National Institute for Health and Clinical Excellence

Osteoporosis
Scope Consultation Table
16th June - 14th July 2011

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Arthritis Research UK	20.00	General	Arthritis Research UK welcomes this Osteoporosis guideline and wishes to endorse the response led by the National Osteoporosis Society.	Thank you for your comment.
SH	Arthritis Research UK	20.01	General	Arthritis Research UK is supportive of the broad remit of the guideline, and agrees with the National Osteoporosis Society in welcoming the inclusion of groups previous excluded for NICE guidance i.e. men and glucocorticoid users.	Thank you for your comment.
SH	Arthritis Research UK	20.02	General	Arthritis Research UK would like to see health information for people undergoing risk assessment as part of the overall guideline, along with specific reference to shared decision-making tools that explain the results of the risk assessment, and assist with treatment decisions by explaining risks and benefits.	Thank you for your comment. This information, including shared decision-making (applicable generally to all healthcare contexts) will be covered by the 'Patient experience in generic terms' guideline, due for publication in October 2011. We aim to cross reference recommendations from that guideline into this one.
SH	Arthritis Research UK	20.03	3.1 a)	Arthritis Research UK would also like to see among fracture risk factors, the specific reference to and inclusion of people with systemic inflammatory arthritis (e.g. rheumatoid arthritis, ankylosing spondylitis) who experience substantially increased fracture risk as a direct result of their condition.	Thank you for your comment. The list of risk factors is not exhaustive; the GDG will prioritise the risk factors to investigate for risk assessment.
SH	Arthritis Research UK	20.04	3.1 c)	In addition to hands and feet we would suggest adding in fracture of the head (skull and face) as not generally being regarded as osteoporotic fragility fractures.	Thank you for your comment. The scope has been amended to reflect this.

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SH	Arthritis Research UK	20.05	3.2 d)	The National Osteoporosis Society has recently published updated estimates of the cost of hip fracture. We would recommend using these figures • We currently estimate cost of treating and caring for hip fractures to be £ 2.3 billion in the UK • The cost of treating and caring for hip fractures in the UK could exceed £6billion by 2036 "National Osteoporosis Society 25th anniversary report – A fragile future" can be downloaded from http://www.nos.org.uk/page.aspx?pid=1130&srcid=1126	Thank you for your comment. The scope has been amended accordingly.
SH	Arthritis Research UK	20.06	3.2	The National Osteoporosis Society has recently published updated projections of the number of hip fractures. We would recommend using these figures • Projections show that on current trends, by 2036, there could be as many as 140,000 hospital admissions for hip fracture a year in the UK – this would be an increase of 57% on 2008 admissions. "National Osteoporosis Society 25th anniversary report – A fragile future" can be downloaded from http://www.nos.org.uk/page.aspx?pid=1130&srcid=1126	Thank you for your comment. The scope has been amended accordingly.
SH	Arthritis Research UK	20.07	3.3 b)	Some of the named risk scores are tools for predicting BMD, not fracture (for example OST, ORAI, OSIRIS and SCORE). These should be clearly distinguished from those algorithms that directly assess fracture probability.	Thank you for your comment and this information. The scope has been amended to reflect this.
SH	Arthritis Research UK	20.08	4.1.1	A further group which could merit specific consideration are those patients who are currently receiving osteoporosis treatment.	Thank you for your comment. People currently receiving treatment to prevent fragility fractures have now been included to the groups that will be covered.

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SH	Arthritis Research UK	20.09	4.1.1 b)	Arthritis Research UK recommends that people with systemic inflammatory arthritis (such as rheumatoid arthritis) are included as a specific risk group. This would be in line with tools such as the WHO fracture risk tool (FRAX) that includes this as an independent risk factor.	Thank you for your comment. We are aware of the inclusion of these groups in existing risk assessment tools. The list of risk factors and groups considered is not exhaustive; the GDG will decide what the most important risk factors to investigate are.
SH	Arthritis Research UK	20.10	4.3.1	In some fracture risk assessment tools, BMD measurements are an optional criteria. However, the National Osteoporosis Society considers that for patients at an increased risk of fracture, a DXA scan is an important component of the decision to treat. Clear guidance on the role of DXA in fracture risk assessment is needed. Arthritis Research UK endorses this approach.	Thank you for your comment. We will examine DXA as a risk assessment tool.
SH	Arthritis Research UK	20.11	4.3.1	When assessing the role of DXA in fracture risk assessment it is important to consider the following benefits in addition to the BMD measurement obtained. • The presence of a prior vertebral fracture is an important independent risk factor. It is estimated that fewer than 30% of vertebral fractures are clinically diagnosed. Fan beam DXA scanners can acquire lateral images of the thoracolumbar spine allowing vertebral fracture assessment (VFA) which can give vital information on prior vertebral fractures. • A baseline DXA scan is essential if DXA is to be used to monitor response to treatment or monitor change in individuals not taking treatment. There is also a role for DXA measurements in patients taking 'drug holidays' when considering when to resume treatment. Although not directly related to fracture risk assessment, it is an ideal opportunity to obtain baseline measurements that may otherwise be omitted.	Thank you for your comment and information. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment. The role of DXA in assessing the risk of fragility fracture will be established by the GDG.

