NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Osteoporosis

Date of quality standards advisory committee post-consultation meeting:
25 January 2017

2 Introduction

The draft quality standard for osteoporosis was made available on the NICE website for a 4-week public consultation period between 30 November 2016 and 3 January 2017. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 11 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

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

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

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.

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.

Stakeholders were also invited to respond to 2 statement specific questions for draft quality statement 1 and draft quality statement 2.

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- The addition of a definition of ‘fragility fracture’ was suggested.
- There was support for the quality standard, but it was felt that the statements need the supporting information from the full document to be interpreted accurately.
- Stakeholders felt that Fracture Liaison Services (FLS) would help to achieve the different statements, and areas without them might struggle to.

Consultation comments on data collection

- Stakeholders felt that systems are in place, or could be put in place, to capture the data for the proposed measures.
- Stakeholders highlighted that fragility fractures are not always recorded, which would make it difficult to collect data for some of the measures.
- Ensuring national audits cover the areas in the quality standard was encouraged.
- Consideration of how to incentivise GPs to collect the data for the measures was raised.

Consultation comments on resource impact

- Concerns were raised about the achievability of statement 1 given the large at-risk population and available resources locally. The resource implications of treatment for this group was also mentioned.
- Stakeholders felt that services could achieve the statements for people with a fragility fracture with available resources.
- Cost savings from prevention of fractures by FLS was raised.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

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

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Statement:
  - Primary prevention should be mentioned before secondary prevention in the statement and be made clearer.
  - The wording of the statement could be improved, for example by changing ‘have high-risk factors’ to ‘risk factors’, or describing the people as high-risk rather than the factors.
- Audience:
  - Stakeholders felt that the audience and setting for the statement are not clear, and this would differ for those who have had a fracture and those at risk.
- Measures:
  - Guidance on how to determine the number of adults with high-risk factors was requested. However, another stakeholder felt this could be achieved through local audit of primary care records by CCGs or individual practices.
  - A suggested outcome measure was ‘time to receiving a scan’.
  - ‘Evidence of local arrangements’ should include any vertebral fracture reported on spinal images (plain film or CT) having a recommendation to return for a DXA assessment, if appropriate.
- Definitions:
  - The definition of risk factors should include high dose inhaled steroids, asthma, interstitial lung disease and not reaching peak bone mass. It should also mention that people may have multiple factors and define what ‘frequent use’ of steroids means.

- More detail is needed on assessing fracture risk in different age groups, particularly younger adults not covered by the tools.
- Be clearer that fracture risk assessment does not always require a DXA scan.

Consultation question 5

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?

Stakeholders made the following comments in relation to consultation question 5:

- Multiple barriers to achievement were raised:
  - insufficient capacity and time in primary care
  - lack of incentives for primary care
  - capacity available for DXA scanning
  - staff resource to screen and manage extra patients
  - poor recognition of fragility and vertebral fractures
  - reporting and coding of fragility and vertebral fractures
  - costs of the different assessment tools and confusion over which to use.
- Stakeholders felt that the primary prevention aspect of the statement would be more difficult to achieve.
- Additional pharmacists in primary care might be needed to achieve the statement.

5.2 Draft statement 2

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

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Statement:
  - Stakeholders raised issues around the lack of intervention thresholds and conflicting guidance on when to offer treatment.
  - It was felt that this statement does not reflect the Clinical Knowledge Summary or NICE technology appraisal guidance recommendations.
  - Initiation of treatment should be based on clinical judgement for some groups, such as people with low spinal BMD and younger patients, and high-risk patients with a T-score over -2.5. Some local areas currently treat the latter group, but they are not included in the statement.
  - Drug treatment for people with hip or vertebral fracture without a risk assessment or DXA scan was suggested as an alternative statement.
  - Bone-forming treatment and interventions to reduce modifiable risk factors should be included in the statement.
- Rationale:
  - Change the text to: 'Immediate initiation of drug treatment to improve bone density reduces the risk of future fractures and the associated negative consequences.'
- Measures:
  - Outcome A is unrealistic and data is not available to measure it.
- Definitions:
  - The definition of 'high or intermediate risk' needs more detail, such as links to guidance for the use of the assessment tools.
  - Be clearer that results from FRAX and QFracture are not interchangeable.

  - The definition of ‘diagnosis of osteoporosis’ should state that diagnosis only be assumed in older women once a vertebral collapse has been confirmed to be osteoporotic.
  - All causes other than osteoporosis should be considered before starting drug treatment without a DXA scan for people with a vertebral fracture.
  - Ibandronate and HRT should be included in the definition of ‘bone-sparing drug treatment’.
- Equality and Diversity
  - A stakeholder mentioned that males with low T-scores are often overlooked and carry a higher risk of fracture than females.

Consultation question 6

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

Stakeholders made the following comments in relation to consultation question 6:

- One stakeholder felt that the at-risk groups were well defined.
- Another stakeholder felt that the statement is not measureable due to assessment tools producing different results, no provision of intervention thresholds and NICE technology appraisal guidance not being linked to fracture risk assessment.

5.3 Draft statement 3

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

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Statement:
  - Include the '4 month' and 'annual' timeframes in the statement.
  - Include necessary actions if adherence issues and adverse effects are found, for example offering alternative treatment and how to improve adherence.
  - Can the wording of the statement be changed to allow more flexibility around review, for example if adverse effects are apparent before 4 months.
  - The statement has significant resource implications and will be difficult to carry out thoroughly during a GP consultation.
  - Patients are asked about taking bisphosphonates at falls assessments.
  - Reference should be made to statement 6 of the medicines optimisation quality standard.
- Audience descriptors:
  - It is not clear who should do the review.
- Measures:
  - It will be difficult to collect data as reviews take place in different settings.
- Definitions:
  - Asking about symptoms of atypical femoral fractures at every review is unnecessary as they are rare. Furthermore, this could cause concern and lead to unnecessary imaging.

