Osteoporosis – Scope Consultation Table - Stakeholders
10 February-10 March 2003

Organisation/Individual name	Comment	Response/Changes made by Guideline developers
Arthritis and musculoskeletal alliance (ARMA)	The British Society for Rheumatology (BSR) and the Arthritis and Musculoskeletal Alliance (ARMA) are pleased to work with NICE in developing a clinical guideline on osteoporosis. We have read and endorse the comments made by the National Osteoporosis Society on the draft scope. We would like to draw particular attention to general issues that NOS raise in their response because of the relevance it has to the musculoskeletal community. **General Comments:** • 4.1.2 b) We note the omission of primary prevention strategies and are concerned at this. For the guidelines to be comprehensive they should recognise the importance of prevention strategies such as information for the general public on prevention and specifically on the secondary causes of osteoporosis. Placing them outside the remit of the guidelines substantially limits the prevention strategy. • 4.3 The scope of the guidance does not fully reflect the patient-centred approach to management of osteoporosis. Management of osteoporosis should include non-pharmaceutical interventions including strategies to help patients cope with pain and disability, such as hydrotherapy, physiotherapy, hip protectors, pain management and self-management; and should encompass information provided to patients.	The title of the guideline has been amended to reflect the content of the scope. That is, to clarify that the guideline is addressing individuals at high risk of the condition. Information on prevention for osteoporosis patients will be considered in the section on non-pharmacological interventions. This point is referred to NICE. As stated above, several of these aspects will be covered in the non-pharmacological interventions section. However the scope does not cover a comprehensive examination of post-fracture management. This point is referred to NICE. With regard to hip protectors this is being looked at in the Falls guideline, which we will cross-refer to.

	Specific clinical points:	
	• 4.1.1 c) It would be useful if the definition of a fragility fracture was stated more explicitly.	Thank you. This has now been clarified in the scope.
	• 4.1.1. d) We recommend that the guidelines specify men and women receiving oral corticosteroids in any dose for a consecutive period of three months or greater.	Noted. Specific details regarding doses, time used etc. will be given in the full guideline after examining the evidence.
	• 4.1.1. e) Like NOS we think it would be appropriate to include rheumatoid arthritis as a secondary cause.	Thank you. This has been added.
	• 4.1.1 e) We wonder if this should read hypercorticism rather than hypercortisolism?	Further clarification required from stakeholder here. No other medical experts have commented on this.
	• 4.1.1. f) Premature menopause should include secondary amenorrhoea as a result of excessive exercise.	Thank you. This has been added.
	• 4.1.1. h) We recommend that the guidelines specify maternal history of hip fracture in particular and other fragility fractures in general. *(The evidence is best for a maternal history of hip fracture - Study of Fracture New England Journal of Medicine 1995)*	Noted with thanks.
	• 4.3.a) We would emphasise that biochemical markers of bone turnover are more useful in monitoring response to treatment rather than in predicting those at risk of fracture.	Noted with thanks. The GDG will be reviewing the evidence for this.
	• 4.3.a) Under Bone mineral density specify DXA at hip and spine then go on to say QCT, QUS and peripheral DXA will be considered.	Thank you. This amendment has been made.
	• Routine vertebral morphometry can be carried out through DXA in those undergoing bone density measurements by this means. It would be sensible in terms of cost and lower doses of radiation if this mechanism was employed routinely. We acknowledge that not all DXA scanners have such a software package but this perhaps should	Further clarification is required from stakeholder. Perhaps more information can be provided during the evidence submission process for consideration by the GDG. This point is referred to NICE.

	DXA scanners have such a software package but this perhaps should be considered by NICE. Moreover, this point should be cross-referenced with the Clinical Standards Advisory Group recommendations on the management of back pain; those guidelines should be amended so as not to deter referral for plain X-ray of the spine; a suggestion is that acute back pain occurring in men or women age 50 or over warrants a routine X-ray. We hope you find this feedback useful. Please do not hesitate to contact us for further information. We are looking forward to working with you on the osteoporosis guidelines.	Thank you for your helpful comments.
Association of the British Pharmaceuticals Industry (ABPI)	No comment	
Aventis Pharma	Thank you for the opportunity to make comments on the scope for the NICE guidelines for the prevention, assessment and treatment of osteoporosis and osteoporotic fracture. Overall, The Alliance for Better Bone Health (Aventis Pharma and Procter & Gamble Pharmaceuticals) welcomes the development of these guidelines on the basis of the current scope. We believe the challenge for NICE will be to ensure that these guidelines are integrated with the NICE falls guidelines to provide the NHS with guidance that can be implemented locally to meet the standards set out in standard 6 of the NSF for Older People. It is unfortunate that the proposed publication of the osteoporosis guidelines, in 2005, comes at a time when the NSF for Older People expects PCTs to have already established an integrated falls service that includes the assessment and treatment of osteoporosis. Clearly, the timelines set out in the NSF and the delay between the publication of NICE's falls guidelines and those on osteoporosis, will mean that PCTs will not be able to draw on complete NICE guidance as they attempt to an integrated falls and osteoporosis	Thank you. Noted and referred to NICE. The guideline developers are working closely with the developers for the Falls guideline to ensure cross-reference is made.

	service. We therefore recommend that the NICE falls guidelines stress the importance of retaining flexibility in the development of local services in order to be able to accommodate the guidance from the osteoporosis guidelines.	
	The NICE osteoporosis guidelines are not the first national guidelines to address osteoporosis. Indeed there are numerous national guidelines for the management of osteoporosis aimed at both primary and secondary care e.g. Royal College of Physicians Guidelines and the Primary Care Rheumatology Guidelines. Despite these excellent evidenced based guidelines the implementation of the guidelines throughout the NHS remains woefully poor. A recent survey by the International Osteoporosis Foundation estimated that only 10-20% of women in the UK with osteoporosis actually receive treatment for their condition. A weakness of many of the current guidelines has been the lack of clear, auditable clinical standards. The RCP Clinical Effectiveness and Evaluation Unit are addressing this issue for the RCP Glucocorticoid Induced Osteoporosis through the development of a dedicated audit tool. We hope that the NICE guidelines will set clear clinical standards and provide dedicated audit support to allow physicians to track the implementation of these standards at a local level.	Thank you for this point. As with all the NICE clinical guidelines audit criteria will be included to enable implementation in clinical practice.
	Below we provide detailed comments on the scope:	
	1. Guideline Title - The current title is misleading as it could be read to include the orthopaedic management of osteoporotic fractures. We believe that a clearer title could be: Assessment of osteoporosis and the prevention of osteoporotic fractures.	Agreed. The title of the guideline has been altered to better reflect its content.
	4.1.1 Groups that will be covered - No reference is made of assessing fallers as a group. A group at particularly high-risk of fracture is older people with a history of falling who also have osteoporosis. In excess of 95% of all hip fractures in older people occur as the result of a fall. However, only 1% of falls result in a hip fracture. The missing link is osteoporosis. Over 90% of all hip fractures in the over 75s occur	Thank you for this comment. We agree this is an important group at high risk. This is part of the Falls guideline currently under way and its findings will be cross-referenced to the osteoporosis guideline.

	in people who have osteoporosis. It is therefore critical that all fallers are thoroughly assessed for osteoporosis and all elderly patients with osteoporosis are assessed for risk of falling. We believe the NICE guidelines should make recommendations for the appropriate osteoporosis assessment in individuals who have a history of falling.	
	4.1.2 Groups/clinical aspects that will not be covered - It would be helpful if NICE would clarify the definitions of "population-wide primary prevention strategies" and "mass screening strategies".	Agreed. These have been clarified by giving examples within the scope and also by the amended title now reflecting that the guideline will be directed at high-risk individuals.
	4.3 Assessment of fracture risk - Assessment of bone mineral density by DXA should include peripheral as well as central DXA.	Thank you. This amendment has been made.
	4.4 Audit support within guidelines - As mentioned earlier, we hope that NICE will produce both clear clinical standards and appropriate audit tools to monitor the implementation of these standards. Furthermore, as the NSF for Older People requires the development of an integrated falls and osteoporosis service, it would be beneficial to produce an audit tool for osteoporosis that could be used in conjunction with the audit tool for falls.	Thank you. As previously stated, audit criteria will be included and we will work closely with the Falls guideline developers in this area.
	Please do not hesitate to contact us should require any further information. On behalf of the Alliance for Better Bone Health.	Thank you for your comments.
Bone and Tooth Society	Comments on draft scope for NICE guidelines on osteoporosis on behalf of the Bone and Tooth Society of Great Britain, The British Society of Gastroenterology and the Royal College of Physicians (London). 1. Title: The assessment of fracture risk is an important part of these guidelines and should be given more prominence in the title. The use of	Agreed. The title has been changed to better reflect the scope of the guideline.

	the words prevention, treatment, osteoporosis and osteoporotic fractures in the title is confusing – the aim of intervention is the prevention of osteoporotic fractures. A clearer title might be “Assessment of fracture risk and the prevention of osteoporotic fractures”.	
	4.1 Population: Groups 4a), b) and c) describe populations in whom a diagnosis of osteoporosis has already been made (with the exception of subjects with radiological evidence of osteopenia) and who would normally be considered for pharmacological intervention. The remaining categories describe populations in whom risk factors are present and in whom assessment of fracture risk is required (usually including bone densitometry). It would be better to distinguish between these two types of population.	Noted. This level of detail will be described in the full guideline and this comment will be referred to the GDG.
	Gastrointestinal disorders may lead to osteoporosis in the absence of chronic malabsorption, for example in inflammatory bowel disease. It would therefore be preferable to omit the words “resulting in chronic malabsorption”.	Thank you for this comment. This section has been clarified.
	4.1.2 Groups/clinical aspects that will not be covered: The section under a). is blank.	Thank you. Many stakeholders informed us of this formatting error which has now been corrected. Please note no content is missing.
	4.3 Clinical management: Consideration should be given to the inclusion of genetic markers in the prediction of fracture risk.	Thank you for this suggestion. This will be referred to the GDG to consider when it meets to clarify the final clinical questions.
	The diagnosis of vertebral fractures should be included in this section, in particular the indications for spinal X-rays and the reporting of vertebral fractures by radiologists (the latter has been shown to be seriously inadequate and therefore results in missed diagnoses).	Again thank you for highlighting this point. It will be referred to the GDG for consideration.
	The monitoring of treatment by bone densitometry or biochemical markers of bone turnover should be included in the guidelines.	The draft scope did not include treatment monitoring, largely because expert opinion suggested there is

		currently a lack of evidence. However this question will be referred to the GDG to make a decision on whether its inclusion is justified.
	The duration of therapy should be considered in the guidelines.	Thank you for identifying this point. This aspect will be incorporated in the evidence on interventions. Recommendations will be made where adequate evidence is identified to guide practice.
British Dental Health Foundation	I have no problems with the scope - our interest in the guideline resulted from any possibility of consideration of the role of fluoride. It does not appear that this is on the agenda. If this is not added at this stage I do not think we need to be further involved in this consultation.	Noted with thanks.
British Dietetic Association	Thank you for giving us the opportunity to comment on the above treatment guideline. The document was reviewed on behalf of the BDA. Additionally, a list of relevant references that were not included in the draft consultation document have been identified and are included at the end of the comments section. *BDA stakeholder response to the NICE Osteoporosis Scope Consultation, March 2003* Osteoporosis is a slowly progressing disease, and one with devastating financial and physical consequences for the patient and the health care provider alike. Many earlier guidelines on the prevention of osteoporosis (including the COMA report on Diet and Bone Health) have strongly promoted preventative strategies in the first 30 years of life - such as diet and lifestyle factors - as a means of arresting its progression. It is somewhat disconcerting to find that the remit of the NICE Osteoporosis	Thank you for these. Noted. As previously responded to other stakeholders comments, the remit for this guideline is to address prevention of osteoporotic fractures in high-risk groups. Your comments regarding the role of health promotion in primary prevention of osteoporosis are

