more serious pathology is being considered. Patients with back pain are frequently not considered as candidates for vertebral fracture especially if the pain is not severe as much back pain especially lumbar is not considered important to investigate with imaging.	Patients with vertebral fracture have high risks of further fractures and their detection can afford an opportunity to intervene before the patient progresses to the debilitating state of multiple vertebral fractures. Vertebral fractures are also the fractures best prevented with osteoporosis therapies.	The importance of detection of vertebral fracture
2	British Thoracic Society	Key area for quality improvement 1: Assessment of osteoporosis in (respiratory) patients taking long term oral steroids or taking 3 or more short term courses of steroid/year	Oral prednisolone is widely recognised to increase the risk of osteoporosis, which in turn increases the risk of fractures. These may be particularly dangerous in patients with pre-existing disease that limits fitness for surgery.	This is not an area that has been audited nationally. Receipt of a quality standard would prioritise the area for Trusts such that data could be obtained. Anecdotally, in published cohorts, and in local audits under-recognition of co-morbid disease is an issue.	The NICE guidance for COPD recommends assessment of co-morbidities at diagnosis and regularly thereafter. It is therefore important to ensure that there is consistency across guidelines and standards.
3	NHS Improvement: Patient Safety	Key area for quality improvement 1	3.2. Key development sources (NICE and NICE-accredited sources). The QS would benefit from stronger links to NICE CG 161 (falls) in terms of case finding for osteoporosis risk. Specifically the prevention and risk assessment of fragility fractures.	Older people who present for medical attention because of a fall, or report recurrent falls in the past year, or demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment to include assessment of osteoporosis risk.	https://www.nice.org.uk/guidance/cg161/chapter/1-Recommendations#multifactorial-assessment-or-multifactorial-falls-risk-assessment

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4	National Osteoporosis Society	Key area for quality improvement 1 Systematic identification of patients at high risk of fragility fracture	There is good evidence that osteoporosis treatments reduce fracture risk when properly targeted. Current practice does not systematically identify people at risk. The key groups for consideration are as follows: All patients over aged 50 with a new fragility fracture or newly reported vertebral fracture. All patients aged 50 and over who have one or more risk factors for fracture should be, when identified, be assessed in terms of their future fracture risk. Patients aged 50 and over on drug therapies which are known to be associated with increased fracture risk - particularly oral corticosteroids (7.5mg/day for over 3 months), aromatase inhibitors (in females) and androgen deprivation therapies (in males) should be systematically and proactively identified. Patients aged 50 and over with co-morbidities commonly associated with increased fracture risk - particularly systemic inflammatory arthritis, primary hyperparathyroidism, inflammatory bowel disease associated with malabsorption and patients before	The numbers of people using drugs or living with a long term condition which impact on bone density is increasing and with improvements to care, these people are more likely to survive into older age. Systematic, proactive approaches are needed to ensure their bones are protected to reduce future fractures. There is good evidence that fragility fractures are an important risk factor for future fractures and anti-osteoporosis therapies can reduce this risk. Fracture Liaison Services (FLS) undertake effective systematic case finding as well as ensuring that people are assessed and receive the interventions they need. These services are not universally available throughout the UK.	The Royal College of Physicians manages a new audit programme called the Fracture Liaison Service Database (FLS-DB). A facilities audit has been carried out and reported earlier this year. Patient level data collection in 2016 will report in early 2017. This will provide information about the secondary fracture prevention activity carried out in sites in England and Wales. 'FLS-DB facilities audit - FLS breakpoint: opportunities for improving patient care following a fragility fracture'. Royal College of Physicians, 2016 https://www.rcplondon.ac.uk/projects/outputs/fls-db-facilities-audit-fls-breakpoint-opportunities-improving-patient-care Falling Standards, Broken Promises: Report of the national audit of falls and bone health in older people 2010. Royal College of Physicians. 2011. https://www.nos.org.uk/document.doc?id=1516 'SIGN 142 - Management of osteoporosis and the prevention of fragility fractures'. Scottish Intercollegiate Guidelines Network, 2015 http://sign.ac.uk/pdf/SIGN142.pdf 'Effective Secondary Prevention of Fragility Fractures: Clinical Standards for Fracture Liaison Services'. National

