Osteoporosis

NICE quality standard

Draft for consultation

April 2017

This quality standard covers management of osteoporosis in adults (aged 18 and over), including risk assessment and prevention of fragility fractures. It describes high-quality care in priority areas for improvement.

It is for commissioners, service providers, health, public health and social care practitioners, and the public.

This is the draft quality standard for consultation (from 30 November 2016 to 3 January 2017). The final quality standard is expected to publish in April 2017.

Quality statements

Statement 1 Adults who have had a fragility fracture, or who have other high-risk factors for fragility fracture, have an assessment of fracture risk.

Statement 2 Adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis are offered bone-sparing drug treatment.

Statement 3 Adults with osteoporosis prescribed bone-sparing drug treatment are asked about adverse effects and adherence to treatment at each routine medication review.

Statement 4 Adults with osteoporosis who have been taking bisphosphonates for at least 3 years have a review of the risks and benefits of continuing treatment.

NICE has developed guidance and a quality standard on patient experience in adult NHS services (see the NICE pathway on patient experience in adult NHS services), which should be considered alongside these quality statements.

Other quality standards that should be considered when commissioning or providing osteoporosis services include:

- Falls in older people (2015) NICE quality standard 86
- Hip fracture in adults (2012, updated 2016) NICE quality standard 16
- Menopause. Publication expected February 2017

A full list of NICE quality standards is available from the quality standards topic library.

Questions for consultation

Questions about the quality standard

Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement?

Question 2 Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?

Question 3 Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

Question 4 Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Questions about the individual quality statements

Question 5 For draft quality statement 1: Does the statement focus on the key quality improvement area in terms of the assessment of at-risk adults, and are there any specific barriers to achievement, such as workload implications?

Question 6 For draft quality statement 2: Is the statement measurable in terms of describing a well-defined (intermediate or high-risk) population for whom bone-sparing treatment should be prescribed?

Quality statement 1: Assessment of adults at risk of fragility fracture

Quality statement

Adults who have had a fragility fracture, or who have other high-risk factors for fragility fracture, have an assessment of their fracture risk.

Rationale

Risk assessment of adults who may be at increased risk of a fragility fracture enables healthcare professionals to determine their fracture risk score. This can be used to consider options for prevention and treatment, which will reduce the risk of future fractures.

Quality measures

Structure

Evidence of local arrangements to ensure that adults who have had a fragility fracture, or who have other high-risk factors for fragility fracture, have an assessment of their fracture risk.

Data source: Local data collection.

Process

a) Proportion of adults who have had a fragility fracture who have an assessment of their fracture risk.

Numerator – the number in the denominator who have an assessment of their fracture risk.

Denominator – the number of adults who have had a fragility fracture.

Data source: Local data collection. The Fracture Liaison Service Database collects data on patients aged over 50 years who have suffered a fragility fracture and whether risk of fracture was assessed using FRAX or Q-Fracture.

b) Proportion of adults who have other high-risk factors for fragility fracture who have an assessment of fracture risk.

Numerator – the number in the denominator who have an assessment of fracture risk.

Denominator – the number of adults who have other high-risk factors for fragility fracture.

Data source: Local data collection.

Outcome

Incidence of fragility fractures.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (general practices, secondary care services and fracture liaison services) ensure that systems are in place for adults who have had a fragility fracture, or who have other high-risk factors for fragility fracture, to have an assessment of fracture risk.

Healthcare professionals (GPs, specialists, specialist nurses and fracture liaison practitioners) carry out an assessment of fracture risk, or confirm that one has taken place, in adults who have had a fragility fracture, or who have other high-risk factors for fragility fracture, to determine their risk of fracture and what their treatment options are.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults who have had a fragility fracture, or who have other high-risk factors for fragility fracture, have an assessment of fracture risk.

Adults who may be at increased risk of fragility fracture have an assessment to confirm their risk of fracture. Fragility fractures happen in people with fragile bones that break easily, usually older people with a condition called osteoporosis. There are treatments available to help prevent fractures in people who are at increased

risk. An assessment can help to decide if treatment will reduce the chance of having a fracture.