	guidelines are for the management subjects perceived to be at the far end of the osteoporosis risk spectrum. The BDA considers this a limited approach, and request that NICE consider inclusion of other agencies such as the Food Standards Agency, the NHS, and Dept of Education to develop and support a concerted campaign of health promotion to reduce osteoporosis risk.	referred to NICE.
	Section 4.1. Population	
	The BDA supports the scope of the guidelines covered to include those subjects considered at risk under this section ie those at risk of developing or with pre-existing osteoporosis. The scope should be extended to include the diagnosis and management of osteoporosis risk and fractures in the following groups considered to be at high risk: 4.1.1 (e) *clinical conditions that may adversely influence BMD* i) Cancer patients +/- cachexia; influence of radiotherapy and chemotherapy on bone density/ bone turnover ii) Chronic renal failure iii) Transplant recipients iv) Diabetes v) Coeliac disease*	Thank you for highlighting these groups. Coeliac disease, transplant recipients and chronic renal failure have been added to the list of named groups. In order not to provide an unnecessarily long list in the scope we have stated that no high-risk groups will be excluded. Greater detail of other groups will be provided in the full guideline.
	* Coeliac disease is associated with an increased risk of osteoporosis. Controversy exists as to whether the calcium needs of the coeliac individual are higher than that of the average population, or whether osteoporosis merely reflects poor dietary compliance to this rigorously restrictive diet. Calcium supplementation of gluten free foods accorded ACBS status is variable. There is a need for clarification of calcium requirement in the coeliac subject.	Noted with thanks.
	4.1.1(h) *influence of lifecycle on BMD* Advancing age, maternal history of osteoporotic fracture, low body weight (< 127lbs / 58 kg) and a low body mass index (<20 kg/m^2) are all	Agreed. These factors are listed in the scope as risk factors that will be

	positively associated with an increased risk of fracture. <u>Other groups considered at risk of increased fracture also include:</u> i) *institutionalised individuals without outside access*: long term immobile hospital patients (e.g. post fracture repair, post CVA); nursing and other residential care home residents; the housebound (including agoraphobics). ii) *lack of skin exposure to UV light*: secondary to ethnic or religious consideration, particularly in dark skinned or veiled women; prolonged and frequent use of high factor sunblock (> factor 25). iii) *nutritional compromise*: primary or secondary lactase deficiency manifesting as lactose intolerance; coeliac disease; chronic anaemia (especially pernicious anaemia); perceived or diagnosed multiple food allergies; pre-existing protein-energy malnutrition presenting in hospitalised patients; inadequate calcium and/ or vitamin D provision during periods of rapid bone growth, eg toddlers, adolescence iv) *Compromised physical function*: low exercise threshold, inability to weight bear secondary to other conditions eg OA knee; inability to feed independently, for example post-CVA; progressive neurological conditions eg MS, MND; postural hypotension secondary to dehydration as a risk factor for falls. The BDA consider the role of the multi-disciplinary team, including dietitian, occupational therapist, speech and language therapist, and physiotherapist core providers in optimising management of the above at-risk clients. 4.2 (c) healthcare setting The BDA accept that the concept of a national food and health policy for the prevention of osteoporosis is outside the remit and scope of this report. Nevertheless, the level of evidence supporting lifestyle and dietary measures as short and long term moderators of osteoporosis risk and	assessed. Thank you for identifying these groups. As previously stated, it is not within the purpose of the scope to provide this level of detail. This list will be referred to the GDG to consider and the evidence referring to these will be covered in the full guideline. We have stated that no groups considered to be at high risk will be overlooked. We agree a multidisciplinary approach is necessary for osteoporosis and consequently the GDG is made up of a broad range of healthcare professionals and patients. This suggestion is noted and will be referred to the GDG.

	progression cannot be dismissed. The BDA suggest that targeted public health measures to high risk groups are feasible within the remit, and that a multi-agency approach could be considered. <u>Groups containing high risk populations by virtue of age or health include:</u> i) residential and nursing homes with a large proportion of people >60y ii) community and day centres for the frail elderly and/ or ethnic elderly iii) Sure Start community projects iv) primary and first schools not adopting subsidised or free school milk schemes v) hospital patients, particularly those with reduced mobility secondary to fractures, arthritis and stroke, or global malnutrition 4.3 (a) assessment of fracture risk Direct measurement of BMD remains the gold standard, despite lack of widespread availability and access for mass population screening. Radiological methods give limited interpretation in the presence of clinical conditions such as osteoarthritis, gross obesity or ascites. The use of validated nutritional screening tools to identify protein-calorie malnutrition risk is well established in clinical and community dietetic practice. The BDA recommend NICE consider the feasibility of a primary care screening tool as a potentially cost-effective way of selecting at high risk individuals who would benefit from direct BMD measurement in the community. Predictive factors to be considered could include nutritional intake; current BMI and weight history; concurrent high-risk social and medical conditions; and frequency and duration of weight bearing activity. 4.3 (b) Interventions *Pharmacological interventions:* dietary intake should be considered an adjunct to pharmacological intervention in the prevention and	Thank you for identifying these groups. Noted. We will be assessing the utility of various technologies for their ability to predict fracture as outlined in the scope document. We are not assessing their diagnostic abilities. The guideline will be examining various methods of identifying individuals at high risk after reviewing the evidence. Thank you for highlighting this point. The GDG will consider whether any

	management of osteoporosis. There is evidence from supporting drug literature (eg the *BNF*) that diet may augment or hinder the bioavailability and/ or efficacy of drugs used to halt or treat osteoporosis. Selective dietary recommendations and/ or the use of nutritional supplements could theoretically improve the effectiveness of drug therapy. The BDA request guidance on this for its members.	guidance can be issued on this point after examining the evidence available from pharmacological intervention studies.
	Non-pharmacological interventions: Dietary adequacy and weight bearing physical exercise are the cornerstones of osteoporosis prevention. The importance of these two lifestyle factors should not be undermined, as they not only reduce osteoporosis risk, but also CHD risk as well. The BDA believe that dietary adequacy should be given a status similar to fall prevention in the management of osteoporosis.	We agree that these non-pharmacological factors are important for individuals at risk of osteoporotic fracture. The GDG will review the evidence relating to these.
	<u>The role of nutritional supplementation requires clarification, in particular:</u> i) The amount of calcium supplementation to optimise bone restoration in osteoporosis, and the influence (if any) of calcium uptake inhibitors such as dietary oxalates and phytates. ii) Recommendation of supplementary calcium and vitamin D to all hospitalised patients iii) The role of protein-energy nutritional supplements to patients with fracture presenting with low BMI iv) The need for, and dose of calcium required, with concurrent HRT v) The potential for calcium supplements to reduce bioavailability of other minerals eg iron, which could predispose to anaemia and early fatigue, curtailing stamina for weight bearing activity. vi) The role of other nutrients in the prevention and management of osteoporosis eg. Vitamin K, vitamin B12, boron vii) The potentially antagonistic influence of nutrients on bone density eg vitamin A supplementation viii) The role of long term vitamin D supplementation to high risk groups, and frequency of administration (daily intakes versus quarterly supplements)	Thank you for identifying these points requiring clarification. Again these will be presented to the GDG during the development of the clinical questions for the guideline.

	Guidelines In addition to the NICE report, the BDA request that resources should be made available to the public to increase awareness of diet and lifestyle in preventing osteoporosis. Public information could be made available through a number of routes: The British Dietetic Association NHS Direct Department of Health Department of Social Services NeLH Food Standards Agency The Dairy Council Supporting references: Bianchi ML, Bardella MT (2002). Bone and celiac disease. Calcif Tissue Int 71(6):465-71 Brown JP, Josse RG (2002). Scientific Advisory Council of the Osteoporosis Society of Canada. 2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. CMAJ 167(10 Suppl):S1-34 Brunner LC et al (2003). Hip fractures in adults. Am Fam Physician 67(3):537-42 Delmas PD (2001). Osteoporosis in patients with organ transplants: a neglected problem. Lancet 357(9253):325-6 Dhonukshe-Rutten RA, et al (2003). Vitamin B-12 status is associated with bone mineral content and bone mineral density in frail elderly women but not in men. J Nutr 133(3):801-7 Di Stefano M, et al (2002). Lactose malabsorption and intolerance and	Thank you for this useful information. In the version of the guideline written for the public reference will be made to these sources of information for the public on preventing osteoporosis. Thank you for these useful references.

	peak bone mass. Gastroenterology 122(7):1793-9 3. Feskanich D, et al (2003). Calcium, vitamin D, milk consumption, and hip fractures: a prospective study among postmenopausal women. Am J Clin Nutr 77(2):504-11 Freeman R et al (2001). Addressing children's oral health inequalities in Northern Ireland: a research-practice-community partnership initiative. Public Health Rep 116(6):617-25 Fuller KE, Casparian JM (2001). Vitamin D: balancing cutaneous and systemic considerations. South Med J 94(1):58-64 Hauselmann HJ, Rizzoli R (2003). A comprehensive review of treatments for postmenopausal osteoporosis. Osteoporos Int 14(1):2-12 Kirchgatterer A et al (2002). Examination, prevention and treatment of osteoporosis in patients with inflammatory bowel disease: recommendations and reality. Acta Med Austriaca 29(4):120-3 Oliveri B, et al (1996). Vitamin D prophylaxis in children with a single dose of 150,000 IU of vitamin D. Eur J Clin Nutr 50:807–10 Trivedi DP, Doll R, Khaw KT (2003). Effect of four monthly oral vitamin D3 (cholecalciferol) supplementation on fractures and mortality in men and women living in the community: randomised double blind controlled trial. BMJ 326(7387): 469 Nowson CA, Margerison C (2002). Vitamin D intake and vitamin D status of Australians. Med J Aust 177(3):149-52	
British Geriatrics Society	The scope is reasonable. We would like make the following minor comments and suggestions: 1. The qualitative definition of osteoporosis used in section 3a on page 2 has recently been replaced by one less dependent on low bone mass. The NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy has defined osteoporosis as a skeletal disorder	Thank you. Thank you this is noted. The introductory paragraph now provides an additional simpler definition for osteoporosis at the suggestion of

	characterised by compromised bone strength, predisposing a person to an increased risk of fracture (JAMA 2001; 285: 785-795).	another stakeholder.
	The concept of "risk of fracture" by incorporating skeletal and non-skeletal factors other than BMD is important and should be included in the scope	Agreed. Identification of individuals who will benefit from intervention will be as a result of a combination of risk factors both skeletal and non-skeletal as outlined in the scope.
	2. The risk of fracture is indeed determined by bone mineral density (BMD), other skeletal factors and non-skeletal factors (section 3c, pages 2-3). It is misleading, however, to imply that BMD is the only skeletal risk factor that can be measured, as the biochemical markers of bone turnover, hip axis length and femoral neck shaft angle have all been shown to predict fracture risk independently of BMD. Nevertheless, the optimal use of these different factors in fracture risk assessment in clinical practice remains unclear.	Thank you for highlighting this. The paragraph has been amended to clarify this.
	There is a great opportunity to include other diagnostic techniques such as markers and the subject of peripheral densitometry and ultrasound. The reality is that these techniques are being used out there in the real world, sometimes appropriately but sometimes inappropriately and some guidance would be useful.	Noted. The evidence relating to the utility of these various methods for predicting fracture will be examined by the GDG.
	3. I note that no exclusive recommendations will be made about practice in residential and nursing homes (section 4c, page 5), but it is important to appreciate that care home residents are at 2.3-3.6 fold higher risk of fracture than community-dwelling older people (Johansen et al, Int J *Consumer & Product Safety* 1999; 6: 215-221). Furthermore, vitamin D deficiency and secondary hyperparathyroidism is common in this group, which can be corrected by calcium and vitamin D supplementation. This has been shown to improve BMD, decrease the risk of falls and reduce the incidence of hip and other non-vertebral fractures (Chapuy MC et al, *N Engl J Med* 1992; 327: 1637-1642; Pfeifer et al, *J Bone Miner Res* 2000; 15: 1113-1118). There are few studies of other osteoporosis treatments in elderly care home residents, who are more physically and mentally frail than older people living in the community. Nevertheless, a	Thank you for this point. NICE guidelines do cover care in NHS residential and nursing homes. This population will be considered by this guideline and also cross-reference will be made to the Falls guideline examining evidence in this population.

	recent study in 327 women (aged 65-91 years) with osteoporosis living in long-term care facilities showed that alendronate significantly increased BMD at the lumbar spine and hip compared with the placebo treated group (Greenspan et al, *Ann Intern Med* 2002; 136: 742-746). There were also fewer fractures in the group receiving alendronate (8%) than in the placebo group (11%), although this was not statistically significant, as the study was not powered to examine fracture incidence. We are glad that cross-referring to the NICE Falls guidelines is included (which will also cover the hip protector issue). Indeed we would like to urge that the osteoporosis guideline development group liaise very closely with the falls guideline development group at an early stage. If not there may be a danger that some important topics may be left between two stools. For example, there is evidence coming through that Vitamin D may work in reducing hip fractures not only by any action on bone, but by being able to improve neuromuscular function and reducing falls. This aspect should be included in the literature search by one of the two guideline development groups. 4. The title includes treatment of osteoporotic fractures which theoretically could mean the orthopedic treatment of fracture. We do not think that it is intended to include the latter, but it does need clarifying in the title or included in the groups "not to be covered".	As stated above we will liaise closely with the Falls GDG to ensure no area is left uncovered. The two guidelines are being produced within the same collaborating centre. Thank you for highlighting the double effect of Vitamin D. Agreed and in response to comments from several stakeholders the title has now been changed to reflect more closely the content of the scope.
British Menopause Society	I attended the stakeholders meeting on Wednesday, 5th March 2003 on behalf of RCOG and am the named contact for BMS. The comments are as follows : Section: 4.1.1 Topic – Groups to be covered Comments: 1. Differentiate between ‘good’ and ‘bad’ steroids and steroid doses 2. Patients with a strong family history of osteoporosis to be included. Section: 4.2 b	Thank you. This will be referred to the GDG and fuller details of steroids given in the full guideline. This is now included.