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SH	Arthritis Research UK	20.12	4.3.1	The presence of a prior vertebral fracture is an important independent risk factor. Vertebral fractures can be diagnosed using lateral X-rays of the spine or vertebral fracture assessment (VFA).	Thank you for your comment. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment.
SH	Arthritis Research UK	20.13	4.4	However fracture risk is being calculated, the output needs to be meaningful and easily understood by heath professionals and the public. This is best characterised in terms of a persons absolute fracture risk over a defined time period. We would also welcome clear guidance on communication about risk assessment as seen in CG67 Lipid modification.	Thank you for your comment. We recognise the complexity of understanding risk and will endeavour to provide recommendations on how results should be presented. Recommendations on risk communication (applicable generally to all healthcare contexts) will be covered by the 'Patient experience in generic terms' guideline, due for publication in October 2011. We aim to cross reference recommendations from that guideline into this one.
SH	Arthritis Research UK	20.14	4.4	We would suggest the addition of "the likelihood of effective anti-fracture treatment" as an outcome.	Thank you for your comment. This is outside of the remit for this guideline.
SH	Arthritis Research UK	20.15	General	The National Osteoporosis Society's publication 'The Reporting of Dual Energy X-Ray Absorptiometry Scans in Adult Fracture Risk Assessment' contains information relevant to the development of this guideline. Including the use of BMD measurements in fracture risk assessment, FRAX, follow-up scans and a proposed structure for fracture risk assessment reporting.	Thank you for your comment and information.
SH	Bone Research Society	18.00	General	The assessment of fracture risk is an area in which significant advances have been made over the past few years. A clinical guideline on this topic is therefore to be welcomed.	Thank you for your comment.
SH	Bone Research Society	18.01	General	In the introduction, it should be acknowledged that many studies over the past 5 or so years have shown that the	Thank you for your comment. We consider this is implicit in our inclusion in the scope of people without

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				majority of low trauma fractures in postmenopausal women occur in individuals with a BMD T-score ≥ -2.5. This emphasises the importance of including independent clinical risk factors in algorithms to assess fracture risk.	osteoporosis.
SH	Bone Research Society	18.02	General	Recently it has been shown that low trauma fractures occur almost as frequently in obese as in non-obese postmenopausal women, despite higher BMD in obese women. The ability of fracture risk algorithms to predict fracture probability in the obese population should therefore be addressed in the clinical guidelines.	Thank you for your comment. We will bring this to the attention of the GDG when considering risk assessment.
SH	Bone Research Society	18.03	3.2 d)	Costs associated with hip fracture should be updated, according to the estimates shown below: • Estimated cost of treating and caring for hip fractures is £ 2.3 billion in the UK • The cost of treating and caring for hip fractures in the UK could exceed £6billion by 2036 "National Osteoporosis Society 25th anniversary report – A fragile future" can be downloaded from http://www.nos.org.uk/page.aspx?pid=1130&srcid=1126	Thank you for your comment. The scope has been amended accordingly.
SH	Bone Research Society	18.04	3.2	Projections for the number of hip fractures should be updated, according to the estimates shown below: • Projections show that on current trends, by 2036, there could be as many as 140,000 hospital admissions for hip fracture a year in the UK – this would be an increase of 57% on 2008 admissions. "National Osteoporosis Society 25th anniversary report – A fragile future" can be downloaded from http://www.nos.org.uk/page.aspx?pid=1130&srcid=1126	Thank you for your comment. The scope has been amended accordingly.

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SH	Bone Research Society	18.05	3.3 b)	OST, ORAI, OSIRIS and SCORE are algorithms for predicting BMD, not fracture. These should be clearly distinguished from algorithms that directly assess fracture probability. In addition, it should be recognised that some of the algorithms (including GARVAN) are not calibrated for the UK fracture and mortality rates.	Thank you for your comment and this information. The scope now distinguishes the algorithms predicting BMD from those predicting the risk of fracture. The GARVAN tool has been removed from the scope.
SH	Bone Research Society	18.06	4.3.1 a)	The NOF guideline is not a fracture risk assessment tool – rather, it is a guideline that utilises FRAX to predict fracture risk probability. It is therefore unclear why it is included in this list.	Thank you for your comment. NOF is no longer listed in 4.3.1.a.
SH	Breast Cancer Care	4.00		This organisation responded and said they had no comments to make.	Thank you for your comment.
SH	British Geriatrics Society	10.00	General	The BGS welcomes the guideline and complements NICE on the planned extensive review.	Thank you for your comment.
SH	British Geriatrics Society	10.01	3.1 a)	Other factors that predispose to fracture are falls related risk factors and these must be eluded and defined as per the NICE Falls guidelines.	Thank you for your comment. The list of risk factors is not exhaustive; the GDG will prioritise the risk factors to investigate for risk assessment.
SH	British Geriatrics Society	10.02	4.1 a)	Frequent fallers needs to be defined and we would suggest 2 or more falls over a 6 month period.	Thank you for your comment and suggestion. We do not want to agree a definition at this stage in case we inadvertently omit evidence. We will finalise the definition with the GDG and take your suggestion into account.
SH	British Geriatrics Society	10.03	4.1 a)	Other specialist grps that need to be considered and who often present treatment difficulties. These include patients with : cognitive impairment renal impairment	Thank you for your comment. The guideline will seek to provide recommendations on simple measures that can indicate potential risk and risk assessment measures. We will not be able to establish the association between all possible risk factors and fragility fracture. The list of risk factors is not exhaustive; the GDG will prioritise the risk factors to investigate for risk assessment.
SH	British Lung	11.00	4.1.1 b)	There is a particular issue which has been ignored up to	Thank you for your comment. The guideline will seek to