Source guidance

Osteoporosis - prevention of fragility fractures (2016) NICE clinical knowledge summary

Definitions of terms used in this quality statement

Other high-risk factors for fragility fracture

Factors that increase the chance of fragility fracture include:

- age 65 years and over in women and age 75 years and over in men
- age 50-64 years in women and age 50-74 years in men with any of the following risk factors:
  - current use or frequent recent use of oral or systemic glucocorticoids
  - history of falls
  - family history of hip fracture
  - other causes of secondary osteoporosis:
    - ◊ 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
    - ◊ immobility (due for example to neurological injury or disease)
  - 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
- age under 50 years with any of the following risk factors:
  - current or frequent recent use of oral or systemic glucocorticoids
  - untreated premature menopause
  - previous fragility fracture

[NICE's guideline on osteoporosis: assessing the risk of fragility fracture recommendations 1.1 and 1.2]

Assessment of fracture risk

An assessment of fracture risk should include estimating absolute fracture risk (for example, the predicted risk of major osteoporotic or hip fracture over 10 years, expressed as a percentage). Either FRAX (without a bone mineral density value if a dual-energy X-ray absorptiometry scan has not previously been undertaken) or QFracture should be used within their allowed age ranges. Above the upper age limits defined by the tools, consider people to be at high risk. [NICE's guideline on osteoporosis: assessing the risk of fragility fracture recommendations 1.3 and 1.4]

Question for consultation

Does the statement focus on the key quality improvement area in terms of the assessment of at-risk adults, and are there any specific barriers to achievement, such as workload implications?

Quality statement 2: Starting drug treatment

Quality statement

Adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis are offered bone-sparing drug treatment.

Rationale

Fragility fractures can cause substantial pain and severe disability, often leading to a reduced quality of life and sometimes to decreased life expectancy. Taking drug treatment to improve bone density reduces the chance of future fractures and the associated negative consequences.

Quality measures

Structure

Evidence of written clinical protocols to ensure that adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis are offered bone-sparing drug treatment.

Data source: Local data collection

Process

Proportion of adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis receiving bone-sparing drug treatment.

Numerator – the number in the denominator who receive bone-sparing drug treatment.

Denominator – the number of adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis.

Data source: Local data collection.

Outcomes

a) Average number of months from diagnosis of osteoporosis to initiation of bone-sparing drug treatment.

Data source: Local data collection.

b) Incidence of fragility fractures.

Data source: Local data collection.

c) Hospital admission rates for fragility fractures.

Data source: Hospital episode statistics from NHS Digital.

What the quality statement means for different audiences

Service providers (general practices and secondary care services) ensure that systems are in place for adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis to be offered bone-sparing drug treatment.

Healthcare professionals (GPs, specialists and specialist nurses) are aware of when to prescribe bone-sparing drug treatments and offer them to adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis are offered bone-sparing drug treatment.

Adults assessed as having a moderate or high chance of fragility fracture and diagnosed with osteoporosis are offered medicine to help strengthen their bones and prevent fractures.

Source guidance

Osteoporosis - prevention of fragility fractures (2016) NICE clinical knowledge summary

Definitions of terms used in this quality statement

Assessed as at high or intermediate risk of fragility fracture

QFracture or FRAX risk assessment tools should be used within their allowed age ranges to estimate absolute fracture risk. These tools predict the absolute risk of hip

fracture and major osteoporotic fractures (spine, wrist, or shoulder) over 10 years. Above the upper age limits defined by the tools, consider people to be at high risk.

Both tools have accompanying guidance that allows the risk scores to be interpreted.

[NICE's guideline on osteoporosis: assessing the risk of fragility fracture recommendations 1.3 and 1.4 and clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Diagnosed with osteoporosis

A diagnosis of osteoporosis is given when the measurement of bone mineral density by dual-energy X-ray absorptiometry (DXA) scanning gives a T-score of −2.5 standard deviations (SD) or below. However, the diagnosis may be assumed in women aged 75 years or older, or in people with vertebral or hip fractures, if the responsible clinician considers a DXA scan to be clinically inappropriate or impractical. [World Health Organisation's technical report series on Assessment of fracture risk and its application to screening for postmenopausal osteoporosis and NICE's technology appraisal guidance on Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women and clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Bone-sparing drug treatment

Bone-sparing drugs that can be prescribed to prevent fragility fractures include bisphosphonates (alendronate, risedronate, and zoledronic acid) and non-bisphosphonates (raloxifene, strontium ranelate, denosumab and teriparatide).

[NICE's clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Equality and diversity considerations

Guidance on treatment to prevent fragility fractures has been focused on treatment for post-menopausal women, because of the increased risk in this population. Clinicians should ensure that other populations who might benefit from recommended treatments are also considered.

Question for consultation

Is the statement measurable in terms of describing a well-defined (intermediate or high-risk) population for whom bone-sparing treatment should be prescribed?