	Topic: Healthcare setting Comments: To stress the importance of collaboration between primary & secondary healthcare sectors and to look at ways to facilitate this e.g. role of outreach nurse programmes, (based on specialist units) the specialist menopause pharmacist role; the place for medication management clinics; supervised prescribing by specialist nurse & pharmacist. Section: 4.3 b Topic: Under non-pharmalogical interventions Comments: Add phyto-oestrogens as many women drift towards alternative approaches and need clear guidance if there is insufficient data to support usage. Add natural progesterone cream (see above). Add occupational therapy / life style interventions. CONSIDER ECONOMIC IMPACT OF INTERVENTIONS Clinical questions to pose :- 1) Positioning of adequate bone densistometry fairly across the UK to allow access. 2) Can we consider 2 tier screening process? i.e. calcaneal, ultrasonography or calcaneal DEXA initially to identify those patients to go on to formal spine & hip DEXA 3) Are there any grounds to consider biochemical indices of bone turnover as a primary screening tool? 4) How far are we away from having a reliable clinical risk score for use in primary care?	Agreed. The multidisciplinary GDG will be examining service provision collaboration between sectors throughout the guideline development process. This will also refer to the NSF for Older People. These additions will be referred to the GDG for inclusion during the setting of the clinical questions. Some dietary and physical activity lifestyle factors are already included. The economic impact of interventions is considered by expert health economists who are part of the multidisciplinary GDG for all NICE guidelines. (See 2a in the scope) Thank you for your suggestions for clinical questions. The GDG meets to set clinical questions for the guideline in the early stages of development. Your suggestions will be referred to the group for consideration.
British National Formulary (*BNF*)	Comments written on document received – forwarded to NCC	Thank you for your helpful suggestions. Many of these were taken up to help improve the readability of the document.
British Orthopaedic	In general we are very supportive of this initiative. However we would	Thank you.

Association	make two points: 1. Whilst it is clear, from the original referral in appendix 1, that the guideline is about prevention of osteoporotic fracture by treatment of the underlying osteoporosis, the guideline title and several other references in the text (2a, 4.3) state that it covers the *treatment of osteoporotic fractures*. This it does not do, according to the scope outlined. We would be extremely concerned that the successful completion of this exercise would be perceived by politicians as having 'dealt with' the problem of osteoporotic fractures. a. Treatment of osteoporotic fractures is a surgical issue. It is very problematic, due to the unfavourable mechanical properties of osteoporotic bone. Improved methods are under development, including better fixation devices and the use of locally-implanted pharmacological adjuvant therapies. b. Prevention of the appalling mortality and morbidity following osteoporotic fractures depends on integrated systems of care that combine the skills of orthopaedic and geriatric doctors, nurses and other staff. Such systems are grossly under-provided and huge investment is needed in this area. 2. The key area of secondary prevention – that is the diagnosis and treatment of osteoporosis in patients who present with their first fracture, with a view to preventing further fractures – is rightly included and will form a major component of our response to the epidemic. a. Much thought is needed to define the best system for surveillance *in fracture units* and setting in motion the appropriate therapeutic response. The BOA and NOS are collaborating on a document to address this. b. It is not certain that the BMD assessment methods listed in 4.3(a) will be realistic in the fracture clinic setting. If nothing else they are unlikely to produce a result quickly enough for the information about bone material properties to be utilised by the surgeon in making a decision about treatment of the fracture. More rapid methods based on radiographic absorptiometry are under evaluation in Belfast, Edinburgh and	Agreed. The title of the guideline has now been amended to better reflect the content of the scope. Post-fracture management is not within the remit. This has been referred to NICE. Agreed. Thank you for informing us of this work. We would invite more detail during the submission of evidence process. Noted. This will be referred to the GDG to consider.

	Middlesborough and should be included.	
British Society for Rheumatology	See joint comment with the Arthritis and musculoskeletal alliance (ARMA).	
British Society of Gastroenterology	See joint comments under Bone and tooth society.	
British Society of Rehabilitation Medicine	I have been asked by the British Society of Rehabilitation Medicine to comment on the SCOPE consultation on osteoporosis document. One of the high risk groups of patients which might be considered under 4.1.1 (i) are patients who have become immobile due to spinal paralysis from various causes, traumatic and non-traumatic. In regard to these patients it may be that during the next few years pharmacological approaches using neuro-spinal drugs which might maintain neuro-function which inhibits osteoporosis may be significant. Thus, pharmacology other than Bisphosphonates and analogues might be of significance in the eventual guidance. Some of the research in regard to exercise therapy and maintenance of mobility is carried out on the above patients in a controlled environment and hence significant positive or negative responses in these groups may also be of significance.	Thank you for identifying this group. We agree this is an important group and an addition has been made to the list of groups covered to reflect this. Noted. This will be taken into account by the GDG when considering non-pharmacological interventions.
BUPA	Thank you for the opportunity to comment on this 'Scope'. I am doing so on behalf of BUPA. It tackles the topic admirably. There was one area on which it seemed ambiguous: the question of whether or not the work would cover imaging to confirm the diagnosis in asymptomatic people apparently at high risk of the disease. The people in groups (a) to (g) in section 4.1.1 are apparently being treated for some pathology, as may be those in (h) & (i). Could the wording of (h) be changed to something like 'Men and women whose bones have not been subject to investigation and who are not being investigated or treated for pathologies associated with osteoporosis, but who are exposed to the risk factors for osteoporosis, for instance advancing age, maternal history of osteoporotic fracture, low body mass index.'?	Noted with thanks. Thank you for this comment. We did not want to overcomplicate the description of those at high risk within the scope document. We believe we have clarified that all those at risk of the condition will be considered within points h) and i). This would include those situations you describe.

	We appreciate the point being made in (c) under 4.2, but feel that there is little that would be completely exclusive to services outside the NHS, and that it would be desirable for the health of the population if this document were clearly to set expectations about good bone health (so healthcare, diet and exercise) in care homes.	Noted. Thank you for this point. NICE guidelines cover care in NHS residential and nursing homes. This population will be considered by this guideline and also cross-reference will be made to the Falls guideline examining evidence in this population. Any recommendations may be applicable to other settings.
Chartered Society of Physiotherapy	This response is set out using terms and numbering derived from the draft scope for the guideline. Response The development for clinical guidelines on the prevention, assessment, and treatment of osteoporosis and osteoporotic fractures is very welcome. Page 4 4.1.1 f. This should also include women who do high amounts of exercise and women who use certain types of contraception (depo medroxy progesterone acetate). There is evidence that both of these groups become amenorrhoeic and are at risk of osteoporosis and osteoporotic fracture. Page 4 4.1.2 a. What will this be? b. We accept the decision to exclude population-wide primary prevention strategies, however it might be useful to clarify later, page 5, section 4.3, first paragraph, that the intention to provide guidelines on prevention will be *'at the individual person level'*.	 Thank you. Thank you. These have now been added to the scope. As explained above, this was an editing error made by NICE which has now been corrected. Apologies for this. Thank you for your suggestion. We have amended this in the scope and have also changed the guideline title to better reflect this.

	Page 6 Non Pharmacological Intervention Physical Activity This should include the various forms of physical activity (opportunistic, general physical activity/exercise, and specific exercise) and how this is provided. It should also include how advice to change physical activity levels is given. For example, Salford NHS Trust physiotherapy department runs an osteoporosis exercise programme, which includes educational sessions and other related issues (pain relief following fracture). Physiotherapists often run these programmes (e.g. at the Bristol Royal Infirmary) which aim to reduce the risk of fracture by: 1. Encouraging life style changes through education. 2. Improving balance, muscle strength and function through dry land exercises and hydrotherapy The guidelines should include how physical activity is provided, by whom, and when. The DH has published a framework on exercise referral systems: a national quality assurance framework (www.doh.gov.uk/exercisereferrals). . Other non-pharmacological interventions The Society would wish to see the management of pain by non-pharmacological means included. For example, in the management of pain from vertebral compression fractures physiotherapists can offer tailored postural and spinal stability exercises, hydrotherapy, TENS and acupuncture.	Thank you. The full guideline will consider the evidence for various forms of physical activity. Thank you for informing us of these points. The information will be referred to the GDG during the development of the guideline. We would invite further detail from the stakeholder during the submission of evidence process. Noted. As above, further evidence is invited. The guideline will also refer to other guidelines that consider pain management.

	Page 7 The list of guidelines fails to mention the CSP-endorsed Guidelines for the physiotherapy management of osteoporosis (CSP, 1999). This, and the supplementary audit pack (CSP, 2002) should be included here.	Thank you. These references have now been added.
College of Occupational Therapists	Introduction The College of Occupational Therapists is pleased to provide a response to this draft scope document. Overall comments We would welcome the inclusion of a glossary within the scope, as discussed at the stakeholder meeting, on 5th March 2003, including a definition of a fragility fracture (Ref 4.1.1 c) and a consensus on the term 'primary prevention'. The World Health Organisation defines primary prevention as: "Measures seeking to prevent the initial occurrence of a disease or other health problems such as low birth weight, through such measures as health education, immunization, improved nutrition, improvement of the environment and appropriate care of women during pregnancy." (WHO Terminology Information System) The following comments are numbered according to the draft scope document. 3. Clinical need for the guideline ▪ Although section a) recognises the affect that osteoporosis has upon the whole skeleton, noting the wrist, spine and hip as the most common fracture sites, the following section b) concentrates upon the effects of hip fractures alone. The scope needs to expand upon the effects of vertebral fractures and kyphosis, of which there is minimal reference. Kado et al (1999) state that studies in vertebral fractures are difficult, as up to two thirds may be asymptomatic. ▪ There is also research available concerning Colles fractures and their use as indicators of Osteoporosis and further fractures.	Thank you. Thank you for your comments on clarity. A comprehensive glossary will be provided in the full guideline. However, within the scope we have now defined fragility fracture and primary prevention. Thank you for highlighting this. Another stakeholder also pointed this out and the scope has now been amended to provide a more balanced picture of the impact of osteoporosis on the lives of individuals. Thank you for providing this information. It is not within the function of the scope