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	Foundation			now of people with COPD who receive intermittent treatment with steroids but over an extensive period of time. They are an identifiable group but are usually missed out from consideration concerning osteoporosis. Could you please include them in the scope? This would mean all those people with severe or very severe COPD as defined in your clinical guidelines. They are particularly at risk as they have no idea that the treatment to help their breathlessness during exacerbations will put them at risk of osteoporosis causing considerable pain, fractures and extra need for hospitalisation. This is likely to shorten their lives.	provide recommendations on simple measures that can indicate potential risk, and risk assessment measures. We will not be able to establish the association between all possible risk factors and fragility fracture. Use of steroids will be considered by the GDG in detail.
SH	British Nuclear Medicine Society	6.00		This organisation responded and said they had no comments to make.	Thank you for your comment.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	5.00	4.1.1	"Groups that will be covered, including those without osteoporosis or previous fracture". We would like to highlight the young adults with chronic disease that will be getting transitioned from paediatric services. Up to 25-30% of cases of Inflammatory Bowel Disease (IBD) develop in young people prior to 18 years of age. Other specific groups eg people with Osteogenesis Imperfecta, Juvenile Arthritis, Liver disease, Thalassaemia, Cerebral Palsy and a number of other conditions requiring long term steroids will place young people at risk of bone disease. These young people may or may not have a diagnosis already of osteoporosis when transitioned to adult services. in view of the fact that adolescents with IBD will have more extensive and dynamic disease than adult IBD *(Van Limbergen J et al Gastroenterology 2008; 135: 1114-22),* then these are a high risk group of young adults for	Thank you for your detailed comment. We recognize the needs of this group of people, however, young people under 18 are outside of remit for this guideline. The guideline will look at steroid therapy in details, but will not be able to look at people under 18.

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				osteoporosis and special consideration should be given to their particular needs in this guideline *(Inflamm Bowel Dis. 2007 Jan;13(1):42-50.Natural history of bone metabolism and bone mineral density in children with inflammatory bowel disease.Sylvester FA, et al*).. Consideration of young people with specific chronic diseases may be pertinent also *(Health Technol Assess. 2008 Mar;12(3):iii-ix, xi-xiv, 1-208. A systematic review of the effectiveness of strategies for reducing fracture risk in children with juvenile idiopathic arthritis with additional data on long-term risk of fracture and cost of disease management. Thornton J, et al)* .	
SH	British Thoracic Society	16.00	3.1 a) & 4.4.1 b)	It is very important that in 3.1 (a) and 4.1.1(b) the use of glucocorticoids should distinguish ORAL from inhaled steroids. It may be that diagnosis (asthma vs COPD) may be important and duration of disease. Some measure of physical activity is likely to be relevant. It would also be useful to separate, as far as possible, different doses of inhaled steroid ie low, (medium if possible) and high. Duration of treatment is important- regular short bursts of prednisolone often used in airways disease (rather than maintenance therapy) with concurrent inhaled corticosteroids as well. Family history of osteoporosis, rather than just fracture, may be important in deciding who to screen (presumably the point of the exercise)	Thank you for your comment. We recognise the issues about route of administration and duration of treatment but this is too much detail for inclusion in the scope. Use of steroids will be considered by the GDG in detail and they will decide what the important factors to consider are. The list of risk factors is not exhaustive; the GDG will decide what the most important risk factors to investigate are.
SH	British Thoracic Society	16.01	4.1.1	Patients with interstitial lung disease (ILD) need to be specifically mentioned under the category of those on long term glucocorticoids.	Thank you for your comment. The guideline will seek to provide recommendations on simple measures that can indicate potential risk, and risk assessment measures. We will not be able to establish the association between

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					all possible risk factors and fragility fracture. Use of steroids will be considered by the GDG in detail and they will decide which other factors to prioritise.
SH	British Thoracic Society	16.02	4.1.1	Those who are going to be on a protracted course of oral corticosteroids do not need bone mineral density measurements before treatment to protect from bone mineral loss.	Thank you for your comment. Use of steroids will be considered by the GDG in detail and they will decide whether people using steroids need further assessment risk for fragility fracture or not.
SH	British Thoracic Society	16.03	4.3.1	COPD may well be an independent risk factor for fracture – regardless of steroid use (though steroids are also clearly important) – this is mainly because smoking, low BMI and low SES are all risk factors for osteoporosis and fracture. Concern that the long term steroid use risk factor section might focus mainly on rheumatoid arthritis – and there is an equally important case to be made for COPD – whether or not they are using long term steroids.	Thank you for your comment. The guideline will seek to provide recommendations on simple measures that can indicate potential risk, and risk assessment measures. We will not be able to establish the association between all possible risk factors and fragility fracture. Use of steroids will be considered by the GDG in detail and they will decide whether people with COPD need further assessment risk for fragility fracture or not.
SH	British Thoracic Society	16.04	4.3.1	Include: 1. the risk of osteoporosis from smoking (is this an independent risk) 2. the risk of osteoporosis from inactivity (often linked to disabling long term condition - eg COPD) 3. specific risk of inhaled corticosteroid and oral CS (to ensure that all not lumped in same boat and steroid fearful patients discontinue on low dose ICS if safe 4. the risk of osteoporosis and corticosteroid / azothioprine.... used in conjunction. 5. Do we need to investigate prior to treatment all people or is there a case to commence treatment if (for example on 10mg prednisolone or more daily for more than 3m). 6. to consider women of child bearing age on regular oral corticosteroids as a separate group, given the long half life of bisphosphonates and potential risks to the	Thank you for your comment. The guideline will seek to provide recommendations on simple measures that can indicate potential risk, and risk assessment measures. We will not be able to establish the association between all possible risk factors and fragility fracture. Use of steroids will be considered by the GDG in detail and they will decide whether to consider smoking and inactivity as independent risk factors.