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			and after solid organ transplantation.		Osteoporosis Society, 2014 https://www.nos.org.uk/document.doc?id=1941
5	Primary Care Rheumatology Society	Primary Care to ensure risk assessments of patients at risk of fragility fractures	Recommended in the Quality and Outcomes Framework (QOF) to minimise the risk of fragility fractures in the ageing population.	The amount of risk assessments carried out in primary care is mixed. Many patients at risk are not assessed and started on appropriate treatments	
6	Royal College of Physicians (RCP)	Key area for quality improvement 1: All patients presenting to the NHS with a fragility fractures should be identified and offered assessment, treatment and compliance support.	There is good evidence that fragility fractures are an important risk factor for future fractures and anti-osteoporosis therapies can reduce this risk.	The QOF for 2014/15 has shown that 34,992 patients were registered on secondary fracture prevention since 1st April 2012 for those aged 50 – 74 and 1st April 2014 for those aged 75 and over. This compares with over 60,000 hip fractures per year and an estimated 300,000 fragility fractures of which 50% would be expected to be on therapy. In 2014 the NHFD found that 80% of hip fracture patients had been started on bone protection treatment, or were referred for a DXA scan or bone clinic assessment. A further 16% of patients were recorded as having been assessed but not considered appropriate for treatment. There was considerable variation between hospitals in both of these figures, with some still labelling more than half of patients as inappropriate for treatment.	QOF outcomes 2014/15 Please see the Royal College of Physicians 2015 NHFD report. https://www.rcplondon.ac.uk/projects/outputs/nhfd-annual-report-2015 This outcome is currently measured by this Royal College of Physicians FLS-DB patient audit.

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7	Royal College of Physicians (RCP)	Key area for quality improvement 2 Improved case finding for vertebral fractures	Vertebral fractures are the most common fragility fracture attributable to osteoporosis but they are the most difficult to identify. Only a third of vertebral fractures come to clinical attention yet many a detectable of radiology images taken for other reasons and either not reported or not acted upon.	The FLS-DB facilities audit found that while 65% of FLSs routinely identified patients presenting with a clinical vertebral fracture. Only 33% of FLS routinely opportunistically identified radiological vertebral fracture patients.	Please see the Royal College of Physicians FLS-DB facilities audit which highlights findings for indicators relating to case finding. https://www.rcplondon.ac.uk/projects/outputs/fls-db-facilities-audit-fls-breakpoint-opportunities-improving-patient-care This outcome is currently measured by this Royal College of Physicians FLS-DB patient audit.
8	SCM 1	Key area for quality improvement 1 Identification of postmenopausal women and older men with fragility fracture	Previous fragility fracture is a strong independent risk factor for future fracture.	Systematic identification of postmenopausal women and older men with fragility fracture, followed by appropriate assessment and treatment has been shown to be cost-effective, using the Fracture Liaison Service model of care. Such services are not available in many Trusts.	https://www.rcplondon.ac.uk/projects/fracture-liaison-service-database-fls-db
9	SCM 1	Key area for quality improvement 2 Fracture risk assessment in postmenopausal women and older men	Estimation of fracture probability, with or without BMD (FRAX only), identifies individuals at risk and aids treatment decisions.	Case finding strategies using clinical risk factors (FRAX or QFracture) have been evaluated by NICE in CG146 but are not routinely implemented.	NICE CG146 SIGN guideline 142 Management of osteoporosis and the prevention of fragility fractures NOGG guideline https://www.shef.ac.uk/NOGG/
10	SCM 2	Key area for quality improvement 2 Patients with new and incident vertebral fractures would benefit from investigation and treatment for osteoporosis. Increased liaison between osteoporosis services, primary care,	The presence of vertebral fractures is indicative of further vertebral and non-vertebral fractures. Early identification would allow for treatment options to be considered with a consequent reduction in the risk of further fracture.	Identification of patients with vertebral fractures is difficult. The fracture(s) may be identified incidentally during other investigations, and the patient may not attend fracture clinic. Patients with vertebral fractures are considered to have osteoporosis even if their BMD is not in the therapeutic range (SIGN) Increased liaison/communication between radiology and osteoporosis	SIGN Management of Osteoporosis and the Prevention of Fragility Fracture 2015: Section 5 Targeting Treatment

