Web comments and other comments received by non consultees and commentators

9/30/2005-Sep-2005 10:55:3	
role:	Public
Section_1:	Why is there a difference between primary and secondary prevention recommnedations? Shouldn"t it be the same?
10/4/2005-Oct-2005 7:29:31	
role:	NHS Professional
Section_1:	Could the committee clarify the statement "who have sustained a clinically apparent osteoporotic fracture" . Does this mean a recently acquired fracture, a fracture sustained after 50yr (eg patient is now 75 but had wrist fracture aged 55yr), or a lifetime fracture?
Section_2:	Could the committee clarify the sentence ""{Osteoporotic fractures occur most commonly in the vertebrae, hip and wrist, and are associated with substantial disability, pain and reduced quality of life} "" in section 6.. Does this mean that any fracture can be construed as osteoporotic or does it restrict osteoporotic fractures to vertebrae, hip and wrist?
10/4/2005-Oct-2005 13:6:52	
role:	NHS Professional
Section_1:	Section 1.1 has changed the wording - age independent risk factors to clinical risk factors, is the document now implying that only Parental history of hip fracture and Rheumatoid arthritis are the main conditions for use? There needs to be some clarification regarding other medical conditions associated with bone loss. To include malabsorption syndromes, hyperthyroidism, bowel disease etc to ensure general awareness of all conditions related to bone loss. Other age independent risk factors should make reference to section 2.11 and risk factors should be highlighted in greater detail. It is my understanding from this section that strontium should be used in preference to Raloxifene. And raloxifene if conditions in 1.4 do not apply. An algorithm to summarise the main points of the guidance would be helpful as many GP"s have admitted that they do not read the full guidance!
Section_2:	Section 2.11 needs to be more prominent - possibly earlier in the document. Needs to specify other conditions associated with bone loss- until assessment of fracture risk guideline is produced.
Section_3:	If these drugs are in order of preference for use, I would put Strontium above Raloxifene. It would be helpful if some comment could be made to the first line bisphosphonates- I would use Alendronate and Risedronate as first line medications and would use Etidronate (Didronel PMO) as second line. There are often medications errors with the complicated regime for taking Didronel, that is not reflected in the bisphosphonate information. Also many GP"s are not aware that Cacit tablets, included in the pack do not contain any Vitamin D3 which is essential for the frail and elderly. The cost of Etidronate may be used as a deciding factor for prescribing, if issues around the complicated regime and drug errorrs are not addressed.
Section_4:	4.3.22 - Consider adding a comment about Cacit in the Didronel PMO pack. One incident I encountered was that - Didronel had been prescribed and a new GP had prescribed additional calcium and vitamin D3 supplements not realising that the product contained calcium. The document refers to Etidronate - but does not specify that this is usually prescribed as a 3 montly pack or can be prescribed individually- There needs to be some reference to this in the document and also there needs to be some reference to the lack of VIt D in the Didronel Pack
Section_5:	Other bisphosphonates are being developed which have not been reviewed by NICE- Ibandronate etc - Would it be possible for NICE review this information as new treatments become available.
Section_7:	Audit of GP practice information is often difficult. Fractures may not be coded on the practice records, as most information is entered onto practice systems by none medical staff, who have little knowledge of anatomy. I have worked with audit assistants in our area to try to improve this information collection. The terms osteoporotic/fragility fracture is rarely used by orthopaedic medical staff and therefore would not be coded unless this was highlighted by the GP. Further problems are mainly around read coding of information, often treatment is discontinued, but the reason for this is often not documented in the patients records. Unsatisfactory response, intolerance, contraindication or physical inability to comply is very rarely documented as it is difficult to read code this information. It would be more helpful if audit could be directed at information that is available and easy to read code. I have found that audit of prescribing trends is a more effective way of identifying uptake of NICE guidance. In our area this has shown a year on year increase in the prescribing of both bisphosphonates and calcium and vitamin D3 supplements (number of items prescribed
Section_8:	It would be helpful if NICE developed guidance around the treatment and prevention of osteoporosis in men. Also it would be helpful if further information could be provided about prevention of osteoporosis in pre-menopausal women. A guidance that provides information about treatment and advice in premenopausal women who often present with specific medical conditions other than steroid use i.e malabsorption problems, oestrogen deficiency etc. would be helpful.
10/11/2005-Oct-2005 15:24:35	
role:	NHS Professional