Quality statement 3: Routine medication review

Quality statement

Adults with osteoporosis prescribed bone-sparing drug treatment are asked about adverse effects and adherence to treatment at each routine medication review.

Rationale

People taking bone-sparing drugs for osteoporosis may experience adverse effects that cause them to stop taking them. Adherence to treatment, including following the recommended method of taking it, is needed to ensure that fracture risk is reduced effectively. A routine medication review to check how a person is managing their treatment means that any problems can be discussed and their treatment adjusted if needed, which will improve adherence and quality of life.

Quality measures

Structure

Evidence of local arrangements to ensure that adults with osteoporosis prescribed bone-sparing drug treatment are asked about adverse effects and adherence to treatment at each routine medication review.

Data source: Local data collection.

Process

Proportion of adults with osteoporosis prescribed bone-sparing drug treatment asked about adverse effects and adherence to treatment at each routine medication review.

Numerator –the number in the denominator in which adults with osteoporosis prescribed bone-sparing drug treatment are asked about adverse effects and adherence to treatment.

Denominator – the number of routine medication reviews for adults with osteoporosis prescribed bone-sparing drug treatment.

Data source: Local data collection.

Outcomes

a) Proportion of adults with osteoporosis adhering to bone-sparing drug treatment.

Data source: Local data collection at annual review.

b) Proportion of adults with osteoporosis taking bone-sparing drug treatment who experience adverse effects.

Data source: Local data collection.

c) Incidence of fragility fracture.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (general practices, secondary care services and pharmacies) ensure that systems are in place for adults with osteoporosis prescribed bone-sparing drug treatment to be asked if they have had any adverse effects and about adherence to treatment at each routine medication review.

Healthcare professionals (GPs, specialists, specialist nurses and pharmacists) carry out routine medication reviews with adults prescribed bone-sparing drug treatments, and ask if they have had any adverse effects and about adherence to treatment at these reviews.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults with osteoporosis on bone-sparing drug treatment are asked if they have had any adverse effects and about adherence to treatment at each routine medication review.

Adults with osteoporosis taking medicine to help prevent fractures have regular medicine reviews with their doctor to check whether they are having any side effects and that they are taking the medicine correctly. The first review should be carried out within 4 months of starting treatment, and then should happen annually.

Source guidance

Osteoporosis - prevention of fragility fractures (2016) NICE clinical knowledge summary

Definitions of terms used in this quality statement

Adults with osteoporosis

A diagnosis of osteoporosis is given when the measurement of bone mineral density by dual-energy X-ray absorptiometry (DXA) scanning gives a T-score of −2.5 standard deviations (SD) or below. However, the diagnosis may be assumed in women aged 75 years or older, or in people with vertebral or hip fractures, if the responsible clinician considers a DXA scan to be clinically inappropriate or impractical. [World Health Organisation's technical report series on Assessment of fracture risk and its application to screening for postmenopausal osteoporosis and NICE's technology appraisal guidance on alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women and clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Bone-sparing drug treatment

Bone-sparing drugs that can be prescribed to prevent fragility fractures include bisphosphonates (alendronate, risedronate, and zoledronic acid) and non-bisphosphonates (raloxifene, strontium ranelate, denosumab and teriparatide).

[NICE's clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Routine medication review

A medication review should take place within 4 months of starting drug treatment, and then annually. The review should include:

- asking about adverse effects, including upper gastrointestinal adverse effects, such as dyspepsia or reflux, and symptoms of atypical fracture, including new onset hip, groin, or thigh pain.

- asking about adherence to treatment, including following the recommended method of taking the treatment.
- discussing alternative treatment options if adverse effects are unacceptable or the person has difficulty adhering to treatment.

[National Osteoporosis Society's Clinical standards for fracture liaison services and NICE's clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Quality statement 4: Long-term follow-up

Quality statement

Adults with osteoporosis who have been taking bisphosphonates for at least 3 years have a review of the risks and benefits of continuing treatment.

Rationale

People prescribed bisphosphonates can sometimes take them for a long time without having a review. The optimal duration of bisphosphonate therapy is unclear and there are possible adverse effects of long-term treatment. A review of the risks and benefits of continuing treatment allows for consideration of whether continuing, changing or stopping treatment is the best option, and evaluation of the response to treatment if needed.

Quality measures

Structure

Evidence of local arrangements to ensure that adults with osteoporosis who have been taking bisphosphonates for at least 3 years have a review of the risks and benefits of continuing treatment.

Data source: Local data collection.