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				developing foetus.	
SH	Department of Health	12.00		This organisation responded and said they had no comments to make.	Thank you for your comment.
SH	Hip Impact Protection Ltd	1.00	3.3 a)	Preventive treatment should include medical devices such as hip protectors and special impact absorbing flooring as these have and effect or hip fracture rates. These are apparently not to be discussed in the report, though such interventions can be at least as effective as any other in preventing hip fracture.	Thank you for your comment. Specific Interventions to prevent fracture are outside the remit of the guideline.
SH	Hip Impact Protection Ltd	1.01	4.3.1	Use of electronics to monitor patients' gait and alert carers/nurses to irregularities.	Thank you for your comment. People who fall frequently will be included in the guideline. Mechanisms to prevent falling and to alert people to those who are likely to fall will not be included.
SH	Hip Impact Protection Ltd	1.02	General	No mention of hip protectors, or other methods, in preventing fractures.	Thank you for your comment. The guideline is not addressing the prevention of fractures.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	2.00		This organisation responded and said they had no comments to make.	Thank you for your comment.
SH	Napp Pharmaceuticals	9.00	General	Napp has reviewed the content of the draft scope and welcomes the development of the SCG as described.	Thank you for your comment.
SH	National Osteoporosis Society / British Society for Rheumatology	19.00	General	The National Osteoporosis Society welcomes the development of a short clinical guideline on 'Osteoporosis: assessing the risk of fragility fracture'. We hope that this will provide a foundation for NICE to produce comprehensive guidance for the management of all patients with osteoporosis and/or at risk of fragility	Thank you for your comment.

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				fractures.	
SH	National Osteoporosis Society / British Society for Rheumatology	19.01	General	The National Osteoporosis Society is pleased to see that this guideline will not exclude any subset of people at risk. And that specific consideration will given to groups previous excluded for NICE guidance i.e. men and glucocorticoid users.	Thank you for your comment.
SH	National Osteoporosis Society / British Society for Rheumatology	19.02	3.1 c)	In addition to hands and feet we would suggest adding in fracture of the head (skull and face) as not generally being regarded as osteoporotic fragility fractures.	Thank you for your comment. The scope has been amended to reflect this.
SH	National Osteoporosis Society / British Society for Rheumatology	19.03	3.2 d)	The National Osteoporosis Society has recently published updated estimates of the cost of hip fracture. We would recommend using these figures • We currently estimate cost of treating and caring for hip fractures to be £ 2.3 billion in the UK • The cost of treating and caring for hip fractures in the UK could exceed £6billion by 2036 "National Osteoporosis Society 25th anniversary report – A fragile future" can be downloaded from http://www.nos.org.uk/page.aspx?pid=1130&srcid=1126	Thank you for your comment. The scope has been amended accordingly.
SH	National Osteoporosis Society / British Society for Rheumatology	19.04	3.2	The National Osteoporosis Society has recently published updated projections of the number of hip fractures. We would recommend using these figures • Projections show that on current trends, by 2036, there could be as many as 140,000 hospital admissions for hip fracture a year in the UK – this would be an increase of 57% on 2008 admissions. "National Osteoporosis Society 25th anniversary report –	Thank you for your comment. The scope has been amended accordingly.

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				A fragile future" can be downloaded from http://www.nos.org.uk/page.aspx?pid=1130&srcid=1126	
SH	National Osteoporosis Society / British Society for Rheumatology	19.05	3.3 b)	Some of the named risk scores are tools for predicting BMD, not fracture (for example OST, ORAI, OSIRIS and SCORE). These should be clearly distinguished from those algorithms that directly assess fracture probability.	Thank you for your comment and this information. The scope has been amended to reflect this.
SH	National Osteoporosis Society / British Society for Rheumatology	19.06	4.1.1	A further group which could merit specific consideration are those patients who are currently receiving osteoporosis treatment.	Thank you for your comment. People currently receiving treatment to prevent fragility fractures have now been included to the groups that will be covered.
SH	National Osteoporosis Society / British Society for Rheumatology	19.07	4.3.1	In some fracture risk assessment tools, BMD measurement is an optional criterion. However, the National Osteoporosis Society considers that for patients at an increased risk of fracture, a DXA scan is an important component of the decision to treat. Clear guidance on the role of DXA in fracture risk assessment is needed.	Thank you for your comment. The use of DXA scan in assessment of fragility fractures will be reviewed as part of the guideline.
SH	National Osteoporosis Society / British Society for Rheumatology	19.08	4.3.1	When assessing the role of DXA in fracture risk assessment it is important to consider the following benefits in addition to the BMD measurement obtained. • The presence of a prior vertebral fracture is an important independent risk factor. It is estimated that fewer than 30% of vertebral fractures are clinically diagnosed. Fan beam DXA scanners can acquire lateral images of the thoracolumbar spine allowing vertebral fracture assessment (VFA) which can give vital information on prior vertebral fractures. • A baseline DXA scan is essential if DXA is to be used to monitor response to treatment or monitor	Thank you for your comment and information. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment. The role of DXA in assessing the risk of fragility fracture will be established by the GDG.

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				change in individuals not taking treatment. There is also a role for DXA measurements in patients taking 'drug holidays' when considering when to resume treatment. Although not directly related to fracture risk assessment, it is an ideal opportunity to obtain baseline measurements that may otherwise be omitted.	
SH	National Osteoporosis Society / British Society for Rheumatology	19.09	4.3.1	The presence of a prior vertebral fracture is an important independent risk factor. Vertebral fractures can be diagnosed using lateral X-rays of the spine or vertebral fracture assessment (VFA).	Thank you for your comment. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment.
SH	National Osteoporosis Society / British Society for Rheumatology	19.10	4.4	However fracture risk is being calculated, the output needs to be meaningful and easily understood by heath professionals and the public. This is best characterised in terms of a persons absolute fracture risk over a defined time period. We would also welcome clear guidance on communication about risk assessment as seen in CG67 Lipid modification	Thank you for your comment. We recognise the complexity of understanding risk and will endeavour to provide recommendations on how results should be presented. Recommendations on risk communication (applicable generally to all healthcare contexts) will be covered by the 'Patient experience in generic terms' guideline, due for publication in October 2011. We aim to cross reference recommendations from that guideline into this one.
SH	National Osteoporosis Society / British Society for Rheumatology	19.11	4.4	We would suggest the addition of the following outcome "Ability to identify groups of patients who would benefit from effective anti-fracture treatment"	Thank you for your comment. We recognise that importance of this aspect of risk assessment and treatment but we cannot cover this in a short guideline.
SH	National Osteoporosis Society / British Society for Rheumatology	19.12	General	The National Osteoporosis Society's publication 'The Reporting of Dual Energy X-Ray Absorptiometry Scans in Adult Fracture Risk Assessment' contains information relevant to the development of this guideline. Including the use of BMD measurements in fracture risk assessment, FRAX, follow-up scans and a proposed structure for fracture risk assessment reporting. The	Thank you for your comment and information.