5.4 Draft 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.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Statement:
  - The review should be every 5 years unless there is a reason to review sooner, such as a new fragility fracture. DXA scanning every 3 years has resource implications.
  - The statement should include information on the review of non-bisphosphonates, or make it clear that the statement does not apply to them: if this statement is inappropriately applied to non-bisphosphonates there are risks in suddenly stopping treatment.
  - It was felt that users might misunderstand what is meant by 'review of the risks and benefits'.
  - The statement wording should more closely match the multimorbidity guidance.
  - Determining duration of treatment from GP IT systems may be challenging.
- Definitions:
  - The decision of whether or not to continue treatment also includes consideration of the extent of bone mineral density improvement, further fractures whilst on treatment and other risk factors.
  - It is unclear what should be done when people have received treatment for 7 or 10 years.
  - The DXA scan should be an axial scan.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	National Osteoporosis Society	General	We welcome is Quality Statement which highlights key areas for improvement covered in NICE guidance. The detail needed to accurately interpret and implement the quality statements is given in the full document. It will be important for audiences to use the full document and not the statements in isolation.
2	Royal College of General Practitioners	General	Sorry general points that cross domains. Only advice calcium and vitamin d if dietary calcium is low .If not just vitamin d. In our area bone density scans are not available over 75. There is no comment about the value of thiazide diuretics offering what appears to be benefits way beyond that of bisphosphonates
3	The Society and College of Radiographers	General	There needs to be a clear definition of what a fragility fracture is in this document to avoid ambiguity and over calling of fragility. "it is a fracture sustained from a fall at standing height" and maybe use examples e.g. scaphoid/toe/finger are not fragility fractures.
4	The Society and College of Radiographers	General	**People younger than 40 years of age** •The recommendation to offer a DXA scan to people under 40 years of age and not use FRAX® or QFracture® to calculate fragility risk is based on: The fact that these risk assessment tools are not applicable in people younger than 40 years of age - **The Society and College of Radiographers has some concerns regarding this statement in that FRAX and QFRACTURE are databases that do not include patients under the age of 40 years. So the assumption would be that patients under 40 years would all be referred for a DXA and this is not appropriate and potentially unnecessary. These patients need to be assessed clinically to decide if a DXA is worthwhile in relation to their clinical risk factors.**

[1] PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

5	The Society and College of Radiographers	General	DXA scan is recommended in younger people who have had a fragility fracture because they may be at high risk of future fractures – **Doing a DXA on younger patients is not always appropriate and should be considered on a case by case basis looking at other cofounding factors. The evidence shows that patients at this age are actually less likely to fracture as a patient gets older – age is the most significant risk factor of sustaining a fragility fracture**
6	British Thoracic Society	Question 2	Systems exist, or could be put in place, to capture most of the quality standards proposed. Fragility fractures & assessment should be captured at present. Many important risk factors (including oral corticosteroid use and smoking among respiratory patients) could be identified from existing data sources.
7	National Osteoporosis Society	Question 2	Fragility fracture is not always recorded, so it will be difficult to measure incidence of fragility fracture and hospital admissions for fragility fracture without changes in coding practice.
8	Public Health England	Question 2	**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? The RCP's Falls and Fragility Fracture Audit Programme has recently carried out a national clinical audit of fracture liaison services which aim to identify, assess and treat all patients with a fragility fracture. Ensuring ongoing national coverage of the areas covered by the draft QS by clinical audit is desirable in that the systematic use of clinical audit data used in conjunction with a service support Programme has been shown to improve patient outcomes – Neuburger et al (2015) showed that the introduction of the National Hip Fracture Database improved 30 day mortality. In addition to this, GP IT systems are in place that would support the collection of these data – however there is a need to consider how to incentivize collection.
9	Somerset County Council (Public Health)	Question 2	Fracture Liaison Service–database and National Hip Fracture Database collect information on fracture patients and one or two time points for follow up of medication. But I am not sure what mechanism would pick up whether high risk primary prevention patients are being assessed. Primary Care Quality Outcomes Framework picks up those diagnosed with osteoporosis but no other information re risk (although in Somerset this is difficult as many GPs are not under QOF, but a Somerset system).
10	British Thoracic Society	Question 3	Local resources that encourage responsible prescribing in picking up all people at risk with respiratory problems on steroids (oral / injection / inhaled) and the many side effects that are part of the risk. such as https://www.networks.nhs.uk/nhs-networks/london-lungs/responsible-respiratory-prescribing-rrp
11	Somerset County Council (Public Health)	Question 3	No, however National Osteoporosis Society has Fracture Liaison Standards.
12	Public Health England	Question 4	**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.