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		and radiology services would lead to improved identification.		services would significantly increase identification.	
11	SCM 2	Key area for quality improvement 3 Fracture Liaison Services provide an integrated approach towards the management of fragility fractures.	There is good evidence that a previous low trauma fracture is associated with an increased risk of further fracture (NICE CG 146) Fracture liaison services bridge the gap between identification of the fracture and assessment for osteoporosis.	There is a wide variation in the provision fracture liaison services ranging from no provision, to telephone assessments, to DXA scanning in fracture clinic. Although the National Osteoporosis Society have produced standards for fracture liaison services scope remains to develop a more integrated approach between primary and secondary providers, for example with follow up, medication reviews and referral for systemic treatments	NICE CG 146 Osteoporosis: assessing the risk of fragility fracture National Osteoporosis Society: Standards for Fragility Fracture Management
12	SCM 3	Identification of at risk patients on GP list by analysis of risk factors	This will create a targeted primary prevention program	It will reduce the number of fragility fractures	National Institute for Health and Care Excellence. Osteoporosis: assessing the risk of fragility fracture. London: NICE; 2012. (CG146). [cited 02 Dec 2014]. Available from url: http://www.nice.org.uk/ guidance/cg146/resources/guidance-osteoporosis-assessing-therisk-of-fragility-fracture-pdf

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13	Society for Endocrinology	Our lead on Bone and Calcium for the Society for Endocrinology has looked at the Topic Engagement information and we would like to comment as below. The committee appears to be sourcing data from the majority of key documents relevant to osteoporosis management however the National Osteoporosis Guidance Group (NOGG) guidelines are not specifically mentioned as source data (these are endorsed by the Society for Endocrinology). Glucocorticoid Induced Osteoporosis (GIO) is not directly mentioned or highlighted (see attached RCP/NOS guideline). Nevertheless, GIO is mentioned in a number of the referenced guidance. GIO is an important secondary cause and its prevention should be highlighted			
4.2 How to assess for fragility fracture risk: Use of DXA scanning					
14	National Osteoporosis Society	Key area for quality improvement 2 Fracture risk assessment including DXA of those at high risk	Fracture risk assessment tools have been evaluated by NICE and information about their use is given in CG146. DXA remains an important component of risk assessment, particularly where treatment decisions are being made.	Guidance on assessment is given in NICE CG146, which details use of fracture risk assessment tools. Clarity is needed about appropriate use of DXA. In practice this varies with some sites using only in 'at risk' patients and others carrying out DXA in anyone requiring an osteoporosis treatment (as outlined in SIGN guidance)	*"Osteoporosis: assessing the risk of fragility fracture'.* NICE, 2012 https://www.nice.org.uk/guidance/cg146?unlid=768074842015289155 'SIGN 142 - Management of osteoporosis and the prevention of fragility fractures'. Scottish Intercollegiate Guidelines Network, 2015 http://sign.ac.uk/pdf/SIGN142.pdf
15	Primary Care Rheumatology Society	Patients at risk of osteoporosis should have ready access to DEXA screening services locally	The National Osteoporosis Guideline Group recommends access to DEXA service for ease of diagnosis of osteoporosis.	Some CCGs around England are cutting back on DEXA services due to cost cutting measures to enable CCGs balance their budgets	

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16	Royal College of Physicians (RCP)	Key area for quality improvement 3 Timely DXA assessment of those at high risk	DXA is an important component of fracture risk assessment after a fragility fracture. The purpose of DXA scanning is to determine if the patients has osteoporosis so they can be targeted with treatment to prevent secondary fractures. It is important to start therapy as soon as possible after fragility fracture given the rate of re-fracture is high in the first 24 months and most pharmacological interventions take at least 6 to 12 months to starting reducing fracture risk.	The Fracture Liaison Service Database facilities audit found that 62% of Fracture Liaison services had access to DXA on site. The National Audit of Falls and Bone Health 2010 found that 25% of non-hip fracture patients and 29% of hip fracture had a new DXA scan following a fragility fracture.	Please see the Royal College of Physicians National Audit of Falls and Bone Health which highlights findings of data collection for quality indicators relating to DXA assessments. https://www.rcplondon.ac.uk/news/nhs-services-falls-and-fractures-older-people-are-inadequate-finds-national-clinical-audit Please see the Royal College of Physicians national FLS-DB facilities audit which highlights findings of data collection for quality indicators relating to access to DXA. https://www.rcplondon.ac.uk/projects/outputs/fls-db-facilities-audit-fls-breakpoint-opportunities-improving-patient-care. This outcome is currently measured by this Royal College of Physicians FLS-DB patient audit.
4.3 Management for people at risk of fragility fracture					
Lifestyle advice					
17	SCM 3	How many of primary or secondary cohort are undertaking regular exercise	Decrease number of fragility fractures	Decrease number of fragility fractures	
Drug treatment					
18	British Thoracic Society	Key area for quality improvement 2: Prescription of prophylaxis against osteoporosis in at risk (respiratory) patients	There is good evidence from RCTs for products that reduce risk of fracture and improve bone density in such patients	As above	There is RCP guidance on prophylaxis in at risk groups such as these