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				document is currently in press; please contact us if you would like copies.	
SH	NHS Direct	13.00	General	NHS Direct welcome the guideline and have no comments on the draft scope.	Thank you for your comment.
SH	NHS Wakefield District	14.00	General	Can the guideline provide clarity on when to refer for a DXA scan to confirm osteoporosis and gather information as to the impact on the number of DXA scans a population may need?	Thank you for your comment. The guideline will consider assessment of fragility fracture including use of DXA scans. The implementation team produce costing templates for each guideline which can allow costings per area/trust.
SH	Nottingham University Hospitals NHS Trust	3.00	3.3 b) & 4.3.1b)	We welcome the guidance on this topic from NICE and are pleased to see that NICE is issuing guidance on this topic and that QFracture is included in the risk assessment tools. The original research which described the development and validation of QFracture published in the BMJ in Nov 2009, identified some advantages of QFracture compared with FRAX. For example, QFracture - has a broader age range and bigger sample - has better characterisation or men - is base on UK data and ability to be able to update the algorithm as risk factors and populations change - it has additional predictors (including falls, HRT, asthma, type 2 diabetes, tricyclics) - more accurate and less likely to over predict c.f. with FRAX The independent validation of QFracture on an external dataset by Oxford University has now been published in the BMJ (June 2011) http://www.bmj.com/content/342/bmj.d3651.long This latest research confirms that QFracture has good discrimination and calibration both for predicting hip fracture and overall osteoporotic fracture in another very	Thank you for your comment and further information on QFracture.

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				large dataset from primary care. Qfracture has been made freely available as web calculator (www.qfracture.org) and as open source software which can be downloaded. This means that it is transparent, open to scrutiny and can be implemented reliably and consistently in clinical computer systems. To date, FRAX has not been published or made available for independent verification. Consequently, the Oxford team report in their paper that they were unable to an independent verification and validation of FRAX. Competing interests: JHC is the lead author of QFracture and director of ClinRisk Ltd which published the open source implementation of Qfracture.	
SH	Nutrition and Diet Resources UK	21.00	4.1.1 b)	Groups for special consideration should include young adults who have long term chronic conditions including physical disabilities For example people with learning and/or physical disabilities who are unable to weight bear and and spend long parts of their day in wheelchairs or in bed.	Thank you for your comment. The guideline will seek to provide recommendations on simple measures that can indicate potential risk, and risk assessment measures. We will not be able to establish the association between all possible risk factors and fragility fracture. The list of groups that will be covered is not exhaustive; it will be GDG decision whether people unable to weight bear need special consideration. People with disabilities are included in the equality form relative to the scope for this guideline.
SH	Nutrition and Diet Resources UK	21.01	General	It would be valuable to consider the role of diet in the prevention of osteoporosis.	Thank you for your comment. The guideline is not addressing the prevention of osteoporosis.
SH	Royal College of General Practitioners	15.00	General	NO new additions ,draft scope seems appropriate	Thank you for your comment.
SH	Royal College of Nursing	17.00	General	The Royal College of Nursing welcomes proposals to develop this guideline. It is timely. The draft scope	Thank you for your comment.

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				seems comprehensive.	
SH	Society and College of Radiographers	7.00	General	There is some concern as to the remit for the guideline. Limiting this to the 'risk assessment of people with osteoporosis' has ignored the prediction of fragility fracture in groups with risk factors not directly related to a diagnosis of osteoporosis, and the title/remit could be broadened to 'produce a clinical guideline on risk assessment to prevent fragility fracture'.	Thank you for your comment. The guideline will examine risk assessment of fragility fractures in people who do not have osteoporosis. NICE is currently looking into providing clarity in terms of the title.
SH	Society and College of Radiographers	7.01	4.3.2	Excludes risk assessment of people who have received treatment for cancer. It is felt that some guidance on risk assessment of this group would be valuable, notably for those receiving aromitase inhibitors or other drug treatments known to affect hormonal control of bone mineral density (BMD).	Thank you for your comment. People receiving treatment for breast and prostate cancer are included in the scope.
SH	Society and College of Radiographers	7.02	4.3.1.a)	A list of fracture risk assessment tools is given. The use of these tools in clinical practice and their relative 'user friendliness' and efficacy in predicting fracture risk needs consideration. Is any research currently available comparing these different tools? FRAX (World Health Organisation fracture risk assessment tool) appears to be the most widely used by clinicians at present. It is easy to use but has limitations: • Lack of refinement in questions relating to risk factors e.g. use of corticosteroids requires a 'yes/no' answer with no account taken for level or period of use. • Fracture risk is assessed only on the basis of femoral neck (NOF) BMD. This ignores the potential (and not infrequent) discrepancy in patients who exhibit greater BMD in their hips than in their spine.	Thank you for your comment and further information on FRAX. It is the aim of this guideline to establish efficacy of different assessment tools in predicting risk of fragility fracture.