			It is likely that local services would be able to achieve quality statements 1-4 relatively easily in terms of resource allocation for those patients with a fragility fracture. Modelling carried out by the National Osteoporosis Society shows that an effective fracture liaison service reduces the hip fracture rate by 2.66% which results in cost savings for both acute and social care. However, given the very large at risk population – NICE currently recommend considering assessment of risk in all women aged 65 and older and all men aged 75 and older and in men and women younger than this in the presence of risk factors – it is highly unlikely that local services could carry out risk assessment within net resources. There are also resource implications in terms of treatment for patients identified as being at risk e.g. the need for additional medicines and strength and balance programmers for those at risk of falling.
13	Somerset County Council (Public Health)	Question 4	You could extend the scope of Fracture Liaison Services (FLS) (with more resource) to work in primary care and search for patients age 50+ with risk factors - fracture patients (including digit fractures) often have other risk factors that could have been acted on earlier. There would be resource implications for DXA scanning, staff to screen and manage these extra patients. National Osteoporosis Society cost-benefit calculator details cost-savings for FLS, presumably something similar could potentially be done for high risk patients?
14	British Thoracic Society	Statement 1	It is appropriate to include primary prevention, and not simply focus on secondary intervention, but: a) suggest mention primary prevention first, and then secondary; b) there is apparent inconsistency. Statement 1 states "..or who have other high-risk factors for fragility fracture, have an assessment of fracture risk". Statement 2 includes intermediate risk. In addition, we note that: a. smoking, reduced activity are risk factors for osteoporosis (and impact on many patients with chronic breathlessness) b. steroids (oral and high dose inhaled) are risk factors for osteoporosis and there is considerable evidence of this in the COPD population c. it is argued that the systematic effect of COPD on the lung is an additional risk. The importance of primary prevention should be clearer. On the basis that prevention is better than treatment after the fracture (and many of these are iatrogenic caused by our prescribing or recommendations to prescribe) we suggest that there should be a statement relating to identification before the first low impact osteoporotic fracture as part of good clinical care (in COPD / Asthma / ILD patients and others with high dose corticosteroid use in other disease areas along with those with reduced activity).

15	British Thoracic Society	Statement 1	Primary prevention: the target population is very large. Most patents within the intermediate and high risk groups should be identifiable from current data sources. Verifying whether an assessment had already been performed may be more difficult, but of importance. Secondary prevention (patients with fragility fractures) – is information available on data quality/ completeness of the Fracture Liaison Service Database?
16	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 1	We agree broadly with the priorities identified within this quality standard but have some reservations about the resource implications if it is applied widely. This particularly applies to statement 1 which identifies a substantial proportion of the population over 50 as being potentially at risk of fracture and requiring a risk assessment. A significant number of these patients will subsequently require a DXA scan for which adequate capacity may not exist currently.
17	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 1 (measures)	Due to the potential resource implications of assessing fracture risk in all of the listed groups of patients, we feel it should be stressed that a fracture risk assessment does not necessarily require a DXA scan in every case.
18	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 1 (measures)	Some fractures, such as radiographic vertebral fractures, are poorly recognized and coded which makes it difficult to gather data on all incident fractures. Inconsistent radiological reporting of vertebral fractures seen incidentally on imaging, means that they are not always recognized and acted upon by the referrer. This is a potential barrier to application.
19	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 1 (measures)	We feel that ensuring widespread provision of good quality fracture liaison services should be a priority with respect to this statement.
20	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 1 (measures)	There appears to be no guidance on how a denominator can be reliably calculated for the number of adults in the community that have high-risk factors for fragility fracture. Hence, calculating the proportion that has had a fracture risk assessment would be difficult.
21	Lancashire Care Foundation Trust	Statement 1	This statement would be easier to achieve if our area had a fracture liaison service. We currently do not have this set up.
22	National Osteoporosis Society	Statement 1	CG146 used the terms ‘risk factors’ and ‘major risk factors’ in those aged under 50 years. We suggest changing the wording ‘high-risk factors’ used in Statement 1 so that the language used throughout the statement is consistent with CG 146.
23	National Osteoporosis Society	Statement 1	We do not believe that the document contains adequate clarity on assessing fracture risk for different age ranges. Fracture risk assessment tools are validated for older adults only. In younger adults, DXA should be used. As the Quality Standards are aimed at all adults over the age of 18, we feel that information should be given for assessment of younger adults.

24	National Osteoporosis Society	Statement 1 Quality Measures (Process a)	Fragility fracture is not always coded. It is difficult to ascertain from routine fracture coding whether a fracture resulted from a low trauma event. It is therefore difficult to accurately calculate this denominator (the number of adults who have a fragility fracture) as we do not know which fragility fracture patients we are missing. This could result in under-reporting of fragility fractures resulting in an inflated levels of achievement. The FLSDB has carried out some work to evaluate denominators for fragility fracture. They currently estimate total number of fragility fractures by multiplying the locality's hip fractures by 5, using this estimate to assess data submitted via the National audit. In time, the Audit will provide reliable fragility fracture figures. Data is likely to be of better quality in locations with an FLS who keep their own records of patients with fragility fractures. Accurate measurement of this statement in primary care is likely to be difficult. Analysis of data reported for QOF indicators on osteoporosis suggests significant under reporting of fragility fractures in primary care records. Accurately defining the denominator for Statement 1 is key and will improve the accuracy of measures in subsequent statements.
25	National Osteoporosis Society	Statement 1 Quality Measures (Process b)	This measure could be achieved through local audit of primary care records by CCGs or individual practices, with resource implications. We are unable to comment on the quality of data for fracture risk factors held in primary care records.
26	Public Health England	Statement 1	Q1. Does this draft quality standard accurately reflect the key areas for quality improvement While the assessment of fracture risk for those who have had or who are at intermediate to high risk of a fragility fracture is to be welcomed, the statement does not make clear how or by whom this is going to take place. For those who have had a fragility fracture this is relatively unproblematic as assessment could take place in an acute setting either in a Trauma and Orthopaedics Department / fracture clinic or preferably in a fracture liaison service. However there are a huge additional number at high risk and a primary care setting is probably the best site for risk assessment for this group.
27	The Society and College of Radiographers	Statement 1	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. – **Any vertebral fracture reported on spinal images (plain film or CT) should have a recommendation to return for a DXA assessment if appropriate.**