Process

Proportion of adults with osteoporosis who have been taking bisphosphonates for 3 years who have a review of the risks and benefits of continuing treatment.

Numerator –the number in the denominator who have a review of the risks and benefits of continuing treatment.

Denominator – the number of adults with osteoporosis who have been taking bisphosphonates for 3 years.

Data source: Local data collection.

Outcomes

a) Proportion of adults with osteoporosis who have been taking bisphosphonates for 3 years who are satisfied with the treatment they are taking.

Data source: Local data collection.

b) Health-related quality of life for adults with osteoporosis.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (general practices, secondary care services and pharmacies) ensure that systems are in place for adults with osteoporosis who have been taking bisphosphonates for at least 3 years to have a review of the risks and benefits of continuing treatment and their response to treatment assessed if needed.

Healthcare professionals (GPs, specialists, specialist nurses and pharmacists) offer adults with osteoporosis who have been taking bisphosphonates for at least 3 years a medication review to discuss the risks and benefits of continuing treatment and assess their response to treatment if needed.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults with osteoporosis who have been taking bisphosphonates for at least 3 years have a review of the risks and benefits of continuing treatment and their response to treatment assessed if needed.

Adults with osteoporosis who have been taking a type of medicine called a bisphosphonate for at least 3 years have a medication review to discuss with their doctor the risks and benefits, and whether they should continue with the treatment. They might also have a scan to check whether their bone strength has improved to help with the decision to continue treatment.

Source guidance

- Multimorbidity: clinical assessment and management (2016) NICE guideline NG56, recommendation 1.6.16

- Osteoporosis - prevention of fragility fractures (2016) NICE clinical knowledge summary

Definitions of terms used in this quality statement

Adults with osteoporosis

A diagnosis of osteoporosis is given when the measurement of bone mineral density by dual-energy X-ray absorptiometry (DXA) scanning gives a T-score of −2.5 standard deviations (SD) or below. However, the diagnosis may be assumed in women aged 75 years or older, or in people with vertebral or hip fractures, if the responsible clinician considers a DXA scan to be clinically inappropriate or impractical. [World Health Organisation's technical report series on Assessment of fracture risk and its application to screening for postmenopausal osteoporosis and NICE's technology appraisal guidance on alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women and clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Bisphosphonates

These are drugs that can be prescribed to strengthen bones and include alendronate, risedronate and zoledronic acid.

[NICE's clinical knowledge summary on osteoporosis - prevention of fragility fractures]

Review of the risks and benefits of continued treatment

Review the risks and benefits of continuing treatment, which should include discussing:

- That there is no consistent evidence of:
  - further benefit from continuing bisphosphonate for another 3 years
  - harms from stopping bisphosphonate after 3 years of treatment.
- Whether to stop taking bisphosphonate after 3 years.
- The patient's choice, fracture risk and life expectancy.

For some people, continuing treatment is recommended:

- For 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.
- 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.

For 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 to 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.

[NICE's guideline on multimorbidity: clinical assessment and management and clinical knowledge summary on osteoporosis - prevention of fragility fractures]

About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

Information about how NICE quality standards are developed is available from the NICE website.

See quality standard advisory committees on the website for details of standing committee 4 members who advised on this quality standard. Information about the topic experts invited to join the standing members is available on the quality standard's webpage.

This quality standard has been incorporated into the NICE pathway on osteoporosis.

NICE has produced a quality standard service improvement template to help providers make an initial assessment of their service compared with a selection of quality statements. This tool is updated monthly to include new quality standards.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

Improving outcomes

This quality standard is expected to contribute to improvements in the following outcomes:

- health-related quality of life for people with osteoporosis

- fragility fracture incidence
- mortality rates associated with fragility fractures
- emergency admissions associated with fragility fractures.

It is also expected to support delivery of the Department of Health's outcome frameworks:

- Adult social care outcomes framework 2015–16
- NHS outcomes framework 2016–17
- Public health outcomes framework for England, 2016–19.

Resource impact

NICE quality standards should be achievable by local services. The potential resource impact is considered by the quality standards advisory committee, drawing on resource impact work for the source guidance. Organisations are encouraged to use the resource impact products for the source guidance to help estimate local costs:

- costing report and template for the NICE guideline on osteoporosis: assessing the risk of fragility fracture
- resource impact statement for the NICE guideline on multimorbidity: clinical assessment and management.

Diversity, equality and language

During the development of this quality standard, equality issues were considered and equality assessments are available. Any specific issues identified during development of the quality statements are highlighted in each statement.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.