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19	National Osteoporosis Society	Key area for quality improvement 3 Initiation of treatment to reduce fracture risk	Fracture risk can be modified by the use of clinically proven, cost-effective treatments. There is good evidence that early use of secondary care-initiated therapies including (but not limited to) teriparatide and denosumab can drive significant improvements in the quality of life and health status of people with multiple vertebral fractures, and reduce the misery of recurrent severe vertebral fractures. These people would benefit from prompt referral to specialist secondary care service.	Implementation of CG146 has been limited by the lack of associated treatment thresholds. The largest UK data series found that secondary care anabolic treatment of severe osteoporosis reduced the risk of vertebral fractures compared with standard care in routine clinical practice. Calcif Tissue Int. 2014;94(2):176-82. Individual GP's and CCG's differ widely in their thresholds for referral to secondary care.	*'SIGN 142 - Management of osteoporosis and the prevention of fragility fractures'.* Scottish Intercollegiate Guidelines Network, 2015 http://sign.ac.uk/pdf/SIGN142.pdf 'Guideline for the diagnosis and management of osteoporosis in postmenopausal women and men from the age of 50 years in the UK'. National Osteoporosis Guideline Group, 2014 https://www.shef.ac.uk/NOGG/NOGG_Pocket_Guide_for_Healthcare_Professionals.pdf "Anabolic therapy has a place as first-line therapy in patients at high fracture risk (in patients having two or more prevalent vertebral fractures)". From 2014 French National guidelines Briot K, Cortet B, Roux C, Fardet L, Abitbol V, Bacchetta J, et al. 2014 update of recommendations on the prevention and treatment of glucocorticoid-induced osteoporosis. Joint Bone Spine. 2014;81(6):493-501. "Scottish medicines consortium guidance suggested that the use of TPTD is also acceptable as a primary treatment for severe osteoporosis in postmenopausal women under specialist supervision" Scottish Medicines Consortium (2003) Teriparatide

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					(Forsteo®). http://www.scottishmedicines.org.uk/SMC_Advice/Advice/Teriparatide__Forsteo__174__/Teriparatide__Forsteo__. Accessed 4 May 2013 "Teriparatide can be used as a first-line therapy for prevention of non-vertebral and vertebral fractures". Papaioannou A, Morin S, Cheung AM, Atkinson S, Brown JP, Feldman S, et al. 2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada: summary. CMAJ. 2010;182(17):1864-73.
20	Royal College of Physicians (RCP)	Key area for quality improvement 4 Treatment initiation	There is good evidence that re-fractures occur most commonly in the first two years after fracture and there is a need to start bone therapy as soon as possible after the index fragility fracture Also most pharmacological interventions take at least 6 to 12 months to starting reducing fracture risk.	The National Audit of Falls and Bone Health found that 60% of hip fracture patients and 33% of non-hip fracture patients were prescribed bisphosphonate or other appropriate anti-resorptive therapy for osteoporosis (or treatment was unnecessary after a DXA scan result excluded osteoporosis).	Please see the Royal College of Physicians National Audit of Falls and Bone Health which highlights findings of data collection for quality indicators relating to treatment initiation. https://www.rcplondon.ac.uk/news/nhs-services-falls-and-fractures-older-people-are-inadequate-finds-national-clinical-audit This outcome is currently measured by this Royal College of Physicians FLS-DB patient audit.
21	SCM 1	Key area for quality improvement 3 Bone protective therapy in people with vertebral or hip fracture	Prior vertebral or hip fracture indicates a high imminent risk of future fracture	Currently only a minority of such individuals receives bone protective therapy, despite strong evidence for the anti-fracture efficacy of several interventions.	SIGN guideline 142 NOGG guideline https://www.shef.ac.uk/NOGG/