28	UCB Pharma	Statement 1	Dual-energy X-ray absorptiometry (DXA) scans play an important role in the diagnosis and management of osteoporosis. NICE CG146 recommends a DXA in people whose risk fracture is in the region of an intervention threshold for a proposed treatment after a risk assessment, and for a recalculation of absolute risk using FRAX with the bone mineral density (BMD) value thereafter. It also recommends measuring BMD with DXA in people who are being initiated on treatments that may have a rapid adverse effect on bone density or in those under the age of 40 years who have a major risk factor. NICE Osteoporosis CKS also recommends DXA in people who are at intermediate and high fragility fracture risk. Stakeholders have highlighted variation in access to DXA scans across the country and that some areas are reducing the number of scans undertaken due to financial constraints (Briefing paper, page 16 & 19). The 2013/14 musculoskeletal atlas of variation by Public Health England reported that there is a 46.7-fold variation in the rate of DXA activity across England. We would thus propose the following addition to 'Outcome' for Quality Statement 1 (text underlined): · **Outcome** (page 5) *"Average number of weeks to receiving DXA in those assessed to be at intermediate or high fragility fracture risk."* **References:** 1) NICE Clinical guideline: Osteoporosis: assessing the risk of fragility fracture (CG146); August 2012; https://www.nice.org.uk/guidance/cg146 2) NICE Clinical Knowledge Summary (CKS): Osteoporosis - prevention of fragility fractures; 2016; https://cks.nice.org.uk/osteoporosis-prevention-of-fragility-fractures 3) Public Health England, NHS Atlas of Variation in Healthcare, 2015 Compendium; https://fingertips.phe.org.uk/documents/Atlas_2015_MuscSkel.pdf
29	Wales Osteoporosis Advisory Group	Statement 1	This is fine although I am not sure that "high-risk factors" is the best language to use for major or important risk factors. They are high risk groups who have risk factors. The risk factor itself is not high risk

30	British Thoracic Society	Question 5	See above. Workload / data quality issues are more likely to arise within primary prevention (identifying and assessing “at risk” patients prior to a fragility fracture), but this is of key importance. QS1 – says if at high risk – including COPD. It only refers to systemic / oral steroids, not high dose inhaled. Smoking is also in there as making someone high risk. Include a comment that recognised some patients may have multiple factors. COPD and CF are listed as respiratory disorders in their own right but reference could be made to ILD and asthma.
31	National Osteoporosis Society	Question 5	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? Statement 1 refers to all adults with fragility fractures and those with risk factors for fragility fractures. By highlighting the need for assessment in both groups, the Statement covers the populations where assessment should be focussed. Barriers Assessment for those who have had a fragility fracture is effectively carried out in a systematic way by a Fracture Liaison Service (FLS). When fully implemented, an FLS will also improve data capture for Statements 1, 2 and 3. FLS have been established successfully in many areas of the UK and many more locations are interested in setting up an FLS. There is a national work programme led by the National Osteoporosis Society to support this (www.nos.org.uk/fls). Those areas without an FLS will find this statement more difficult to achieve - a lack of an FLS could be a barrier to implementation. CG146 provides guidance on targeting fracture risk assessment dependent on age and risk factors. If this guidance were to be implemented systematically, there would be resource implications, most likely for Primary Care where this patient data is held. We believe that an opportunistic approach is more common at present. Insufficient capacity in Primary Care and the absence of an alternative process could be a barrier to implementation
32	Royal College of General Practitioners	Question 5	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?

			There is considerable variation within England about the variability of bone density scans particularly to the over 75 years. With 2 validated risk score methodologies (FRAX and Qfracture) it is unclear for general practitioners and primary care staff which to use and when. The cost of the risk score assessment needs further evaluation with QFracture considers more risk factors than FRAX and has been developed to incorporate further risk factors in the future so is more time intensive and costly. Automation of the process in electronic medical records with some patients self-inputting may help but there is still likely to be a considerable amount of GP and other primary care health care professional clinical time and input needed in collecting the data. Poku et al (2016) showed in analysis of large databases FRAX appears more cost effective whilst QFracture specifically developed for the UK population. The implementation of this quality standard within primary care within the context of a 10 minute GP consultation, at the same time as trying to deal with other multimorbidity, is unlikely to be successful. Protected resourced time such as the elderly person health check is no longer funded in England and the NHS Health check does not include osteoporosis screening. Whilst the event of a fragility fractures will provide a focus for an episode of care and focus on osteoporosis it is the resources needed to identify those at high risk before a fracture on a population basis and then to engage the patients and their carers to discuss treatment options. Micro-costing studies need to be conducted in primary care to involve the direct enumeration and costing out of every input consumed in the treatment of a particular patient. Any planned implementation needs to be piloted and evaluated. There needs to be an economic impact particularly on primary care workload particularly in the context of many other competing priorities. It would require substantial additional primary care work force in order to achieve this quality standard. With GPs and primary care nurses currently in such short supply in the UK it would probably require additional input and expansion of pharmacists in primary care. This standard may be more practical and measureable if it only applies to those in long term care homes. Rodondi et al. (2012) demonstrated that age and clinical risk factors were more important than bone mineral density in the calculation of 10-year fracture probability in nursing home residents and suggested that bone mineral density is removed from the fracture risk assessment In Canada Sultan H et al (2015) reported the difficulty in obtaining necessary patient information (medical history, information about osteoporosis and fracture diagnoses, and annual height assessments) and concluded data collection was a significant barrier to Canadian GPs. Poku E et al A multi-study cost-effectiveness comparison of the QFracture and FRAX fracture risk algorithms Risk and Decision Analysis vol. 6, no. 1, pp. 1-6, 2016