	Owen et al (1988) stated that postmenopausal women who have sustained a distal radial fracture have nearly twice the risk of sustaining future hip fractures. Dolan et all (1998) stated that the burden to the NHS of distal radius fractures resulted in 4 extra visits to the GP per year for 50,000 affected patients per year.	to allow a detailed discussion on every point, but further detail on this will be discussed within the full guideline.
	▪ This is further supported by Heath (1990) - stating that patients with one fracture would be at greater risk of fractures at the other sites.	We have stated that previous fracture is a risk factor for further fracture and this will be assessed by the GDG.
	▪ With regards to clinical diagnosis in section c), the Royal College of Physicians (1999) state that the use of BMD has a low sensitivity, meaning that half of all osteoporotic fractures will occur in women who do not, by definition of BMD, have osteoporosis.	Agreed. We are assessing other risk factors for predicting osteoporotic fracture.
	▪ This guideline provides an opportunity to assess all the factors involved in recognising the presence of osteoporosis, and providing guidance or recommendations to enable early and accurate diagnosis.	Completely in agreement. This is the goal for this guideline.
	4.1 Population ▪ 4.1.1 b) We welcome the fact that people with osteopenia are included in this guideline. This is a very important group, where early intervention and education may be able to prevent or reduce further problems.	Noted with thanks.
	▪ 4.1.1 h) Other risk factors (multiple references) include history of prolonged alcohol consumption, smoking, diet low in calcium/ high in caffeine. Certain ethnic origins have also been identified as having a higher incidence (ie, Asian/ white).	Noted. We are considering all recognised risk factors. As previously stated, this detail will be in the full guideline but such a level of detail is beyond the function of the scope, which serves to summarise what will be covered.
	▪ 4.1.2 a)	

	There will be some inevitable blurring with other diagnosis specific groups eg, patients with osteogenesis imperfecta. This may need further clarification within the scope.	As above.
	4.2 Healthcare setting ▪ Section a) Intervention cannot be separated from the enablement of independence, quality of life and the management of risk, which occurs primarily in the person's home. Therefore the collaboration between primary/ secondary care and professionals working within residential and nursing homes, social services and the voluntary services is a key factor within the ongoing care of this group and needs to be recognised within this guideline.	Agreed. The guideline will be relevant to all these settings and will take a multidisciplinary approach with any recommendations.
	4.3 Clinical Management ▪ The prevention and treatment of osteoporosis and osteoporotic fracture involves the early diagnosis of the condition and the identification of those at risk. The assessment of fracture risk needs to incorporate the assessment of the social, environmental and lifestyle factors that may affect an individual's degree of risk.	Thank you. As stated above the main recognised risk factors will be considered which will incorporate some of these elements.
	▪ The scope needs to include guidance on the identification of people at risk of osteoporosis and osteoporotic fracture, at an early stage. This is necessarily for settings where access to diagnostic procedures outlined earlier in the scope will be limited.	Agreed. This will be part of the full guideline following a review of the evidence.
	▪ Section b) The non-pharmaceutical interventions are key to enabling individuals to manage with their condition, taking practical measures to reduce pain and risk of further injury, for example: - pain management - modification of activities of daily living (e.g. techniques/ assistive devices to prevent stress on bones, joints etc.) - positioning and posture and promotion of transfers techniques (e.g., prevention/ management of bending, lifting, pushing) - assessment of equipment/ furniture /environment, to provide optimal support, posture, protection and comfort	Thank you for all these points. These will be referred to the GDG.

	- working with individuals and their carers, providing education and advice, e.g. limitations/ heavier activities of daily living. Recognition needs to be made within the scope to such activities that may be incorporated into the broad term of “functional assessment and intervention”. References Dolan P, Torgerson DJ (1998) The cost of treating osteoporotic fractures in the United Kingdom female population. *Osteoporosis International, 8(6),* 611-17. Heath DA (1990) *Osteoporosis: some doubts to be answered*. In: Smith R (ed) Osteoporosis, chapter 17. London: Royal College of Physicians. Kado DM, Browner WS, Palerno L, Nevitt MC, Genant HK, Cummings SR (1999) Vertebral fractures and mortality in older women: a prospective study. Study of Osteoporotic Fractures Research Group. *Archives of Internal Medicine, Jun 14; 159(11),* 1215-20. Owen RA, Melton LJ, Ilstrup DM, Johnson KA, Riggs BL (1982) Colles’ fracture and subsequent hip fracture risk. *Clinical Orthopaedics, Nov-Dec; (171),* 37-43. Royal College of Physicians (1999) *Osteoporosis: clinical guidelines for the prevention and treatment.* London: RCP. WHO Terminology Information System, (WHOTERM) http://www.who.int/terminology/ter/genndx.html (accessed 10/3/03)	Your comprehensive list of references is appreciated. Thank you.
Community Practitioners' and Health Visitors' Association	No comment	
Department of Health	Thank you for the opportunity to comment on this draft scope. The following points reflect the views of the Department of Health and the Welsh Assembly Government. We are generally content with the document. However, we would like to	Noted with thanks. Please be reassured

	bring to your attention that point a) in section "4.1.2 Groups/clinical aspects that will not be covered" has been left blank.	this was an editing error by NICE which has now been corrected.
Eli Lilly and Company Ltd.	(Numbers below refer to the numbered sections of the scope) 1.Guideline title We believe that the title as it is currently does not adequately reflect the scope of the guideline and should refer to the “Prevention, diagnosis and risk assessment of osteoporosis and osteoporotic fractures.” 2 Background b) The guideline provides the opportunity to issue practical advice for clinicians and to answer some difficult questions such as the targeting of therapy to those at high risk, treatment algorithms, monitoring and length of therapy. All of these should be linked to NSF by offering practical help in meeting the NSF targets. We believe that the scope should also be specific and refer directly to the NICE Technology Appraisal. Prevention and treatment of Osteoporosis (due for publication Sept 2003) 3 Clinical need for the guideline a) The definition of osteoporosis should be the 2001 National Institutes of Health (NIH) definition as this is being used in the ongoing Health Technology Assessment of osteoporosis. The complexities of osteoporosis as a systemic skeletal disorder have been recognised by NIH, who, in a consensus statement, have emphasised that Bone Mineral Density (BMD) is only one element of bone strength; turnover and architecture also playing a part in the bone quality equation. (NIH consensus statement. 2000. Osteoporosis Prevention, Diagnosis, and Therapy. NIH Consensus Statement 2000 March 27-29; 17(1): 1-36.). The understanding that there are other components of bone quality has implications for monitoring, evaluation and long-term therapy advice.	 Agreed, and commented upon by several stakeholders. The title has now been altered to better reflect the content of the scope. Agreed. Reference will be made to the NSF and other relevant guidelines and technology appraisals as outlined in the scope. Thank you for highlighting this. The scope now contains both medical and patient-centred definitions to clarify this. Noted.

	b) While hip fractures do contribute significantly to the burden of disease, we feel that vertebral fractures are at least as clinically important and have equal if not more impact on quality of life of the individual	Thank you. We have added further detail on the impact of vertebral fractures on patients in an attempt to balance this.
	Costs It is no longer appropriate to focus, purely, on the cost, both human and personal, of hip fractures. With greater knowledge and understanding of the importance of vertebral fractures, both clinical and morphometric, it is essential that steps are taken to address the burden that these fractures impose and instate effective intervention strategies designed to relieve this burden in the future.	Noted. This point will be referred to the health economists working on the guideline to consider the evidence.
	Health and social care costs associated with a hip fracture were estimated to be around £12,000 and were less for other fracture types (wrist £468, vertebral £479, 1995/6 costs).[1,1a,1b] More recently, it has been estimated that the costs of vertebral fractures detected morphometrically are also substantial and may be as high as two thirds of the costs of treating clinical vertebral fractures.[2]	As above.
	Impact –it is widely recognized that: • Vertebral fractures are predictive for future fracture at all sites [3,4,5] • Vertebral fractures are associated with increased morbidity [6,8-14] • Vertebral fractures are also associated with an increase in mortality similar to that observed with hip fracture [8,11,15-17]	Noted with thanks. Greater detail on this will be provided in the full guideline.
	c) We are concerned that the statement 'there is a distinction between diagnosis of osteoporosis and risk thresholds for intervention' might be interpreted that some patients could have osteoporosis but not be considered for treatment, although this is obviously what is intended	Thank you for highlighting this. The sentence has been amended to clarify. It was not the intention to suggest this. The opposite applies, individuals may be considered for treatment without a diagnosis.
	Groups / clinical aspects that will not be covered a) Appears to be missing	As stated above, this error has been corrected.

	b) While the scope excludes coverage of population-wide primary prevention strategies it should acknowledge the importance of health promotion messages as adjuncts to therapy. Pharmacological intervention should be only one aspect of delivering benefit to the individual.	Agreed. This will be acknowledged in the section referring to non-pharmacological interventions.
	c) While it is well known that mass screening strategies would not be a cost effective option in the management of osteoporosis, we believe that targeted screening strategies may, however, be of value in reducing the long term impact of osteoporosis and fractures, which is mentioned in the NSF for the Elderly Standard 6.[7]	Agreed. The focus of the guideline is to identify high-risk individuals who would benefit from intervention. Also as mentioned previously the guideline will tie in with the NSF for Older People.
	4.3 Clinical Management a) Assessment of fracture risk Caution is necessary when considering some of the technologies stated as suitable for assessment of fracture risk. DXA is currently the only truly diagnostic tool and it should be clarified which technology should be used for diagnosis and which should be considered as an assessment of another risk factor.(eg QUS)	Agreed. The guideline will not be addressing diagnosis per se but will be assessing the utility of the specified technological methods for predicting fracture.
	Biochemical markers should include bone specific alkaline phosphatase (BSAP). We would wish the guideline to give clear guidance on the use of these markers in clinical practice.	Noted. The GDG will be assessing the evidence relating to the use of biochemical markers.
	b) Interventions Pharmacological interventions. We are pleased that the Guideline will encompass the NICE Technology Appraisal evidence on the Clinical and Cost Effectiveness of Prevention and Treatment of Osteoporosis, which specifically addresses therapies which are licensed for the prevention and treatment of osteoporosis Therefore, we are concerned that, in the guideline, consideration will apparently be given to unlicensed indications of pharmaceutical interventions. This, potentially, undermines the integrity and credibility of the NICE guidance.	Noted with thanks. We disagree that examining the evidence for currently unlicensed therapies undermines the integrity of the guidance. Such interventions may be licensed by the completion of the guideline. This comment is referred to NICE.

	References 1.Dolan P, Torgerson DJ. 1998. The cost of treating osteoporotic fractures in the United Kingdom female population. Osteoporosis International 8 1998 (6):611-617. 1a.Torgeson DJ. The cost of treating osteoporotic fractures in the United Kingdom female population. (Letter) 2000. Ost Int. 11:551-52 1b.Burge RT, Worley D, Johansen A et al. The cost of osteoporotic fractures in the United Kingdom. Projections for 2000-2020. J Drug Ass. 2001; 4:71-160. 2. Kanis JA.. Unpublished report. Cost-effectiveness of Raloxifene in the UK, an economic evaluation based on the MORE study. (Appendix 9 of the Eli Lilly submission to NICE for the Technology Appraisal-Company Confidential) 3.Lindsay R, Silverman SL, Coope, C, Hanley DA, Barton I, Broy SB, Licata A, Benhamou L, Geusens P, Flowers K, Stracke H, Seeman, E. 2001. Risk of new vertebral fracture in the year following a fracture. JAMA, 285 (3):320-323. 4.Black DM, Arden NK, Palerma L, Pearson J, Cummings SR for the Study of Osteoporotic Fractures Research group. 1999. Journal of Bone and Minerl Density 14(5):821-828. 5.Ismail AA, Cockerill W, Cooper C, Finn JD, Abendroth K, Parisi G, et al. 2001. Prevalent vertebral deformity predicts incident hip though not distal forearm fracture: Results from the European Prospective Osteoporosis Study. Osteoporosis International 12:85-90. 6.Ross PD. 1997. Clinical consequences of Vertebral Fractures. American Journal of Medicine 103(2A):30S-43S. 7.National Service framework for Older People.2001. www.doh.gov.uk/nsf/olderpeople.htm 8.Ismail AA, Cooper C, Felsenberg D, Varlow J., Kanis JA, Silman AJ, O'Neill TW & the European Vertebral Osteoporosis Study Group. 1999. Number and type of vertebral deformities : Epidemiological characteristics and relation to back pain and height loss. Osteoporosis International 9:206-213. 9.Nevitt MC, Ettinger B, Black DM et al. The Assoociation of Radiographically detected vertebral fractures with back pain and	Thank you for your comprehensive list of references.