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Follow up					
22	National Guideline centre	Key area for quality improvement 1	Review of need to continue bisphosphonate treatment	There is a lack of guidance on how long people should continue bisphosphonate for and what sort of monitoring is appropriate. Evidence for stopping bisphosphonates was examined in NICE Multimorbidity guideline.	NICE Multimorbidity guideline which is due for publication at end of September includes a recommendation to review bisphosphonate prescription and the need to continue.
23	National Osteoporosis Society	Key area for quality improvement 4 Review and maintenance of treatment at 4 months and annually thereafter	There is evidence that patients who receive follow up appointments after starting an osteoporosis treatment are more likely to remain on treatment. There is a lack of clarity about duration of osteoporosis treatment; how and when to carry out a treatment review; and when it is appropriate for a patient to pause treatment and for how long.	Adherence of at least 80% is needed to achieve significant fracture risk reduction. In practice, the percentage of patients persisting with bisphosphonate therapy for 1 year ranges from 17.9 to 78%. Attention from a healthcare professional increases adherence to therapy by 57%.	References from *'Effective Secondary Prevention of Fragility Fractures: Clinical Standards for Fracture Liaison Services'*. National Osteoporosis Society, 2014: Siris ES, Harris ST, Rosen CJ. Adherence to bisphosphonate therapy and fracture rates in osteoporotic women: relationship to vertebral and nonvertebral fractures from 2 US claims databases. Mayo Clin Proc 2006; 81(8): 1013. Imaz I, Zegarra P, Gonzalez-Eriquez J. Poor bisphosphonate adherence for treatment of osteoporosis increases fracture risk: systematic review and meta-analysis. Osteoporos Int 2010; 21: 1943-1951 Cramer JA, Gold DT, Silverman SL, Lewiecki EM. A systematic review of persistence and compliance with bisphosphonates for osteoporosis. Osteoporosis Int 2007; 18(8):1023-31. Clowes JA, Peel NFA, Eastell R. The impact of monitoring on adherence and persistence with antiresorptive treatment

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					for post-menopausal osteoporosis: a randomised controlled trial. J Clin Endocrin & Metab 2004; 89(3): 1117-1123.
24	Primary Care Rheumatology Society	Regular medication reviews of patients on bisphosphonates	Advice from the Medicines and Health Regulatory Authority (MHRA) advises to review all patients on bisphosphonates for 5 or more years	There are lots of patients on bisphosphonate therapy but limited numbers have regular reviews of their medication	
25	Royal College of Physicians (RCP)	Key area for quality improvement 5 Treatment adherence at 12 months after fragility fracture	In order to achieve a reduction in fracture risk, good adherence with treatment needs to be maintained for several years. Lack of treatment adherence is an issue in osteoporosis, as it reduces the effectiveness of fracture risk reduction strategies. The non-adherence rate for the recommended first-line anti-osteoporosis medication, alendronate, is up to 70% 6 months after initiation therefore, monitoring treatment reviews are key.	The FLS-DB facilities audit found that all FLSs in Wales and 42% of FLSs in England delegated monitoring to a primary care physician. Where monitoring is delegated to primary care, it becomes almost impossible for the FLS to track. Of the FLSs that carried out their own monitoring 79% included medication adherence and persistence.	Please see the Royal College of Physicians national FLS-DB facilities audit which highlights findings of data collection for quality indicators relating to patient monitoring. https://www.rcplondon.ac.uk/projects/outputs/fls-db-facilities-audit-fls-breakpoint-opportunities-improving-patient-care. This outcome is currently measured by this Royal College of Physicians FLS-DB patient audit.
25	SCM 1	Key area for quality improvement 4 Assessment of all patients who have received bone protective therapy for 5 years	The optimal duration of therapy for osteoporosis is currently unclear and there are concerns about rare but serious adverse effects of long-term treatment. Reassessment of fracture risk after 5 years can identify those in whom the risk/benefit ratio of continued treatment is beneficial.	Standard protocols for monitoring bone protective therapy do not exist at present.	SIGN guideline 142 NOGG guideline https://www.shef.ac.uk/NOGG/