			Rodondi A, Chevalley T, Rizzoli R. Prevalence of vertebral fracture in oldest old nursing home residents. Osteoporosis Int. 2012;23:2601–6. Sultan H et al Strategies to overcome barriers to implementing osteoporosis and fracture prevention guidelines in long-term care: a qualitative analysis of action plans suggested by front line staff in Ontario, Canada BMC Geriatrics 2015 15:94
33	The Society and College of Radiographers	Question 5	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? **The Society and College of Radiographers believes these guidelines offer improvements in terms of at risk adults however there is a gap in considering those patients that have never actually reached peak bone mass (PBM) for example those patients that have had juvenile cancer and were on high doses of steroids before reaching PBM are at risk, teens and adolescence that have eating disorders such as anorexia would not have reached PBM. These are 2 groups of patients that area significant risk of fragility fracture and future fracture.**
34	Somerset County Council (Public Health)	Question 5	What are the high risk factors for fracture? If the definition on page 6 is used – which states that age 65yrs+ in women and 75yrs+ in men are at high risk – this would have huge implications for bone DXA scanning services as this amounts to a screening programme in these age groups. Currently most services would not accept a referral for DXA scanning based on age alone with no other risk factor. As suggested above you could extend the scope of FLS to systematically search for patients with high risk factors which might be a natural extension of their role. If primary care is expected to do this how will it work without providing an incentive to identify these patients? How will anyone be able to say that all patients in a practice at high risk have been assessed? Is there any data about what percentage might be found pre-fracture?
35	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 2	We also have some concerns that statement 2, which states that bone-sparing treatment should be prescribed to those at high or intermediate risk of fracture and diagnosed with osteoporosis, does not reflect the current practice at many centres to offer these treatments to patients with a T score >-2.5 if their fracture risk is identified as high. Evidence is beginning to emerge to support such an approach.

36	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 2	This statement will be difficult to measure due to the current lack of consensus on the population for whom osteoporosis treatment should be prescribed. Some centres use the NOGG (National Osteoporosis Guideline Group) treatment thresholds which vary according to age, whereas others base the decision to treat on fixed intervention thresholds according to FRAX calculated 10-year risk of fracture. With either of these approaches there is not a necessity for patients to have T-score defined osteoporosis. This applies to both primary and secondary fracture prevention. These approaches are not reflected in the current draft quality standard.
37	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 2 (definition of terms)	With reference to this statement, it should be recognised that some patients with disproportionately low spinal BMD may not be identified as being at high or intermediate risk of fracture using risk calculators such as FRAX (based on hip BMD). Treatment should be considered in these individuals on a case-by-case basis, as current treatments are known to be effective in reducing the risk of vertebral fracture. Clinical judgement is also needed for other groups of patients who fall outside the range of the risk calculators e.g. younger patients.
38	Lancashire Care Foundation Trust	Statement 2	This would be easier to manage if a FPS was in use and staff initiated bone health treatment for those appropriate following fragility fracture in secondary care.
39	National Osteoporosis Society	Statement 2	The term 'high or intermediate risk of fragility fracture' needs to be defined. While detail is given under 'definitions', page 10 says that both FRAX and QFracture have accompanying guidance that allows risk scores to be interpreted. We are not aware of guidance for QFracture. We recommend including links for the guidance to which you refer. We do not believe this is sufficiently well defined to aid accurate measurement of the statement.
40	National Osteoporosis Society	Statement 2	The Statement lacks clear intervention thresholds which describe when it is appropriate to prescribe a bone sparing treatment. Intervention thresholds provided by NICE in TA160 and TA161 do not relate to fracture risk assessment. National guidance giving intervention thresholds is urgently needed. This remains a key challenge in the prevention of fragility fractures.
41	National Osteoporosis Society	Statement 2, 3, 4	Ibandronate and HRT are not included in the list of bone sparing treatments given under 'definitions'.
42	National Osteoporosis Society	Statement 2	We would expect some younger people to be at intermediate risk of fractures and to have osteoporosis as defined as a t-score less than -2.5. However not all of these people would require a bone sparing treatment. Recognition of this small group needs be taken into account when measuring performance against statement 2.
43	National Osteoporosis Society	Statement 2	Results from FRAX and QFracture are not interchangeable. It would be helpful to reiterate this.

44	National Osteoporosis Society	Statement 2 Measures (outcomes a)	We feel that 'outcome measure a)' is unrealistic at this point in time and the data is not captured to achieve this measure. However, there is evidence to support the need for prompt treatment so we feel this measure could be aspired to once data capture has improved.
45	Public Health England	Statement 2	Q1. Does this draft quality standard accurately reflect the key areas for quality improvement We are concerned that statement 2 only makes reference to bone sparing treatment and not to the reduction of significant modifiable osteoporosis risk factors such as falls, smoking, high alcohol consumption, Vitamin D deficiency or low BMI. Treatment to reduce the risk of osteoporosis should include systematic and ongoing risk factor reduction interventions. We propose that the statement should be rephrased to read: "Adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis are offered bone-sparing drug treatment and interventions to reduce modifiable osteoporosis risk factors." If possible these risk factors should be listed.
46	Royal College of General Practitioners	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? This is potential measurable provided nationally a single risk score assessment tool is chosen and used and automated in the electronic clinical records with minimum input from GPs and other primary care health care professionals. This is important to offer the lifestyle advice to the patient and carers as well as bone-sparing treatment. In some long term care homes the timing of medication at least 30 minutes before meals may be difficult to achieve. Many health care professionals may not promote bone-sparing treatment if the patient is on a thiazide diuretic in the belief that thiazides reduce hip fractures. In the 2011 Cochrane review by Aung et al. 21 studies of observational nature with nearly 400000 participants were included in this systematic review. Studies looked for an association between thiazide diuretic use and hip fracture. The majority of included studies have low to moderate risk of bias. Thiazide diuretic use was associated with a reduction in risk of hip fracture. Randomized controlled trials are needed to confirm these findings. Whilst there is no available prospective study a recent study by Kruse et al (2016) of national Danish patient data with regard to thiazide diuretics vs. non-treatment found that after age 83 years, thiazides increase the 10-year risk of major fractures. It found that thiazides can be stopped after 63 years old to possibly protect against fracture occurrence