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				• The FRAX tool used in the UK is based on a Caucasian database which may be inaccurate for other ethnic groups. • The FRAX model is constructed from population-based cohorts around the world that have a limited age range. Clinical judgment must be used to interpret results for patients aged below 40 years. A combination of different tools may enhance sensitivity and specificity and this warrants further investigation.	
SH	Society and College of Radiographers	7.03	General	Whilst it is acknowledged that universal screening for bone fragility by DXA (Dual Energy X-ray Absorptiometry) may be desirable, it is clearly impracticable on economic grounds. It is thought that the use of FRAX, or other screening tools, as a questionnaire to identify risk factors for low bone density, without DXA BMD scores, could be more widely employed as a screening tool to flag up patients with potential need for further diagnostic assessment.	Thank you for your comment. The GDG will consider risk assessment including tools that do not include measurement of BMD.
SH	Society and College of Radiographers	7.04	General	Although the National Osteoporosis Guideline Group (NOGG) guidance is widely used in clinical practice, treatment thresholds need clarification. Clarification is also needed to identify which potential fractures are preventable by lifestyle advice in addition to pharmacological treatments i.e. is assessment of falls risk more relevant to prevention of hip fracture than to vertebral fracture risk?	Thank you for your comment. This guideline is limited to considering risk assessment for fragility fracture and will not consider treatment.
SH	Society and College of Radiographers	7.05	4.1.1	We wonder if the group that use the Depo contraceptive should be included as these patients tend to have wide ranging T-Scores when scanned.	Thank you for your comment. The guideline is examining assessment for risk of fragility fracture. NICE guideline on "Long acting reversible contraception: the effective and

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					appropriate use of long-acting reversible contraception" methods reviewed the literature on the effects of progestogen-only injectable contraception on BMD. No studies were identified that evaluated fracture risk in current or past users of progestogen-only injectable contraception. Given the limited time available for this work and the need to prioritise subgroups we do not intend to repeat or update this review.
SH	Society and College of Radiographers	7.06	General	We have a view that the guidance document should include in its scope not just DXA but VFA (vertebral fracture assessment) by radiographs or DXA as a diagnostic tool.	Thank you for your comment and information. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment. The role of DXA in assessing the risk of fragility fracture will be established by the GDG.
SH	Society and College of Radiographers	7.07	4.3.1	We feel that lateral spine imaging (by radiograph or VFA on DXA machines) to confirm vertebral fractures is an important tool and would like to see it included.	Thank you for your comment. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment.
SH	Society and College of Radiographers	7.08	4.3.1 a)	Both radiographically detected and clinical vertebral fractures are associated with significant future fracture risk, morbidity, and mortality and some pharmacological agents have been shown to reduce future fracture risk in patients selected solely on the basis of radiographically detected vertebral fractures. Economic analyses with some of the available pharmacological treatments have shown that it is cost effective in many countries to treat older women with one or more radiographically detected vertebral fractures. These observations indicate that there are benefits to be had from improved detection of vertebral fracture. There is no consensus on the value of vertebral fracture assessment by radiograph or VFA on a bone densitometer. We are of the opinion that it could be included in 4.3.1 a)	Thank you for your comment and information. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment. The role of DXA in assessing the risk of fragility fracture will be established by the GDG.

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				in the risk assessment of fragility fracture guidelines. There are a plethora of studies that have documented the clinical and cost effective advantages of future fracture risk prediction in the prevention and treatment of osteoporosis and prevalent vertebral fracture is a strong predictor of future risk. Using the vertebral fracture assessment tool as an adjunct to DXA will provide more useful information and therefore diagnosis and treatment will encompass a more relevant group of the at risk population. Risk assessments based solely on BMD may overestimate the true risk of future fractures in patients without vertebral fractures and underestimate the true risk of future fractures in patients with vertebral fractures. Results from the European Prospective Osteoporosis Study suggests that the measurement of BMD alone may not be sufficiently predictive for determining who is most likely to suffer from an osteoporotic fracture. Biomechanical properties of bone, such as bone size, shape and its microarchitecture, are also associated with bone fragility but cannot be measured by BMD.	
SH	Society and College of Radiographers	7.09	General	VFA combined with bone mineral density assessment is a simple, patient friendly procedure that provides important additional information in a large proportion of patients at low cost. The method detects previously unknown vertebral fractures in nearly one out of each six patients. In similar populations, we therefore suggest that this method should be considered in every new patient that is referred for BMD assessment. The considered consensus is that any guidance to assess the risk of fragility fracture should incorporate into it a reference to the assessment of vertebral fracture by whatever means is available locally but should	Thank you for your comment and information. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment. The role of DXA in assessing the risk of fragility fracture will be established by the GDG.

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				encompass lateral spine radiography or vertebral fracture assessment using Bone Densitometers.	
SH	United Kingdom Clinical Pharmacy Association (UKCPA) / Royal Pharmaceutical Society of Great Britain	8.00	General	The UKCPA welcomes the development of a short clinical guideline on 'Osteoporosis: assessing the risk of fragility fracture'. We hope that this will provide a foundation for NICE to produce comprehensive guidance for the management of all patients with osteoporosis and/or at risk of fragility fractures, and allow pharmacy professionals to be an additional resource in supporting this patient group.	Thank you for your comment.
SH	United Kingdom Clinical Pharmacy Association (UKCPA) / Royal Pharmaceutical Society of Great Britain	8.01	3.1 a)	We would recommend the addition of diagnosis of osteopenia, in women in their peri-menopause and within 5 years of the postmenopause phase, based on central DEXA, to the other factors currently listed in the draft NICE scope as those considered to predispose to fragility fractures. Recommendation based on Compston JE. Clinical Endocrinology 1990;33:659-682	Thank you for your comment. The focus of the guideline is to establish whether a high risk of fragility fracture can be predicted even without using DEXA.
SH	United Kingdom Clinical Pharmacy Association (UKCPA) / Royal Pharmaceutical Society of Great Britain	8.02	3.2 d)	There are recently published updated estimates of the cost of hip fracture. We would recommend using these figures • Current estimate of cost of treating and caring for hip fractures is 2.3 billion in the UK • Cost of treating and caring for hip fractures in the UK could exceed £6billion by 2036 Ref: National Osteoporosis Society 25th anniversary report – A fragile future" http://www.nos.org.uk/page.aspx?pid=1130&srcid=1126	Thank you for your comment. The scope has been amended accordingly.
SH	United Kingdom Clinical	8.03	4.1.1	A further group that need specific consideration are patients who are currently receiving osteoporosis	Thank you for your comment. People currently receiving treatment for osteoporosis have now been included to the