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26	SCM 2	Key area for quality improvement 1 Annual Medication review in Primary care to include compliance, persistence and adherence with bone sparing therapies	There is evidence that effective monitoring of bone sparing medication can improve compliance, persistence, and adherence with bone sparing therapies. Annual monitoring is recommended by NOS Fragility Fracture standards, RCP Falls & Fragility Fracture Audit. GP's currently conduct an annual medication review that could include particular reference to monitoring of bone sparing therapies.	Monitoring adherence to bone sparing therapies is significant in the effective management of osteoporosis. Non adherence to bone sparing therapies is 70% at six months.(SIGN) Poor adherence to bone sparing therapy can reduce its clinical effectiveness.	Please see RCP Falls & Fragility Fracture Audit Programme. Fracture Liaison Service Database (FLS-DB)- FLS Breakpoint: opportunities for improving patient Care following a fragility fracture -May 2016 SIGN Management of Osteoporosis and the Prevention of Fragility Fracture 2015. NOS standards for Fragility Fracture Management
27	SCM 3	Comprehensive Analysis of identified patients who are receiving primary and secondary prevention ,i.e what is the level of concordance	This will look at if treatment is being used	It will increase concordance	
4.4 Additional areas					
Quality of bone density reporting					
28	British Nuclear Medicine Society	Bone Density reporting quality	Often undertaken by radiographers or radiologists who are poorly conversant with field	Often the bone density report guides decision making by other doctors especially GP's	Bone Density reporting quality
Screening for coeliac disease					
29	Coeliac UK	Key area for quality improvement 1: Screening patients with osteoporosis for coeliac disease.	Osteoporosis can be a complication of untreated or undiagnosed coeliac disease. In line with the NICE guideline for recognition, assessment and management of coeliac disease (NG20) [1], people with reduced bone mineral density or osteomalacia should be screened for coeliac disease.	Although coeliac disease affects 1 in 100 people, only 24% of people with the condition are currently diagnosed [2]. Securing a diagnosis of coeliac disease can take many years and on average it takes 13 years for patients to secure a diagnosis [3]. In order to help patients to secure a diagnosis earlier, healthcare professionals should offer serological testing to	[1] National Institute for Health and Clinical Excellence (2015) Coeliac disease: recognition, assessment and management 2015 [2] West J, Fleming KM, Tata LJ et al. (2014) Incidence and Prevalence of Celiac Disease and Dermatitis Herpetiformis in the UK Over Two Decades: Population-Based Study. Am J Gastroenterol 109:757-768 [3] Gray AM & Papanicolas IN (2010) Impact

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				people with reduced bone mineral density or osteomalacia as listed in recommendation 1.1 of the NICE guideline NG20 [1].	of symptoms on quality of life before and after diagnosis of coeliac disease: results from a UK population survey. BMC Health Serv Res 10: 105. doi:10.1186/1472-6963-10-105
Access to treatments for vertebral compression fractures					
30	Medtronic Ltd	Improved access to percutaneous vertebroplasty for treating osteoporotic vertebral compression fractures	NICE TA279 states that "Treating vertebral compression fractures aims to restore mobility, reduce pain and minimise the incidence of new fractures"	Access to this procedure for this patient group remains variable dependent on multifactorial causes. Guidance on which patients are most likely to derive the best outcomes from this procedure would drive improvement in access for appropriate patients.	
31	Medtronic Ltd	Improved access to percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures	NICE TA279 states that "Treating vertebral compression fractures aims to restore mobility, reduce pain and minimise the incidence of new fractures"	Access to this procedure for this patient group remains variable dependent on multifactorial causes. Guidance on which patients are most likely to derive the best outcomes from this procedure would drive improvement in access for appropriate patients.	
Patient information					
32	National Osteoporosis Society	Key area for quality improvement 5 Patient education, support and information	Drug treatments need to be taken correctly and over time in order for patients to realise the benefits in fracture risk reduction. There is evidence that patients who understand treatment benefits and risks are more likely to continue to take their treatment. This is supported by unpublished analyses of the National Osteoporosis Society's 'Life with Osteoporosis' study. Those who understand how to take	Intentional non-adherence arises from lack of understanding about the expected benefits of treatment and from concerns about side effects. Unintentional non-adherence occurs when patients forget to take the treatment. Another reason for non-adherence in osteoporosis is the complexity of oral bisphosphonate regimens. At least one requirement of the instructions for oral bisphosphonates is disregarded in	Horne R. 'Beliefs and Adherence to Treatment: the challenge for research and clinical practice' in Halligan PW (ed.) The power of belief: Psychosocial influence on illness, disability and medicine. Oxford: Oxford University Press. 2006. Seeman E, Compston J, Adechi J. Noncompliance: the Achilles heel of antiresorptive efficacy. Osteoporos Int 2007; 18: 711-719. National Osteoporosis Society data cited in this section is unpublished but can be