	function: A Prospective Study. 1998. Annals of Internal Medicine 128:793-800. 10.Nevitt MC, Thompson DE, Black D et al. Effect of UK alendronate on limited-activity days and bed-disability days caused by back pain in post menopausal women with existing vertebral fractures. 2000. Arch Int Med 160. 11.Kado DM, Browner WS, Palermo L, Nevitt MC, Genant HK, Cummings SR. Vertebral fractures and mortality in older women: a prospective study. Study of Osteoporotic Fractures Research Group. Arch Intern Med. 1999 Jun 14;159(11):1215-20. 12.Cook DJ, Guyatt GH, Adachi JD et al. 1993. Quality of life issues in women with vertebral fractures due to Osteoporosis, Arthritis and Rheumatism 36(6): 750-6. 13.Gold DT. The clinical impact of vertebral fractures: quality of life in women with osteoporosis. 1996. Bone 18 (3 suppl): 1855-95. 14.Silverman SL, Minshall ME, Shei W et al. The relationships of health-related quality of life to prevalent and incident vertebral fractures in post-menopausal women with osteoporosis: results from the Multiple Outcomes of Raloxifene Evaluation Study. Arthritis Rheumatism 2001 44(11): 2611-9. 15.Cauley JA, Thompson DE, Ensrud KC, Scott JC, Black D. 2000. Risk of mortality following clinical fractures. Osteoporos Int 11(7):556-561. 16.Center JR, Nguyen TV, Schneider D, Sambrook PN, Eisman JA. Mortality after all major types of osteoporotic fracture in men and women: an observational study. Lancet 1999;353:878-882.	
Health Development Agency	No comment	
Institute of Physics and Engineering in Medicine	On behalf of the IPEM I am submitting our comments on the Draft document relating to Prevention, assessment and treatment of osteoporosis and osteoporotic fractures. One aspect that we feel should be considered is: The safety in clinical use of hip protectors as this directly interfaces with the non-pharmacological interventions for reducing fracture risk highlighted in this Guideline rather than the Guidelines dealing with falls. The main reason is that the hip protectors when worn by osteoporotic patients at risk are highly likely to incur tissue damage whilst wearing such devices and that	Thank you. This important point is noted. As stated above, there will be close liaison with the Falls guideline developers. We have already passed on your comments to the Falls developers for incorporation into that guideline and will cross-

	the hip protectors advocated for such patients should be tested not only for impact resistance but for their tissue viability when worn. They should be considered on the lines of a dressing as there is direct contact with the skin of these devices and that appropriate safety guidelines should be considered, and certainly devices should be CE marked at the least. We are concerned that these issues may not be covered in the Guidelines on falls. There is a move to have such devices CE marked and standards are being drawn up for such devices to comply with, before the protectors can be used on patients, I represent the IPEM on the relevant committee drawing up the standards and related technology assessments of hip protectors. I attach a small article related to this aspect which you may find helpful.	reference to this where appropriate. Thank you for the attached article, which has also been referred to the Falls group.
Merck Sharp & Dohme	On behalf of Merck Sharp and Dohme Ltd, I am writing with regard to the scope consultation on the above guideline. We have a number of comments to make on this, many of which were aired at the stakeholder meeting last week. Our comments are summarised below against the specific section in the draft scope. Section 1 - Guideline Title We believe greater clarification is needed on "...treatment of osteoporosis and osteoporotic fractures". The guideline scope should clearly define what is meant by prevention and treatment of osteoporosis and/or fractures. As discussed at the meeting, the terms primary and secondary prevention are also used in this scope therefore definition about the use of these terms would also be helpful. <u>Section 4.1.1 – Population: groups that will be covered</u> The list provided is very comprehensive and some attempt should be made to prioritise these groups. Some of the patient groups could be managed in the primary care setting where others will require intervention from secondary care specialists. Clarity about which patients could be managed in primary care versus those that should be managed in the secondary care setting would be helpful. As the meeting discussed, this would also allow for modular dissemination of the final guidelines.	Thank you. Agreed. As mentioned above, the title and scope have been amended to clarify the areas being addressed by the guideline. Thank you for this important point. This will be referred to the GDG to consider when designing the guideline, and greater detail regarding service provision will be provided in the full guideline.

	For the population group 'receiving prolonged oral corticosteroid therapy' the scope should define 'prolonged' in terms of duration and average daily dose.	As mentioned in a previous response specific details on dose and duration will be in the full guideline after the evidence has been examined.
	<u>Section 4.1.2 – Population: groups that will not be covered</u>	
	The scope excludes population wide primary prevention strategies but does not define primary prevention and secondary prevention in this context. We believe some definition should be agreed and included within the scope as mentioned earlier in this letter and as discussed at the stakeholder meeting.	Agreed. This has now been clarified.
	Although the scope excludes mass screening of populations as a means to reduce osteoporosis and osteoporotic fractures, we believe it may be appropriate for screening in some high risk groups such as men and women with previous osteoporotic fragility fracture.	Agreed. The guideline is targeting selective case finding of high-risk individuals.
	<u>Section 4.3 Clinical Management</u>	
	a) This section could usefully include examples of successful service provisions in both primary and secondary care and recommendations for taking these forward in a wider context. Stakeholders should be encouraged to provide examples of such service provisions in their submissions.	Agreed. We will be pleased to accept such information for consideration by the GDG in the stakeholder submissions of evidence.
	b) We would like to clarify that NICE will accept studies with BMD as a primary endpoint (with no fracture data) given the paucity of fracture data that is available for the populations detailed in the scope.	With advice from experts in the field, the guideline developers will be examining studies with fracture as the endpoint. This has been identified as the clinically significant endpoint.
	We hope you find these comments helpful but if you would like to discuss them further then please do not hesitate to contact me. We would be grateful if you could acknowledge receipt of this letter by return.	Thank you for your helpful comments.

National Osteoporosis Society	The National Osteoporosis Society (NOS) is pleased that NICE is developing a Clinical Guideline on Osteoporosis because of the significant impact that consequent fractures have on all those whom the Society represents. We welcome the opportunity to comment on this draft scope. <u>1.General comments</u> The scope identifies the wide range of clinical issues that need to be addressed to produce a comprehensive guideline, which is practical and pertinent to the needs of health professionals in both primary and secondary care. It is particularly important that the guideline covers all those at risk of osteoporotic fracture. In light of the work that is currently being undertaken to produce a guideline for the assessment and prevention of falls in older people, we would hope that both guidelines would cross-refer wherever this is appropriate, to ensure that osteoporosis and falls services are fully integrated within the health service. We note that this is mentioned further down the document but would also like to see it spelt out in the scope at point 2(b). We would further welcome a prominent link to the NSF for Older People at the same point in the document. The title of the scope needs clearly to reflect the guideline's intended content. Whilst the title can be read as the 'treatment of osteoporotic fractures', it may be interpreted to also include guidance on the 'management of fracture'. The management of vertebral, hip and other fractures is of crucial importance to those suffering pain and disability.We believe that this could be an important subject for a separate future guideline in much the same way as SIGN has done with its guideline on the management of hip fracture. It would be a helpful outcome if the eventual osteoporosis guideline made such a recommendation. <u>2.Specific comments</u> 4.1.1 e) It would also be appropriate for this section to mention other	 Agreed. This is the intention of the developers. Agreed. The NSF for Older People has now been given greater prominence at an earlier point within the scope. Thank you. In light of several other comments to this effect the title has been amended to reflect the content of this scope. The issue of management of fracture warranting a separate guideline has been referred to NICE. Thank you. We have added important

	secondary causes of osteoporosis that are potentially related to immobility, such as rheumatoid arthritis, stroke or quadraplegia. 4.1.2 b) To be fully comprehensive, the guideline should recognise the importance of 'preventing osteoporosis'. It could achieve this by acknowledging the importance of public health messages about bone health and by highlighting the need for provision of drug therapies to prevent bone density falling into the osteoporosis range in some cases, where appropriate. The potential for this should be more clearly stated in the scope, which is currently open to misinterpretation and misunderstanding in respect of what is meant by "primary prevention strategies" 4.3 a) The scope rightly identifies that the guideline will consider the effectiveness of the range of technologies available to assess bone strength.However, it needs to make clear that technologies other than DXA do not diagnose osteoporosis and as such, may not define who will benefit from treatment. In terms of the use of biochemical indices of bone turnover, it would also be useful to include bone specific alkaline phosphatase, in addition to total alkaline phosphatase. 4.3 b) It would be appropriate for the guideline to include the monitoring of osteoporosis treatments as this is an integral part of the long term management of the condition, with technologies such as DXA scanning and biochemical markers being used for this purpose. In recent years changes in biochemical markers of bone turnover have provided relatively rapid indicators of response to therapy in patients with osteoporosis. Clinicians need tools to help with decision-making and patients are keen to see progress but appropriate technologies need to be established to reduce confusion. We do appreciate that the guideline needs to be manageable and as such cannot be all encompassing, however hip protectors are an integral, non-therapeutic component of a comprehensive osteoporosis service. In addition to reducing the impact of a fall, they reduce the risk of hip	other secondary causes of osteoporosis as suggested. Noted with thanks. We have attempted to clarify this point in the amended scope. Thank you. The scope clearly states that these technologies will be examined for their ability to predict fractures and not as diagnostic tools. Thank you. Your suggestion has been added. The draft scope did not include treatment monitoring largely because expert opinion suggested there is currently a lack of evidence. However this question will be referred to the GDG to make a decision on whether its inclusion is justified. Thank you. Hip protectors are within the remit of the Falls guideline and clear cross-referral will be made to this guideline where applicable.

	fracture and as such should be included in this guideline, or at the very least the guideline should ensure clear cross-referral to the Falls Guideline if hip protectors have now been included in its remit. 3.Clinical Questions The NOS would like to suggest the following as appropriate clinical questions: ASSESSMENT AND DIAGNOSIS 1) How do clinicians identify who is at risk? a) Which risk factors, individually or in combination, indicate the need for a DXA scan to assess bone mineral density (BMD) and diagnose osteoporosis? b) Which risk factors, individually or in combination, can be used independently of BMD to indicate the need for treatment to prevent fractures occuring? c) How can other methods of assessment such as peripheral DXA and QUS aid clinical decision-making? d) At what BMD T-score is treatment for osteoporosis recommended? - Are there situations when a higher T-score signifies the need fortreatment? ie. corticosteroid use - How might Z-scores aid clinical decision-making in the elderly? - Is there an age cut off for DXA scanning? e) How does a clinician ensure that vertebral fractures are identified and reported? f) How should the results of a DXA scan be reported back to a GP/referrer? DRUG TREATMENTS	Thank you for your comprehensive list of possible clinical questions for the guideline. These suggestions will be referred to the GDG for consideration during the setting of the clinical questions for the guideline.