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	Pharmacy Association (UKCPA) / Royal Pharmaceutical Society of Great Britain			treatments, with view to ensuring cost effective use, based on good compliance with medication taking, enhanced efficacy and reduction in medicines waste.	groups that will be covered. However, ensuring cost effective use, based on good compliance with medication taking, enhanced efficacy and reduction in medicines waste is outside the remit of this guideline.
SH	United Kingdom Clinical Pharmacy Association (UKCPA) / Royal Pharmaceutical Society of Great Britain	8.04	4.3.1	When assessing the role of DEXA in fracture risk assessment it is important to consider the following in addition to the BMD measurement obtained. • A baseline DEXA scan is essential if DEXA is to be used to monitor response to treatment or monitor change in individuals not taking treatment. • There is also a role for DXA measurements in patients taking 'drug holidays' when considering when to resume treatment. • The presence of a prior vertebral fracture is an important risk factor. It is estimated that fewer than 30% of vertebral fractures are clinically diagnosed.	Thank you for your comment. We will not be addressing monitoring of treatment. Previous fracture (including vertebral fracture) has now been added to the list of simple clinical measurements for risk assessment.
SH	United Kingdom Clinical Pharmacy Association (UKCPA) / Royal Pharmaceutical Society of Great Britain	8.05	4.4	However fracture risk is being calculated, the output needs to be meaningful and easily understood by heath professionals and the public. A percentage figure will not provide enough information. The output needs to relate an individual's percentage risk to: • the risk of the general population • the risk of a person of similar age and gender • is it high / medium / low ?	Thank you for your comment. We recognise the complexity of understanding risk and will endeavour to provide recommendations on how results should be presented.

These organisations were approached but did not respond:

A.Menarini Pharma UK SRL
Abbott (previously Solvay Healthcare Limited)
Abbott GmbH & Co KG
Abbott Laboratories Limited
Adults Strategy and Commissioning Unit
Age Concern Cymru
Age Concern England
Age UK
Airedale NHS Foundation Trust
All About Nocturnal Enuresis Team
All Wales Dietetic Advisory Committee
Alpro UK Ltd
Amgen UK Ltd
AMORE Studies Group
Anglesey Local Health Board
Arthritis and Musculoskeletal Alliance (ARMA)
Association for Clinical Biochemistry
Association of British Clinical Diabetologists (ABCD)
Association of British Health-Care Industries
Association of British Insurers (ABI)
Association of Clinical Biochemists, The
Association of Clinical Pathologists
Association of Dance Movement Psychotherapy UK
Association of the British Pharmaceuticals Industry (ABPI)
Autistic People Against Neuroleptic Abuse (APANA)
Barnet PCT
Barnsley Hospital NHS Foundation Trust
Barnsley PCT
Bayer Healthcare PLC
beat
BMJ
Boehringer Ingelheim Ltd
Bolton PCT
Bonesupport AB
Brighton and Sussex University Hospitals Trust
Britannia Pharmaceuticals Limited
British Association for Counselling and Psychotherapy
British Dental Health Foundation

British Dietetic Association
British Geriatrics Society-Special Interest Group in Diabetes
British Medical Association (BMA)
British Menopause Society
British National Formulary (BNF)
British Orthopaedic Association
British Pain Society
British Association of Oral and Maxillofacial Surgeons
British Psychological Society, The
British Society of Gastroenterology
British Society of Rehabilitation Medicine
British Society of Skeletal Radiology
Buckinghamshire PCT
BUPA
Calderdale PCT
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Camden Link
Cardiff and Vale NHS Trust
Care Quality Commission (CQC)
Care Uks Althea Park Specialist Services
Central Area of North Wales NHS Trust
Chartered Society of Physiotherapy (CSP)
Chesterfield PCT
Chiesi Ltd
City and Hackney Teaching PCT
Coeliac UK
College of Chiropractors
College of Occupational Therapists
Community District Nurses Association
Community Practitioners and Health Visitors Association
Connecting for Health
Conwy LHB
Conwy Local Health Board
Cook Medical
Co-operative Pharmacy Association
Cornwall & Isles of Scilly PCT
Countess of Chester Hospital NHS Foundation Trust
County Durham PCT

Craven Harrogate and Rural District PCT
Crohns in Childhood Research Association (CICRA)
Cytyc UK Limited
Daiichi Sankyo UK
David Lewis Centre, The
Department for Communities and Local Government
Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)
Department of Health, Social Services & Public Safety, Northern Ireland (DHSSPSNI)
Derbyshire County PCT
Derbyshire Mental Health Services NHS Trust
Doddmed Ltd
Doncaster PCT
Dorset PCT
Eating Disorders Association, The
Eaton Foundation
Elective Orthopaedic Centre, The
Eli Lilly and Company Ltd
Epilepsy Action
Equalities National Council
Faculty of Dental Surgery
Faculty of Family Planning and Reproductive Health Care
Faculty of Pain Medicine of the Royal College of Anaesthetists
Faculty of Public Health
Federation of Ophthalmic & Dispensing Opticians (FODO)
Fibroid Network Charity
Food Commission, The
Food Standards Agency
Galen Limited
GE Healthcare
Genzyme Therapeutics
George Elliot Hospital Trust
GlaxoSmithKline UK
Gloucestershire LINk
GP Care
Great Western Hospitals NHS Foundation Trust
Greater Manchester West Mental Health NHS Foundation Trust
Greater Peterborough PCT
Grunenthal UK Ltd