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			their treatment are also more likely to adhere, and to do so correctly.	up to 50% of patients. National Osteoporosis Society Helpline Annual reports show 50% of enquiries relate to drug treatments and 30% are about side effects and health risks associated with treatments.	shared with NICE upon request.
33	SCM 3	How many of the treated cohort have written key side effects of treatment provided	Reduce side effects	Reduce side effects	
Falls: assessing risk and prevention					
34	NHS Improvement: Patient Safety	Key area for quality improvement 1	3.2. Key development sources (NICE and NICE-accredited sources). The QS would benefit from stronger links to NICE CG 161 (falls) in terms of case finding for osteoporosis risk. Specifically the prevention and risk assessment of fragility fractures.	Older people who present for medical attention because of a fall, or report recurrent falls in the past year, or demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment to include assessment of osteoporosis risk.	https://www.nice.org.uk/guidance/cg161/chapter/1-Recommendations#multifactorial-assessment-or-multifactorial-falls-risk-assessment
35	SCM 3	How many patients in the at risk cohorts have received falls prevention attention	It will reduce falls and fragility fractures	It will reduce falls and fragility fractures	http://www.communitypharmacyscotland.org.uk/news,-policy-and-publications/news/latest-news/medicine-sick-day-rules-cards-a-patient-safety-initiative 144. Howe TE, Shea B, Dawson LJ, Downie F, Murray A, Ross C, et al. Exercise for preventing and treating osteoporosis in postmenopausal women. Cochrane Database of Systematic Reviews 2011, Issue 7. 145. Martyn-St James M, Carroll S. Meta-

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36	SCM 4	Timely access to falls risk assessment and intervention	Most fractures occur as a result of a fall, and a prior fall is a leading risk factor for subsequent falls. There are a number of interventions which can reduce falls risk.	The National Audit of Falls and Bone Health found that only 34% of non-hip fracture patients had a multi-factorial falls risk assessment,	The Royal college of Physicians FLS-DB (fracture liaison service database) captures data on falls.
Indicators and implementation support					
37	NHS Improvement: Patient Safety	Key area for quality improvement 2	Existing indicators NHS Outcomes Framework 2016/17 The QS would benefit from stronger links to this indicator in terms of opportunistic case finding and treatment of osteoporosis. Patients with untreated osteoporosis are at greater risk of injury through falling. Incidence of falling is greater in care settings such as hospital.	Domain 5 Treating and caring for people in a safe environment and protecting them from avoidable harm	Overarching indicators 5a Deaths attributable to problems in healthcare 5b Severe harm attributable to problems in healthcare Improvement areas Reducing the incidence of avoidable harm 5.4 Hip fractures from falls during hospital care Improving the culture of safety reporting 5.6 Patient safety incidents reported
38	NHS Improvement: Patient Safety	Key area for quality improvement 3	Other key policy documents, reports and national audits.	Support for implementation – improving staff education.	Endorsed resource - CareFall – elearning package Royal College of Physicians https://www.nice.org.uk/guidance/cg161/resources/endorsed-resource-carefall-elearning-package-498985886
General					
39	NHS England	Thank you for the opportunity to comment on the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.			
40	RCGP	The RCGP welcomes the opportunity to contribute in this consultation but we have no comments at this stage.			
41	RCN	This is to inform you that the Royal College of Nursing has no comments to submit to inform on the above topic engagement at this time.			

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42	Royal College of Physicians (RCP)	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Falls and Fragility Fracture Audit Programme and would like to make the following comments.