			Aung K, Htay T. Thiazide diuretics and the risk of hip fracture. Cochrane Database of Systematic Reviews 2011, Issue 10. Art. No.: CD005185. DOI: 10.1002/14651858.CD005185.pub2. Kruse, C., Eiken, P. & Vestergaard, P. Osteoporosis Int (2016) 27: 1875. doi:10.1007/s00198-015-3451-0
47	The Society and College of Radiographers	Statement 2	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 - **should this state once a vertebral collapse has been confirmed to be an osteoporotic because there are many other causes of vertebral fractures such as multiple myeloma/mets**
48	The Society and College of Radiographers	Statement 2	People with vertebral fractures •The recommendation to consider starting drug treatment in people with a vertebral fracture without a DXA scan is based on: ◦The expert opinion of the SIGN guideline development group which considers that the presence of a vertebral fracture signifies the presence of osteoporosis, even if the bone mineral density (BMD) is not within the diagnostic range – **Only in the correct age range and providing all over causes of a vertebral fracture have been considered such as multiple myeloma and metastatic bone disease.**
49	The Society and College of Radiographers	Statement 2	Clinicians should ensure that other populations who might benefit from recommended treatments are also considered. – **Particularly males with low T scores who are at significant risk of a secondary cause for osteoporosis. This needs highlighting in this document because males with osteoporosis are often overlooked and actually carry a higher risk of fracture than females.**
50	Somerset County Council (Public Health)	Statement 2	There is no guidance for those who have osteopenia with an increased risk of fracture. The guidance only states that those with osteoporosis (T-2.5) should be treated whether high or intermediate risk pre-DXA. As many fractures occur in the osteopenic range what is the guidance for these? Will this still just be according to local guidelines? If so we would be looking at a national standard that only captures a third of patients who fracture who have actually have osteoporosis measured. If it is only those age 75yrs+ and those with DXA score of T-2.5 then there is a well-defined population to measure who should be on bone sparing treatment.

51	UCB Pharma	Statement 2	As per the clinical guidelines and the current evidence, a fragility fracture suggests that one is likely to have osteoporosis and is at high risk for a near term subsequent fracture. Given the limited number of dual-energy X-ray absorptiometry (DXA) in the UK (source: Briefing Document, section 4.1.3, page 16), diagnosis of osteoporosis through the measurement of bone mineral density by DXA in fracture patients could lead to delays in treatment initiation, whilst a previous fracture would make them eligible for treatment without delay. Furthermore most pharmacological interventions take at least 6 to 12 months from initiation to reduce fracture risk. Additionally, in patients with a fragility fracture whichmakes them at high risk of a near term fracture, bone forming drug treatments should be initiated immediately, to reduce the risk. It is thus critical that in patients who had a fracture and are at high risk for subsequent fractures, treatment is initiated immediately, without any delay, in order to reduce the risk of subsequent fractures and the associated negative consequences. We would thus suggest the following revision (text underlined): · **Quality statement 2** (page 8) "*Adults assessed as at high or intermediate risk of fragility fracture and diagnosed with osteoporosis are offered bone sparing or bone forming drug treatment immediately to reduce the fracture risk.*" · **Rationale** (page 8) "…*Immediate initiation of drug treatment to improve bone density reduces the risk of future fractures and the associated negative consequences*." **References**: 1) National Osteoporosis Guideline Group (NOGG). Guideline for the diagnosis and management of osteoporosis in postmenopausal women and men from the age of 50 years in the UK. March 2014. 2) National Osteoporosis Guideline Group (NOGG). Osteoporosis: Clinical guideline for prevention and treatment; January 2016 3) Scottish Intercollegiate Guidelines Network. Management of osteoporosis and the prevention of fragility fractures (SIGN142); March 2015.