Guerbet Laboratories Ltd
Guys and St Thomas NHS Foundation Trust
Hammersmith and Fulham PCT
Hampshire Partnership NHS Foundation Trust
Hampshire PCT
Hayward Medical Communications
Healthcare Improvement Scotland
Healthcare Quality Improvement Partnership
Heart of England NHS Foundation Trust
Help the Aged
Herefordshire Primary Care Trust
Hertfordshire Partnership NHS Trust
Imaging Equipment Limited
Independent Healthcare Advisory Services
Insitute of Biomedical Science
Institute of Biomedical Science
Institute of Physics and Engineering in Medicine
Institute of Sport and Recreation Management
Janssen
Johnson & Johnson Medical
JRI Orthopaedics
Kensington and Chelsea PCT
Kimal Plc
koGEN Limited
Kyphon Europe
Kyphon UK
Lambeth Community Health
Leeds PCT
Liverpool Community Health
Liverpool PCT
Liverpool PCT Provider Services
Long-term Conditions Alliance
Lothian University Hospitals Trust
Luton & Dunstable Hospital NHS Foundation Trust
Maidstone and Tunbridge Wells NHS Trust
Manchester Community Health
Mansfield District PCT
Medtronic Ltd

Medway NHS Foundation Trust
Merck Sharp & Dohme Ltd
Mid Staffordshire General Hospitals NHS Trust
Ministry of Defence (MoD)
Move4Health
MRC Human Nutrition Research
National Council for Disabled People, Black, Minority and Ethnic Community (Equalities)
National Patient Safety Agency (NPSA)
National Pharmacy Association
National Rheumatoid Arthritis Society, The
National Treatment Agency for Substance Misuse
NETSCC, Health Technology Assessment
NeuroDiversity International(NDI)/NeuroDiversity Self-Advocacy Network(NESAN)
Newcastle PCT
NHS Bedfordshire
NHS Bradford & Airedale
NHS Clinical Knowledge Summaries Service (SCHIN)
NHS Derbyshire County
NHS Hertfordshire
NHS Isle of Wight
NHS Kirklees
NHS Milton Keynes
NHS Plus
NHS Sefton
NHS Sheffield
NHS Western Cheshire
Niger Delta University
Norfolk and Norwich University Hospital NHS Trust
North Birmingham Primary Care Trust
North Cumbria Acute Hospitals NHS Trust
North East Lincolnshire Care Trust Plus
North Eastern Derbyshire PCT
North Yorkshire and York PCT
Norwich Primary Care Trust
Novartis Pharmaceuticals UK Ltd
Nuffield Orthopaedic Centre NHS Trust
Nutricia Ltd (UK)
Nutrition Society

Nycomed UK Ltd
Patients Council
Pelvic Pain Support Network
PERIGON Healthcare Ltd
Pfizer Limited
Plymouth PCT
Poole and Bournemouth PCT
Poole Hospital NHS Trust
Powys Local Health Board
Primary Care Pharmacists' Association
Primary Care Rheumatology Society
Princess Alexandra Hospital NHS Trust
Proprietary Association of Great Britain (PAGB)
psc-support
Public Health Wales
QResearch
Relatives and Residents Association
Retreat, The
RioMed Ltd.
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust
Robinson Healthcare Ltd
Roche Diagnostics
Roche Products Limited
Rotherham NHS Foundation Trust
Rotherham Primary Care Trust
Royal Berkshire NHS Foundation Trust
Royal Brompton & Harefield NHS Foundation Trust
Royal College of Anaesthetists
Royal College of General Practitioners Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians Edinburgh
Royal College of Physicians London
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England

Royal liverpool and Broadgreen University Hospitals Trust
Royal National Hospital For Rheumatic Diseases
Royal National Orthopaedic Hospital NHS Trust
Royal Society of Medicine
Rupanyup Hospital/Nursing Home
Sacyl
Salford PCT
Sandwell PCT
Sanofi-Aventis
Schering Health Care Ltd
Scottish Clinical Biochemistry Managed Diagnostic Network
Scottish Dental Clinical Effectiveness Programme (SDCEP)
Scottish Intercollegiate Guidelines Network (SIGN)
Scottish Nutrition & Diet Resources Initiative
Scottish Oral Health Group
Servier Laboratories Ltd
Sheffield PCT
Sheffield Teaching Hospitals NHS Foundation Trust
Shire Pharmaceuticals Ltd
Social Care Institute for Excellence (SCIE)
Society and College of Radiographers
Society for Endocrinology
Society of British Neurological Surgeons
Society of Orthopaedic Medicine
Solent Healthcare
South Asian Health Foundation
South Essex Partnership NHS Foundation Trust
South Staffordshire Health Authority
South Staffordshire PCT
Spinal Injuries Association
St Helens Hospital
Staffordshire Moorlands PCT
Stockport PCT
Strakan Limited
Stryker UK Ltd
Surgical Dressing Manufacturers Association (SDMA)
Synthes Ltd
Tameside and Glossop Acute Trust

Teva UK Limited
Trafford Primary Care Trust
Trinity Pharmaceuticals Limited
UCB Pharma Ltd
UCLH NHS Foundation Trust
UK National Screening Committee
UK Specialised Services Public Health Network
UK Thalassaemia Society
United Lincolnshire Hospitals NHS Trust
University College London Hospitals (UCLH) Acute Trust
University Hospital Aintree
University Hospitals Birmingham NHS Foundation Trust
University of Nottingham
Walsall PCT
Warner Chilcott UK
Welsh Assembly Government
Welsh Endocrinology and Diabetes Society
Welsh Scientific Advisory Committee (WSAC)
West Hertfordshire PCT & East and North Hertfordshire PCT
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Whittington Hospital Trust
Wirral Hospital Acute Trust
Worcestershire PCT
Wyeth
York Teaching Hospital NHS Foundation Trust Wiltshire PCT