	2) How might clinicians be guided in making treatment decisions? a) Which drugs should be prescribed and to whom? b) How should treatment in younger women be managed? (i.e. corticosteroid users, women of child-bearing age and women with early menopause?) c) How should treatment in men be managed? d) For how long should treatment be given? e) How should response to therapy be monitored? - Should follow-up DXA scans be carried out and how often? - What is the place of bone markers for monitoring the response to therapy? f) What is the role of exercise and hip protectors in reducing the risk of fracture? SERVICE STRUCTURE 3) What service structures are needed? a) How should the management of osteoporosis be shared between primary and secondary care? b) How will falls prevention services and osteoporosis services be integrated? c) Who is responsible for overseeing the management of the service? The NOS would like the NICE Clinical Guidelines on Osteoporosis to create a standard of best practice that will ensure all those with osteoporosis receive the care they need from a consistent and seamless service. The NOS is optimistic that this scope will lead to such a guideline and looks forward to supporting the work of the guideline development	Noted. Thank you for your constructive comments.

	group.	
Novartis Pharmaceuticals UK Ltd	No comment	
Novo Nordisk Limited	Please find Novo Nordisk's comments on the draft scope for the above mentioned Guideline following. 1 As was discussed at the stakeholder meeting, this guideline is very extensive; would it not therefore be clearer if there were 2 guidelines? One entitled 'the prevention and assessment of osteoporosis' and the second entitled ' treatment of osteoporosis and osteoporotic fractures. This would also improve the reference to the medicinal products involved, as some of these products are licensed for prevention, and some for treatment. 2 A definition of terms is required, including prevention of osteoporosis, prevention of fractures, treatment of osteoporosis and treatment of osteoporotic fractures. 3c Is there a need to include osteopenia in an assessment of risk to guide decisions regarding which individuals would benefit from interventions aimed at preventing fractures? 4.2b The guideline will consider areas where there needs to be collaboration between primary and secondary NHS services, should it not also consider cross-reference of the patient within secondary services? 4.3b Will there be an order of priority of treatment?	Thank you. We note your suggestion and refer it to NICE. The current scope focuses on identifying individuals at high risk of osteoporotic fracture and assessing the various interventions that may be of benefit to such individuals. The title of the guideline has been amended to reflect this. Noted. We have addressed this. This is included as a recognised high-risk group. Noted with thanks. This will be referred to the GDG to consider in the area of service provision. Thank you for this question. Taking in to account expert advice and the evidence base, there will be no attempt to lay out a hierarchy of interventions.
Nutricia Ltd (UK)	4.1 <u>Population</u> 4.1.1 <u>Groups that will be covered</u>	

	(c) We would suggest that the guideline should also consider men and women during the post operative and rehabilitation periods following repair of osteoporotic fracture – in particular hip fracture.	Thank you. As stated elsewhere, previous fracture will be considered amongst in risk factor assessment. However, immediate post-fracture management is not within the remit of the scope. This point is referred to NICE.
	(e) We would suggest that coeliac disease is given as a particular example of a gastrointestinal disorder resulting in chronic malabsorption in order to highlight its significance as a secondary cause of osteoporosis.	Agreed. This has been done following similar comments from other stakeholders.
	There are currently around 50,000 members of Coeliac UK and the incidence of coeliac disease is reported to be at least 1 in 300. [1] Chronic calcium malabsorption associated with coeliac disease increases the risk of osteoporosis in this patient group and 47% women and 50% men with the disease have been shown to have osteoporosis. [2] In 2000, the average age of diagnosis of coeliac disease was ~ 45 years. [3] Patients may be asymptomatic or experience vague symptoms for many years, resulting in the condition being unrecognised and undiagnosed. As a consequence, they may experience calcium malabsorption after prolonged periods of time, increasing their risk of osteoporosis.	Your information on coeliac disease is noted with thanks. Greater detail will be given in the full guideline.
	4.1.2 <u>Groups/clinical aspects that will not be covered</u> (a) Should anything have been stated here?	This point has been previously addressed above . Nothing is missing.
	4.2 <u>Healthcare Setting</u> (a) As suggested under 4.1.1 (c), we feel the guideline should cover the care of individuals not only at risk of osteoporosis and osteoporitic fracture, but also the care patients receive following an osteoporitic fracture.	Immediate post-fracture management is not within the remit of the scope. This point is referred to NICE.

	4.3 Clinical Management The draft scope states that the emphasis of the guideline will be on the prevention and treatment of osteoporosis and osteoporitic fracture. The interventions outlined, seem to focus mainly on prevention of initial and subsequent fractures. Hopefully it will also look at treatment and interventions that improve rehabilitation and clinical outcomes e.g provision of post-operative nutrition support.	See response above. The guideline title has now been amended to reflect this.
	(a) Assessment of fracture risk As already highlighted, coeliac disease is often diagnosed late, therefore a case finding approach should be recommended to diagnose the disease early and reduce the risk of osteoporosis. [1] In a study by Lindh et al of patients with osteoporosis, 12% were found to have undiagnosed coeliac disease. [4]	Thank you. The guideline is examining selective case finding strategies for identifying high-risk individuals.
	(b) Interventions Non-pharmacological interventions: The draft scope states that dietary factors such as treatment with calcium and vitamin D will be considered. We would suggest that this be broadened to include not only dietary counselling and supplementation with calcium and vitamin D at levels over and above the Reference Nutrient Intake (RNI), but also compliance with a gluten free diet in the case of coeliac disease and strategies to improve nutritional intake and nutritional status.	Noted. These points will be referred to the GDG.
	Studies have shown that the provision of nutritional support (enteral tube feeding or oral nutritional supplements) following osteoporotic fracture can result in a significant reduction in length of hospital stay and incidence of post-operative complications.[5, 6] Evidence of	Thank you. See previous response regarding post-fracture management not being covered within this guideline.

	these benefits has been available for some years, yet such strategies have not been adapted into routine practice. The guideline development group might also consider incorporating into this guideline the guidelines developed by the British Society of Gastroenterology for osteoporosis in coeliac disease and inflammatory bowel disease published in Gut in 2000. [7] Although not British, recent guidelines have also been published on this subject by the American Gastroenterological Association. [8] References 1. Hin H., Bird G., Fisher P., Mahy N. and Jewell D. Coeliac disease in primary care: Case-finding study. BMJ 1999; 318:164-167 2. McFarlane XA., Bhalla AK., Reeves DE., Morgan LM. and Robertson DAF.. Osteoporosis in treated coeliac disease. Gut 1995; 36:710-714 3. Coeliac UK. Coeliac Demographics. Crossed Grain. Winter 2001 Edition Issue 51 4. Lindh E, Ljunghall K, Larsson B and Lavo B. Screening for antibodies against gliadin in patients with osteoporosis. Journal of Internal Medicine 1992; 231:403-406. 5. Bastow MD., Rawlings J. and Allison SP. Benefits of supplementary tube feeding after fractured neck of femur: a randomised controlled trial. BMJ. 1983; 287:1589-1592. 6. Delmi M., Rapin CH., Bengoa JM. et al. Dietary supplementation in elderly patients with fractured neck of femur. Lancet. 1990; 335:1013-1016 7. Scott EM., Gaywood I. And Scott BB. Guidelines for osteoporosis	Thank you for this reference. This will be looked at by the GDG during the development of the guideline. Noted with thanks. Thank you for your reference list.

	in coeliac disease and inflammatory bowel disease. Gut 2000; 46 Suppl. 1:1-8 8. American gastroenterological Association. Medical Position Statement: Guidelines on Osteoporosis in Gastrointestinal Diseases. Gastroenterology 2003; 124:791-794	
Organon Laboratories Limited	No comment	
Pfizer Limited	We welcome the decision to raise the profile of osteoporosis diagnosis and treatment and are grateful for the opportunity to comment on this draft scope. Our comments are attached as a table. We also wish to propose the following clinical questions for consideration by the guideline developers. 1. What is the most clinically and cost effective tool (or combination of tools) for predicting osteoporotic fracture risk? 2. At what level of predicted fracture risk should preventative therapy be initiated? 3. In which patients is it clinically and cost effective to screen for osteoporotic fracture risk? 4. What is the most clinically and cost effective methodology for identifying patients to measure osteoporotic fracture risk? 5. What is the impact of treatment for osteoporosis on other co-existing post-menopausal conditions? We hope these comments are helpful and look forward to the final scope. Section 4.1.2: Groups/clinical aspects that will not be covered • It is unclear why mass screening strategies have been excluded (in spite of the fact these are accepted approaches for other so-called "silent" diseases e.g. breast and cervical cancers, heart disease, diabetes). By excluding this from the scope we are concerned that the available evidence and outcome has been pre-judged and this	Thank you. Thank you for identifying these important questions. These will be referred to the GDG for consideration during development of the clinical questions for the guideline. Expert advice concurs that there is insufficient evidence to promote mass screening in osteoporosis. For this complex condition targeting individuals at high risk is recommended, this is also

	approach may lead to the omission of important recommendations in the final guideline. To capture all people who are at risk would require some form of screening. Any recommendation for healthcare professionals to actively identify people with risk factors, such as by trawling through computerised patient records, will exclude people who are not presenting to the point of care. Alternatively, identification of at-risk individuals may depend on voluntary presentation, which would limit achievement of the guideline objectives.	known as selective case finding. This is the approach requested by the remit. Practical methods of achieving this will be examined by the GDG and full details provided in the full guideline.
	• A definition of 'mass screening' would therefore be helpful. Does this for example, mean that postmenopausal women over a specified age could not be screened for risk factors, possibly as part of a single health assessment for elderly people?	Thank you for your question. We have now clarified this point within the scope.
	Section 4.3: Clinical Management. • Part a) addresses the methods for assessing fracture risk and part b) the interventions, but this section does not address the mechanisms by which potentially higher risk people will be identified in the first instance. We therefore suggest a third part to the section to ensure this is covered, e.g. 'Identification of people at potential risk of fracture', particularly if mass screening is excluded	Agreed. The goal of the guideline developers is to identify "How to" selectively case find individuals who may benefit from intervention.
	• If the assessment of people for potential risk of fracture depends on the use of a number of methods we suggest the guideline include recommendations for which method of assessment should be used in which situation, ie. when the 'best' prognostic tool has been identified, how should it be used to greatest effect?	Noted. See above response.
	• Part a) mentions use of quantitative ultrasound (QUS) for measuring BMD. It is unclear whether all methods will be reviewed (i.e. finger and heel, wet and dry) and it is recommended the scope does specify 'all methods'.	Thank you. This has been amended in the scope.
	• On a technical point, QUS does not measure BMD but rather speed (or attenuation) of sound through bone; its correlation with DEXA measurements of BMD is therefore not perfect. This means that the two techniques (DEXA and QUS) identify two different (but	Agreed. The scope clearly states that a number of technologies will be examined to assess how useful they each are in predicting fracture risk.

	overlapping) populations “at risk” of fracture. While the scope states the guideline will consider both methods for the measurement of BMD, we would suggest this section is expanded to emphasise that QUS measurements are an independent risk factor and that both methods will be assessed on whether they best predict fracture risk. • It is not clear from the draft scope whether all elements of clinical management will be addressed by this guideline. To be of practical benefit to health professionals, recommendations for patient assessment should reflect those methods that are readily accessible, particularly in primary care. The guideline should also address monitoring of treatment effectiveness. It is suggested that the scope reflects these elements.	Noted. It has been agreed that post-fracture management is not covered by this guideline. The draft scope did not include treatment monitoring, largely because expert opinion suggested there is currently a lack of evidence. However this question will be referred to the GDG to make a decision on whether its inclusion is justified.
Pharmacia Limited	Thank you for the opportunity to comment on the draft scope dated 17th February. As a result of the stakeholder meeting held this week we only have one comment as outlined below. If you would like clarification on this, please do not hesitate to contact me. Comment: • <u>Section 4.3 b) re; hormone replacement therapy (HRT):-</u> *We suggest the guideline highlights significant differences between alternative HRT preparations*, *within this treatment class*. Specifically, available HRT preparations vary with respect to licensed indication and constituents, eg: 1.Approximately 20% of HRT preparations are not currently licensed for osteoporosis (in some cases, this depends on dose administered). 2.Norethisterone is considered to prevent further bone-loss, compared to alternative progestogens such as medroxyprogesterone acetate and dydrogesterone. Although such issues may be covered by the technology appraisals listed, or examination of Summaries of Product	Thank you. Thank you for highlighting this important point. Differences between HRT preparations will be taken into account by the GDG during the development of the guideline.

	characteristics, as indicated in 4.3 b), we feel they deserve attention, to ensure that any HRT treatment encouraged by this guideline is both appropriate and as cost-effective as possible. We hope our feedback is informative, and look forward to receiving the final scope in due course, along with further communications as the development of the guidelines proceeds.	Thank you for your helpful comments. Further details on these treatments are invited from the stakeholder during the evidence submission process.
Proprietary Association of Great Britain (PAGB)	The NHS Plan establishes self-care as one of the key levels of care in the NHS and national service frameworks include self-care as a substantial element in the care and treatment offered. People's ability to prevent and manage their health problems must now be included as a matter of routine whenever guidance is being developed. The osteoporosis guideline aims to consider prevention treatment and assessment of the disease but there is no explicit inclusion of the role of self-care in the scope that has been drafted. I would like to recommend therefore that those developing the guideline should include an assessment of how self-care advice can be given, together with the type of self-care mechanisms that could be used. I very much hope that this point is taken into account and look forward to seeing the outcome.	Thank you for your comments. The GDG will consider self-care within the non-pharmacological section of the scope.
Robinson Healthcare	Background The medical literature reports that significant reductions in the likelihood and costs of hip fractures have been achieved by the provision of hip protectors. With hip protectors the intention is to provide immediate protection against osteoporotic hip fracture. The idea of using hip protectors has been around since the 1880s. After which time they recur in the literature several times, but until the 1990s they were not shown to work. There was always the assumption that using a metal plate or a pad of energy absorbent material would control the impact – but unfortunately the physics of the situation was against them. Some of the early hip protector designs probably increased the	Thank you very much for providing this information on hip protectors. This has been passed on to the Falls guideline developers, as it is included within their remit. As we have previously stated, we are working closely with the developers of this guideline to cross-refer relevant information.