52	Wales Osteoporosis Advisory Group	Statement 2	I have a major problem with this statement since it does not accurately reflect the CKS management recommendations nor the TA recommendations for treatments. The CKS states that patients who score above a certain threshold with Qfracture or FRAX that places them in a high risk category should then have a DXA scan. The decision on treatment then rests on the DXA scan result and this is irrespective of age. This is what the SIGN guidelines suggest although this in turn is at odds with guidance from TA 160 and 161 and has created confusion. We have been moving towards adopting the CKS recommendations in light of no further updates from NICE with respect to comprehensive clinical guidelines. However I am aware of further submissions to NICE regarding an update of the FRAX/NOGG management pathway. For patients at intermediate risk, the CKS states that a DXA scan should be organized if FRAX has been used and to repeat the risk assessment in the future if Qfracture used. Consider using bone sparing treatment if hip or vertebral fracture irrespective of risk assessments/DXA would be reasonable but perhaps too specific for a quality standard
53	British Thoracic Society	Question 6	Q6: At risk groups are generally well defined. For COPD in particular, it would be helpful to specify what is meant by “frequent use” of steroids. Quality statement 1 omits those at intermediate risk and requires amendment. You cannot offer these patients treatment to attain QS2, if you do not offer them assessment for QS1.
54	National Osteoporosis Society	Question 6	Is the statement measurable in terms of describing a well-defined (intermediate or high-risk) population for whom bone-sparing treatment should be prescribed? We do not think so for the following reasons: • FRAX and QFracture produce different results which are not interchangeable. • We are not aware of guidance that allows risk scores produced by QFracture to be interpreted. • Intervention thresholds are not given by NICE for either tool. Current NICE Technology appraisals are not linked to fracture risk assessment
55	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 3 (measures)	Collecting complete data on medication reviews (including checking compliance and adverse effects) for patients on bisphosphonates may be difficult because these reviews currently take place in a variety of settings (hospital clinics, with GP, with pharmacist) which may vary by region. Again, this statement has significant resource implications (but is nevertheless important).
56	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 3 (definition of terms)	We feel it should be recognised that atypical femoral fractures represent very rare adverse effects of anti-resorptive treatment in patients with osteoporosis, whereas hip / groin pain is common. Asking about these symptoms at each routine medication review could potentially cause concern and lead to unnecessary imaging.

57	British Thoracic Society	Statement 3	Statement 3: We note that there are often patients who have had bisphosphonates (or calcium) discontinued due to poor tolerance, and left without any therapy. It is not sufficient to merely assess tolerance and adherence. If a patient is intolerant of specific bone-sparing treatment, alternative therapy should be considered.
58	Lancashire Care Foundation Trust	Statement 3	During falls assessments patients are asked if they are taking medication as prescribed (bisphosphonates)
59	National Osteoporosis Society	Statement 3	It would be helpful to incorporate the timings of '4 months' and 'annually' given on page 14 within the text of statement 3.
60	National Osteoporosis Society	Statement 3	The document lacks detail about the actions to be taken where adverse effects or adherence issues are uncovered. It would be helpful to describe discussion/providing supportive information and change to management where required. It might also be beneficial to include some information on barriers to adherence and the options to improve adherence when problems arise.
61	Royal College of General Practitioners	Statement 3	According to Prescribing and Medicines Team at the Health and Social Care Information Centre the average number of prescription items per head of the population in 2014 is 19.6, compared to 19.1 items in the previous year and 13.7 in 2004. Since 2004, use of medicines in this section has risen and costs fallen. Much of the increase in use is of Alendronic Acid (4.8m items) although costs for this have fallen by £70.5m, after generic formulations became available. Falling use of Risedronate Sodium and generic formulations becoming available have reduced costs by a further £23.9m. Since 2004, etidronate disodium has been discontinued; this reduced costs by an additional £10.7m. http://content.digital.nhs.uk/catalogue/PUB17644/pres-disp-com-eng-2004-14-rep.pdf 2014 analysis of Scotland's electronic primary healthcare records showed that 16.9% of adults were receiving four to nine medications (Payne et al 2014). That number rose to 28.6% for adults aged 60–69 years and to a 51.8% of the population aged over 80 years Guidelines, multimorbidity and the rising elderly population have driven this increase in polypharmacy and potentially serious drug interactions (Guthrie 2012). Within the a GP consultation of 10 minutes it is difficult to address compliance and checking for adverse effects other than in a brief manner. The GP Clinical IT systems are not capable of identifying potential adverse effects from drugs and it may requires manually fully reviewing the specific product characteristics of the drug on the electronic medical compendium, particularly for uncommon or new drugs.
			Different types of medication review are required to meet the needs of patients for particular purposes. The classification described below focuses on the purpose of medication review and how medication review fits with other aspects of care and treatment offered to patients (National Prescribing Centre 2008). This can range from Type 1 prescription review, Type 2 Concordance and compliance review and Type 3 a full clinical medication review

			Guthrie B, Makubate B (2012). The rising tide of polypharmacy and potentially serious drug interactions 1995–2010: repeated cross sectional analysis of dispensed prescribing in one region'. Primary Health Care Research & Development, vol 13, supp S1: 45 2E.2 Payne RA, Avery AJ, Duerden M et al. Prevalence of polypharmacy in a Scottish primary care population. European Journal of Clinical Pharmacology 2014;70:575–581. doi: 10.1007/s00228-013-1639-9 A Guide to Medication Review 2008. NPC Plus, Medicines Partnership Programme. http://www.cff.org.br/userfiles/52%20-%20CLYNE%20W%20A%20guide%20to%20medication%20review%202008.pdf
62	Wales Osteoporosis Advisory Group	Statement 3	This is an important standard and is supported
63	Amgen	Statement 4	It is important to differentiate between the classes of anti-resorptives in particular the offset of effects of bisphosphonates are quite different to denosumab. Denosumab, a fully human IgG2 anti-RANK ligand antibody, quickly and substantially inhibits bone remodelling. In patients treated with Prolia for up to 10 years, Bone Mineral Density (BMD) increased from the pivotal study baseline by 21.7% at the lumbar spine, 9.2% at the total hip, 9.0% at the femoral neck, 13.0% at the trochanter and 2.8% at the distal 1/3 radius. Fracture incidence was evaluated as a safety endpoint. In years 4 through 10, the rates of new vertebral and non-vertebral fractures did not increase over time; annualised rates were approximately 1.0% and 1.3% respectively. (Prolia SmPC) Because the pharmacology of denosumab is different to that of the bisphosphonates, the inhibition of remodelling will be reversible upon discontinuation of treatment. Amgen are currently in discussion with the CHMP regarding a variation to the marketing authorisation regarding the occurrence of fracture following treatment discontinuation. In our company core data sheet we are making the following recommendations; 1. Patients should be advised not to interrupt Prolia therapy without their physician's advice 2. Multiple vertebral fractures (MVF) may occur following discontinuation of treatment with Prolia, particularly in patients with a history of vertebral fracture 3. Evaluate the individual benefit/risk before discontinuing treatment with Prolia. If Prolia treatment is discontinued, consider transitioning to an alternative antiresorptive therapy.
			Point 3 has been published in the medical literature and presented at scientific conferences (McClung Osteoporosis International 2016, Brown ACR 2016) For all bone active therapies each physician should have a call – recall register for patients on bone active therapy or to ensure that they are enrolled on a patient support program. This will ensure that they do not discontinue denosumab treatment until the Physician has conducted a review of the risks and/or benefits of continuing or discontinuing treatment.

			References 1. Prolia (denosumab) Summary of Product Characteristics 2. McClung MR. Cancel the denosumab holiday. Osteoporos Int. 2016; 27: 1677-1682. 3. Brown JP, et al. Abstract presented at the American College of Rheumatology Annual Meeting. 2016; Abstract 1028.
64	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 4 (statement)	The requirement to regularly review the risks and benefits of continuing antiresorptive medication puts pressure on local DXA services as a large number of repeat DXA scans are likely to be needed. Currently, many centres routinely review treatment every 5 years rather than every 3 years; changing the wording in the quality standard to reflect this would reduce this pressure and potentially deliver a substantial cost saving. DXA scans could still be repeated more frequently where there is a specific indication e.g. a new fragility fracture whilst on treatment.
65	British Society for Rheumatology (Osteoporosis Special Interest Group)	Statement 4 (definition of terms)	We feel it should be noted that the decision whether to continue or stop treatment does not just consider the post-treatment T-score but other factors including the extent of BMD improvement, occurrence of further fragility fractures occurring whilst on treatment, and other risk factors.
66	Lancashire Care Foundation Trust	Statement 4	FLS would be useful in helping achieve this
67	National Osteoporosis Society	Statement 4	Standard 4 covers the review of people taking bisphosphonates but does not include information on how and when to conduct review for people on non-bisphosphonate treatments. We are concerned that this omission may lead to inappropriate application of the guidance to non-bisphosphonates with rapid offset of action like denosumab, where benefit is not maintained once the drug is stopped. Ideally, the Quality Standard should provide information on the recommended review of patients prescribed non-bisphosphonates. If this is not possible, a clear statement should be added to avoid confusion.
68	National Osteoporosis Society	Statement 4	Page 19, second bullet point: guidance is given on treatment duration for people at high risk of osteoporosis up to 7/10 years. Once a high risk patient has received treatment for the given length of time, should treatment be stopped in all cases? Where treatment is stopped, current evidence suggests that patients should be reassessed following a pause in treatment. How would recall and reassessment be ensured? Clarification is needed to avoid unintended consequences.
69	National Osteoporosis Society	Statement 4	DXA is recommended for people who do not fall into the groups for whom continued treatment is recommended. This could result in a change of practice with resource implications.
70	National Osteoporosis Society	Statement 4	We believe that users may misunderstand what is meant by '…a review of the risks and benefits…' in this statement
71	Royal College of General Practitioners	Statement 4	It would appear to be sensible but for many patients it may be difficult to demonstrate what the benefits are. Optimal duration of bisphosphonate therapy for osteoporosis has not been established (Rossini 2016). The need for continued treatment should be periodically reassessed in each individual patient, taking into consideration benefits and potential risks of therapy, especially after 5 or more years of use. GP IT systems currently do not easily flag duration of treatment and it may require considerable effort to establish.

			Rossini M Guidelines for the diagnosis, prevention and management of osteoporosis (2016) The Italian Society for Osteoporosis, Mineral Metabolism and Bone Diseases (SIOMMMS) Reumatismo 2016 :1:1-39 *All above comments Matthew Hoghton*
72	Royal College of General Practitioners	Statement 4	The 3 year vs 10 year distinction is muddling especially in those aged at the transition of 75 What about those unable to swallow along with the prescribing information i.e. standing up or where the organisation i.e. a nursing home can't give 2 hours before meals – John Sharvill
73	The Society and College of Radiographers	Statement 4	For other people, arrange a dual-energy X-ray absorptiometry (DXA) scan and consider: - **should be clear that this an axial DXA. The evidence base states the hip and spine to be the most accurate at measuring bone density as opposed to other peripheral sites.**
74	Wales Osteoporosis Advisory Group	Statement 4	3 years is the wrong time interval and it should be 5 years. This comes from the multimorbidity guideline NG56 despite the consensus view (including NOS, NOGG, All Wales Medicines Strategy Group and the MHRA) that 5 years is the time to reassess. This was discussed at our recent national meeting and everybody agreed that 3 years is wrong and not justified

Registered stakeholders who submitted comments at consultation

- Amgen
- British Thoracic Society
- British Society for Rheumatology (Osteoporosis Special Interest Group)
- Lancashire Care Foundation Trust
- National Osteoporosis Society
- Public Health England
- Royal College of General Practitioners

- The Society and College of Radiographers
- Somerset County Council (Public Health)
- UCB Pharma
- Wales Osteoporosis Advisory Group