	likelihood of hip fracture, despite them being intuitively designed as protective devices. The situation changed with Prof. Jes Bruun Lauritzen's seminal article in *The Lancet* in 1995, describing work carried out in the early 1990s. Prof Lauritszen took full note of the physics of the situation, and designed a hip protecting shell that shunted the energy of a fall away from the hip joint. The energy of impact from a fall can be high – usually making it impractical to simply try and absorb the energy. Metal plates and the like might protect against the initial impact – but the recoil from the impact would break the hip joint instead. So moving the energy of the fall away from the hip joint ("shunting") was found to be the way forward. Using correctly shaped protective shells, Prof Lauritzen was able to report a statistically-valid and significant reduction in the incidence of hip fracture. He used a specially-designed undergarment to hold his shells in the correct position over the hip joints. Hence the shells are the hip protectors and the undergarment the delivery system. Prof Lauritzen achieved a statistically significant reduction in hip fractures despite a reported 24% compliance rate. This low compliance was almost entirely due to the delivery system – the undergarment. Primarily because of this low compliance reported in the important *Lancet* paper, and in other early papers, low compliance is often quoted as a problem with hip protectors. This has now changed - as the design of the undergarment has dramatically improved – and compliances of 50% and higher are now regularly reported. The Need for Standards or Guidelines There appears to be an assumption that all "hip protectors" are equal, with people taking data on one hip protector and assuming that it is applicable to all hip protectors. Even such bodies as *The Cochrane Review* take this stand – reporting and evaluating hip protector articles and trials for hip protectors as a unitary whole. All "hip protectors" are not equal. One hip protector has a significant amount of clinical evidence generated in several countries reporting good	

	efficacy and a statistical valid reduction in hip fracture rates. This hip protector has also been the subject of numerous compliance and financial benefit studies. Two other hip protectors have some efficacy and some compliance evidence. A few others have limited compliance studies. But importantly, some “hip protectors” appear to have neither clinical nor compliance evidence available in the literature. Some “hip protectors” are, at best, unproven. They may not provide protection and thus may actually increase the risk of fracture. It is often intuitively assumed that all hip protectors work and that the published clinical literature on one hip protector is applicable to all hip protectors. This assumption is often taken advantage of by manufacturers of the less good hip protectors, who have quoted or referred to Prof Lauritzen. It is noteworthy that Prof Lauritzen has on occasion felt the need to publicly disassociate himself and his reports from some “hip protector” products on the market. Hip protectors fall into two types: (1) energy shunting (as developed and proven by Professor Lauritzen) and (2) energy absorbing. These are claimed to work by very different mechanisms – and within each type there are markedly different designs available. Clearly evidence generated for one hip protector cannot normally be applicable to another. There are no standards or regulatory guidelines anywhere in the world concerning hip protectors. This lack is most apparent in the UK, who are leading the way with the widespread adoption of hip protectors. More hip protectors have been successfully used in the UK than in the rest of the world put together. Hip protectors are Class I medical devices and, as such, should carry CE markings as specified in the EC Medical Device Directive. The hip protectors specifically mentioned above as having clinical evidence all carry CE marks under the EC Medical Devices Directive. But so do other “hip protectors”. To work (that is, to provide significant protection against hip fracture when falling and to be practical in use) hip protectors must have the following features:	

	• They must be able to significantly reduce the energy of the fall impact that reaches the hip joint – and thus reduce the likelihood of hip fracture on falling. This must be proven by clinical evidence of efficacy for the individual design. • The hip protecting shells or panels must be correctly positioned and held securely in place. They should not be able to move – especially on impact – as a mispositioned hip protector is likely to be ineffective (or possibly even hazardous). • They must be able to protect against multiple falls. • They must be easy to use and be able to accommodate continence protection if necessary (the overlap of people needing osteoprotection and continence protection may be as high as 70%). There are “hip protectors” available that do not posses some or all of these features. There is thus a risk they could be ineffective – or at worst dangerous. “Hip protectors” that do not work well are likely to devalue the general opinion of hip protectors. A bad experience with an inadequate “hip protector” may well stop someone using or recommending a good hip protector – and thus prevent them gaining benefit from a simply and easy way of preventing hip fractures. Class I medical devices are self certified. As there are no standards or guidelines on which to base the certification, any CE marked product should have adequate clinical evidence in place to prove effectiveness. Without standards or guidelines there is no way for providers or users to properly judge and compare hip protectors. Without standards or guidelines there is no way that CE marking can be consistently applied by the companies self certifying them. Without standards or guidelines there is the risk of a proliferation of unproven products on the market. Standards and guidelines would benefit patients and users most – as they would be assured of a significant reduction in the likelihood of sustaining a hip fracture if they wore a hip protector. At the moment they	

	do not have that assurance, unless they are knowledgeable enough to check the published efficacy data. Test Methods and Standards under Development A working party has been formed under the guidance of the SDMA (Surgical Dressing Manufacturers Association) tasked with establishing appropriate test methods for hip protectors. This work group is international in nature and the work is progressing well. Possible Confusion between Medical Device and Personal Protective Equipment Regulations As described above, hip protectors are Class I devices under the Medical Devices Regulations. Although this would normally be considered to provide a degree of confidence to users, it does in fact introduce a possible additional risk. Hip protectors can be used as personal protective equipment by healthy (non-osteoporotic) people taking part in sports and leisure activities. These products are required to carry a CE mark under the Personal protective Equipment Regulations. But unfortunately there is no way of distinguishing under which set of regulations the product has been CE marked – unless it is clearly stated in the manufacturer's literature. It is clearly possible that some products may be suitable for both applications, but as the circumstances of a fall and the conditions required to cause injury are likely to be quite different, there is the distinct possibility that if chosen purely on the presence of a CE mark, an inappropriate product may be used. Recommendations • That NICE guidance on the use of hip protectors should include a requirement that purchasers or healthcare professionals should ensure that the product they are buying or recommending is both clinically proven and suitable for the purpose intended. • That the development of trustworthy test methods for hip	

	protectors should be encouraged. • That means are found to judge the acceptability of the CE markings on all currently available hip protectors in the UK.	
Roche Diagnostics Limited	Thank you for your invitation to comment on the above mentioned scope as a Stakeholder. We have two major comments to make: 1. Section 4.1: Population We feel it would be appropriate to specifically include within the groups that will be covered those individuals that have been identified as at increased risk of fracture by alternative tests such as biochemical markers of bone turnover, even if they have not yet undergone bone densitometry. This is not to detract from the value of DEXA as the primary diagnostic tool as recommended by the World Health Organisation. Rather it is to recognise the fact that, in the absence of ready and rapid access to these scanners, many physicians may be faced with patients who have undergone other diagnostic investigations and need guidelines on how to deal with this situation. 2. Section 4.3: Clinical Management We feel very strongly that this section is incomplete. To be effective as a guideline for end-users it must be expanded to include a section on the monitoring of efficacy of interventions. This would cover the use of resorption markers (as mentioned in section 4.3 Biochemical Indices) as a means of evaluating the efficacy of pharmacological interventions such as bisphosphonates, and ensuring patient compliance.	Thank you. Thank you for this comment. As stated previously we are not excluding any high-risk scenario. It was not appropriate to outline in detail every single example of high-risk groups within the scope. The utility of biochemical markers to predict fracture is clearly stated in the assessment of fracture risk section. Noted. The draft scope did not include treatment monitoring, largely because expert opinion suggested there is currently a lack of evidence. However this question will be referred to the GDG to make a decision on whether its inclusion is justified.

	I was able to raise both of the issues at the stakeholder consultation meeting on 5th March, and it is the latter point that we are particularly keen to see included. I appreciate that this may involve an incremental amount of evidence reviewing for NICE, but this should not be too great in volume. It represents a vital link in the chain of care, since initiating therapy with no means of monitoring efficacy for perhaps two years (until the next densitometry scan) is not really evidence based medicine, when evidence exists to show that biochemical markers can guide medical decision making. I look forward to receiving the next version of the scope.	Noted. Thank you for your suggestions.
Royal College of General Practitioners	1. CONTEXT UK General Practice is carefully examining its proposed new, quality-based contract. The management of osteoporosis does not form part of this. If the key recommendations of this proposed guidance are to be implemented, then consideration needs to be given to including them within this framework. Especially if the evidence for intervention in osteoporosis is greater than for items already included in the new contract. As it is expected that this guidance will take two years to develop, there is time within which to consider this issue carefully. 2. NEED FOR CLARITY + FOCUS The guidance needs to be produced in a way that has clarity and focus for busy primary care professionals who want to do their best for their patients. E.g. It is little help flagging up that "prolonged" corticosteroids are a risk factor. What is needed is the best interpretation that can be made of current evidence and the inclusion of a total number of milligrams of the different steroids, which if exceeded represents that the patient concerned is "at risk" of osteoporosis. This will enable to clinician to perform further investigation and/or treatment can be instituted. Increasingly practices and PCTs like to set appropriate priorities and clinical approaches. This guidance needs to provide an appropriate framework to enable this to be done.	This point is noted and referred to NICE. Agreed. Thank you for your consideration to the scope. All the points you identify are important practical issues and the detailed response you require will be available in the full guideline after a full assessment of the evidence has been made. No restrictions in terms of detail have been made at the stage of the scope so as not to pre-empt the evidence. The guideline attempts to address the questions you identify.

	3. CLINCIAL MANAGEMENT OF OSTEOPOROSIS 3a. HISTORY i. Which risk factor scoring system should be used? There are a number of questionnaires used to assess level of risk. Patients come in and ask should they have either treatment or a scan for "osteoporosis." Primary care clinicians need an approved, easy to use, validated tool, for this purpose. ii. Post transplant, renal dialysis, rheumatoid arthritis need to be added to the list of secondary causes of osteoporosis. iii. The guidance needs to define the valid questions about family history. E.g. I believe that maternal hip "fragility" fracture is significant. Which other family history features are significant, and which not? iv. Which steroids taken in what dose render a patient "at risk" of osteoporosis? This needs to be stated with clarity. This part of the guidance needs to include the different inhaled steroids. N.B. 6-12% of the UK population has asthma. 3b. EXAMINATION i. The level of "low" BMI that is regarded as a risk factor should be defined. ii. Where there is clinically obvious osteoporotic change can treatment be started without further investigation? 3c. INVESTIGATION i. This is the most difficult issue of all. Patients present wanting scans, or present with the results of a wide range of types of scans. Clinicians need guidance as to what to do! ii. Who should have a DEXA scan? What should happen in areas where this is not available? Guidance should inform commissioners, largely PCTs, what level of provision should be made. Should DEXA be a direct access service as long as certain criteria are met, or available only through secondary care? iii. Under what circumstances are other XR scans and ultrasound acceptable? Primary care professionals need to know the "T-score" at	Thank you for identifying all these clinical questions. These will be referred to the GDG to consider during development of the clinical questions for the guideline. The guideline will aim to inform as many of these questions as possible.

	which treatment should be started. iv. How is the patient who wants a scan, but does not fall into the guidance to be treated? v. When should scans be repeated? vi. Blood tests: In primary care tests for secondary causes of osteoporosis rarely produce positive findings. There should not be translation of blood tests appropriate in secondary care to primary care. (Cooper, Brew, de Lusignan. *BJGP* 2002.) vii. Although dismissed by this guidance, there may be a case for population screening in the very elderly. (Versluis et al *BJGP* 2002, Harvey, de Lusignan *BJGP* 2002.) viii. When is XR evidence alone enough to initiate treatment? E.g. Can the elderly person with loss of vertical height with vertebral fracture/collapse be treated without further investigation? 3d. TREATMENT i. Clear recommendations as to which therapy is best for which patient groups. GPs need to know if there is evidence for using Ca + Vit D compared with other more effective therapies (bisphosponates, calcitonin, HRT.) ii. How long should treatment continue for? (Especially with bisphosphonates.) Is there a justification for treatment holidays? Do weekly preparations offer advantages over daily ones? iii. The guidance should contain a standard set of anti-falls, mobility, and exercise advice. 3.e REFERRAL + FOLLOW-UP i. When should GPs refer to secondary care? Which are the appropriate cases that would benefit from secondary care input? Guidance, as with cancer referral, would be helpful. ii. Discharge procedures and follow-up of those who have had a potential fragility fracture need to be made explicit. Patients at present can be orthopaedic in-patients or attend casualty, have their potential fragility fracture treated - without any further assessment of their osteoporosis risk. What should be recommended in these circumstances? Should they all be DEXA scanned?	

	4. AUDIT 4a. Potentially so many patients in need of treatment: It is difficult to know where GPs should start! With such a high proportion of postmenopausal women suffering from osteoporosis it is hard to know where to start. 4b. A standard baseline audit should be recommended: A standard baseline audit is recommended so that it is possible to monitor progress. Such an audit has been carried out within KSSnet (Kent Surrey and Sussex Primary Care Research Network) and is due to be published in "Public Health" (de Lusignan et al. in press.) The Read codes used in this audit, could be made available/ modified as required. 4c. A pragmatic approach to audit and quality improvement in osteoporosis: Osteoporosis is an enormous problem. It needs to be broken down into pragmatic bite-sized chunks and we would recommend that the following should be considered: Phase I. Finding patients with secondary causes of osteoporosis: Start with patients who potentially have secondary causes of osteoporosis. E.g. Patients with rheumatoid arthritis, coeliac disease etc. These patients are at very high risk of osteoporosis e.g. approximately 40% in RA. This should be the starting point as these patients are relatively easy to find in GP systems. Phase II. Patients on "prolonged" courses of steroids: In this phase patients who have had a larger dose of steroid than that recommended should be screened. Phase III. Finding patients who have had fragility fractures: While Phase I + Phase II is taking place the practice should concentrate on coding fractures in its clinical system. Phase III will include the screening those with fragility fractures. Phase IV. Case finding other at-risk patients: The final phase of the audit will be to look for individual, or groups of risk factors that place individual patients at high risk.	Thank you. As stated above, audit criteria will be included and we will work closely with the Falls guideline developers in this area. We look forward to receiving further information on practical examples of audit tools within your formal evidence submission. Thank you for this. This suggestion will be presented to the GDG for reference during the guideline development process.

	Phase I and Phase II, with Phase III planned for June 2003, of this audit has been performed in a small group of KSS practices and then across a whole PCT in December 2002. Data has been extracted using MIQUEST (a Department of Health developed software used to extract data from disparate GP systems,) then aggregated in a database, processed and fed back in an educational context. This has taken place as part of the PCDQ programme (Primary Care Data Quality - http://www.pcdq.org) based at St. George's. What the guidance needs to consider is exactly what format the "screening" of the at-risk person should take. It could be argued that these patients should all be DEXA scanned. The approach used in this quality improvement programme is to use a validated questionnaire, then forearm scan for osteoporosis. The recommended format of the "screening" of the at-risk case is going to be the most difficult part of this guidance to produce. The experience from working with 25 PCOs who have been involved in the PCDQ cardiovascular audit is that a multi-phase audit of this sort takes 2 years to work through, with most progress occurring between 12 and 18 months. 5. MEMBERSHIP OF THE GUIDELINES DEVELOPMENT GROUP A representative of the RCGP is to be included in the Guidelines development group. 6. ACKNOWLEDGEMENT The members of the KSSnet osteoporosis research group who commented on the guidance:	Thank you for your nominations. A member of the RCGP has been accepted to sit on the GDG. Thank you for your helpful comments, which will be taken into consideration during the development of the guideline.
Royal College of Obstetricians & Gynaecologists	See joint comments under British Menopause society	

Royal College of Physicians	See joint comments under Bone and tooth society	
Royal College of Psychiatrists	No comment	
Royal College of Radiologists	I attended the meeting of stakeholders on behalf of the Royal College of Radiologists. I made some comments at the meeting butwe were told that we had to send these in before 11th March to the website. A)Diagnosing osteoporosis by bone densitometry is site (lumbar spine, totalhip, forearm) and technique specific (DXA); will the scope include someadvice on how the other bone densitometric methods)QCT, ultrasound) mightbe used for diagnosis in individual patients? B) for the non-pharmacological interventions should vibrating plates beadded?	Thank you for this question. As stated in the scope the guideline will not be examining diagnosis per se. The technologies listed will be assessed for their ability to predict fracture. A comprehensive literature search will identify numerous non-pharmacological interventions. The GDG will consider vibrating plates if warranted by the evidence identified.
Royal Society of Medicine	No comment	
Scottish Intercollegiate Guidelines Network (SIGN)	No comment	
Servier Laboratories Limited	We have received the full document and the only comment we have is that on Page 6, 'strontium' should be 'strontium ranelate' This is crucial as strontium is a naturally occurring molecule and the ranelic salt is the one which has been specifically researched and developed for the osteoporosis indication.	Thank you. Apologies. This has now been corrected.
Shire Pharmaceuticals Limited	Thank you for providing us with an opportunity to comment on the draft scope for the consultation on osteoporosis. Our interest in this important area originates from our experience with calcium and vitamin D therapy for preventing and treating loss of bone, particularly in the elderly population, who are at greatest risk. Shire Pharmaceuticals welcomes the guideline process in this area and in general is happy with the broad thrust of the proposed scope. We have a number of detailed observations to make, which are set out below by heading.	Noted with thanks.

	Guideline and Short Title: We are content with these titles, which fully define the work that we believe needs to be undertaken in this area.	Thank you. For your information the title has been amended to better reflect the content of the scope.
	Background: We welcome the fact that the guideline will support aspects of the relevant NSFs. We are particularly interested in the NSF for Older People, which contains a prominent reference to osteoporosis. We are particularly concerned that the osteoporosis guideline should fully join up with other relevant guideline work being undertaken by NICE, in particular the falls guideline which is expected to pre-date this one (we note that this is mentioned at the end of the scope, but given the close link between the two, it deserves greater prominence higher up too).	Thank you. Another stakeholder made a similar comment and in response we have increased the prominence of the NSF for Older People and the Falls guideline by referring to them earlier in the scope.
	Clinical Need for Guideline: We have no additions to propose to this section.	Noted with thanks.
	The Guideline: We have the following specific comments to make on this section.	
	4.1.2 We are particularly concerned that the guideline will not address primary prevention strategies and that it will only concentrate on those at highest risk of the disease (4.2). We are unclear how a guideline that seeks to look at prevention of osteoporosis can exclude prevention strategies at primary level, which will be the first and possibly main interface for patients presenting with osteoporosis (latent or otherwise). We understand that “primary prevention” in this context could mean elements such as provision of school milk, diet, etc rather than the primary healthcare level prevention, which we believe to be vital. If this is so, then this point needs to be clarified.	Noted. The remit requests the targeting of high-risk individuals for intervention. We have attempted to clarify this point within the scope and it is now also reflected in the title. Regarding wider primary prevention for osteoporosis this point is referred to NICE.
	Furthermore, depending on the definition of “highest risk’, this group could form a relatively narrow percentage of affected patients or a much larger population. There is a danger that the group actually covered by the guideline could be unintentionally restricted (based on arbitrary or subjective inclusion criteria), thus excluding large numbers of patients who might benefit from prophylactic therapies that could help them to	Your concerns are noted. We have stated that we intend not to exclude any group at high risk.

	avoid bone loss and therefore fracture. 4.1.2 We note that pt (a) under this section is not filled in. This may be a typographical error. 4.3 We welcome the suggestion that the guideline should examine interventions to prevent subsequent fractures where fracture has already been sustained, since these patients represent a high-risk, readily identifiable, group. 4.3a Different types of osteoporotic fracture (hip, wrist, spine) should be categorised separately because approaches to their management and treatment can vary widely. This will increase the likelihood of a clear and structured guideline resulting from the planned process. 4.3b In the section dealing with treatments for osteoporosis, we believe that the references to calcium and vitamin D should be reworded to read ".....calcium, calcium and vitamin D, vitamin D,.....". Whilst vitamin D has uses as an adjunctive therapy, there is little evidence to suggest that it has a role to play in treating osteoporosis on its own. 4.3b In the list of relevant guidelines and technology appraisals specific mention should be made of the NSF for Older People. We are pleased to see the inclusion of the RCP Osteoporosis guidelines which we believe to be the current gold standard for prevention and treatment of the disease. *Further Information and References* We have no comments to add here. We would be grateful if it were possible to incorporate the above comments into the final scope, which we look forward to reading in due course.	Thank you. As explained above, this was the case and has now been corrected. Noted with thanks. Post-fracture management is not within the remit of this guideline. This point has been referred to NICE. Agreed. Thank you. This has been amended. Thank you. The NSF for Older People has now been added. Thank you for your helpful suggestions.
Society for Endocrinology	Thanks for reminding me. As discussed at the meeting on Wednesday, we would like to highlight the following points:	

	1)The guideline will not deal with orthopaedic management of any fracture. (2) The use of intravenous bisphosphonates should be included. (3) Consideration needs to be given to the duration of treatment with bisphosphonates Please note that I wrote to Bobbie Lloyd on 25th February with a couple of additional points, viz: (1) section 4.1.2 (a) seems to be blank in the version we have received, can you let us know what should be present in this section. (2) we feel that 'growth hormone deficiency' should also be introduced into section 4.1.1 (e) and (f)	Agreed. The title has been amended to reflect this. The route of administration of pharmacological interventions has not been specified in the scope so as not to pre-empt the evidence. All evidence will be reviewed. See above response. The same applies regarding duration of therapy. All evidence will be reviewed. Apologies. This editing error by NICE has now been corrected. Thank you. As stated above, no high-risk groups are being excluded. It is not appropriate to detail every possible group within the scope.
Spinal Injuries Association	I thought the meeting went very well and that the SCOPE document was well prepared and well presented. However I should like to make the following comments. I believe that in paragraph 4.1.1 a further group should be added. "Men and women with osteoporosis secondary to paralysis due to neurological problems such as spinal cord injury, head injury, cardiovascular accidents, multiple sclerosis and other neurological abnormalities." I realise that paralysis is covered in some of the other "catch all" paragraphs. Indeed the paragraph "groups that will be covered" could of course simply read "Men and women with osteoporosis, osteopenia, any	Noted with thanks. Agreed. This has now been added. Thank you. We have attempted to do this.

	other associated abnormality or any associated risk factor." While this might "do the job" I believe that the approach adopted in naming particular groups is the correct one. If this rationale is followed then it is important not to leave out naming a significant osteoporotic group. I also believe that this group should be specifically referred to as a combination of osteoporosis and paralysis does create particular treatment problems and may need different prevention strategies. In paragraph 4.3 b) "Non-pharmacological interventions" I believe the phrase "physical activity" should be expanded. Many people might regard physical activity as referring only to such "normal" physical activities such as walking, cycling, dancing, swimming etc. Such physical activities obviously offer little scope for the prevention of osteoporosis in the paralysed. However "artificial" muscular contractions as can be generated by Functional Electrical Stimulation may offer prevention strategies for those with some types of neurological paralysis. Perhaps the paragraph could end ".....and physical activity including artificially stimulated muscular activity." In my original submission by e-mail I omitted to mention one particular reason for making osteoporosis secondary to neurological paralysis, as in spinal cord injury, being a named category in paragraph 4.1.1 People with osteoporosis secondary to spinal cord injury spend more years in an osteoporotic state than most other categories. (The commonest age for acquiring a spinal cord injury is 19 and the life expectancy for all but the highest legions is near to normal.) This is of course also true for some other types of osteoporosis secondary to paralysis.	Noted. Agreed. This has been added to this section. Thank you for highlighting this. Thank you for bringing our attention to this important point. This will be detailed in the full guideline.
Wyeth	Many thanks for giving us an opportunity to comment on the above Scope document. We have no substantive comments to make regarding the Scope, but would like to ensure that Wyeth products in development such as a low dose version of Premique and our SERM bazedoxifene	Noted. Thank you. We look forward to receiving details of products in development during the formal evidence submission process. All

	are included in the NICE review, as a number of these products are likely to be launched by the time the review is published in April 2005. I presume that we will be able to send you a complete list of these products when we come to the data submission stage?	evidence will be considered by the GDG.