Section_1:	1.1 The elderly have greatest need for Teriparatide, but this cannot be used without first doing a dexa scan. Some of my patients had T scores of -5.6.
Section_2:	Needs to be emphasied that osteoporosis is a killing condition.
Section_3:	IV Pamidronate is generally felt to help acute vertebral collapse back pain. Pain is often ignored in clinical trials
Section_4:	Many patients cannot tolerate oral treatment.
Section_5:	There needs to be research of IV treatment, both for pain relief in vertebral fracture and in those who cannot tolerate oral treatment. The very elderly need to be looked at especially those who have other morbidity
Section_9:	Other treatments are coming, and Ibandronate is available. Suggest review 2007. Should include those with experiece of the very elderly as this group is at most risk
10/20/2005-Oct-2005 15:42:20	
role:	other
Section_1:	1.5-1.6: Does this mean that inorder to go onto Teriparatide you must have a DXA if you are over 75 yrs old, even if the patient has multiple fractures and has been taking bisphosphonates? If a patient is over 75 and taking bisphonates they don"t require DXA and therefore it wont be known if the T score falls below the pretreatment baseline level, so does this mean they won"t be eligible for teriparatide?
10/21/2005-Oct-2005 14:10:16	
role:	NHS Professional
Section_1:	1.6 Over 75 yr old patients may not now have a pretreatment baseline if they presented initially with a fracture 1.7 This is unrealistic as people will not take a drug if it upsets them irrespective of whether they have a well defined severe side effect or not. Surely cheap generic alendronate will alter the conclusions
Section_2:	2.3 and 2.4 the T score definition of osteoporosis is conflicting. Should be below -2.5
Other comments received by non consultees and commentators	
Pharmaceutical industry	1. "Whether you consider that all of the relevant evidence has been taken into account" We consider that all of relevant evidence has been taken into account. 2. "Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate" We wanted to question whether the use of a 10 year time horizon in the Assessment Group's model is appropriate. This horizon is based on an assumption of 5 years treatment plus 5 years linear decline to no treatment effect. It is unclear what evidence base the assumption of 5 years maximum treatment time is based upon considering the lifelong nature of osteoporosis and its treatment. Indeed, a recent survey indicates that 70% of UK physicians believe that bisphosphonate treatment should last indefinitely and only 24% thought it should last for between 3 and 5 years (IOF, "The Adherence Gap" Survey). It is also unclear as to what assumptions were made about the relationship between treatment time and the long-term effect or "offset" time of treatment. We would like to suggest that an appropriate assumption would be that the offset time should be of equal proportion to the time on treatment rather than a fixed offset independent of treatment duration. In summary, we wondered whether a 'lifetime' horizon for the cost-effectiveness model would provide for a more accurate assessment of the treatments under consideration. When adopting a lifetime horizon, the results of the cost-effectiveness analysis of bisphosphonates could be significantly different and the current recommendations for women under 70 years might also change. 3. "Whether you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS" We consider that the provisional recommendations of the Appraisal Committee are appropriate. We would however like to suggest that the Appraisal Committee give consideration to stressing the issues around compliance with bisphosphonate treatments even further in the wording of the guidance. The Committee already recognises the importance of compliance in their statement in paragraph 4.3.12, where it is noted that "compliance with antiresorptive therapy is generally low, and there is evidence that cost effectiveness is sensitive to compliance". The importance of ensuring that patients comply with their medication is therefore paramount in ensuring both the clinical and cost effectiveness of the recommended treatments.

	We respectfully suggest below how the issue of compliance might be further stressed in the final guidance should the Committee wish to do this: - In the recommendation outlined in 1.2, we would suggest that in addition to the considerations mentioned for proven effectiveness profile against tolerability and adverse effects, the likelihood of patients complying with the chosen bisphosphonate should be considered by clinicians. This statement would be supported by the comments made by the Committee in section 4.3.13 - In section 3.5, the Appraisal Committee recognises that gastrointestinal side- effects are common with bisphosphonates. We would like to suggest that this statement is qualified that these side effects are common with oral bisphosphonates - It is unclear in the provisional guidance as to what the Committee's views are on bisphosphonate frequency of dosing. There is evidence available establishing a clear causal relationship between frequency of dosing, side effects and compliance. The SIGN (Scottish Intercollegiate Guidance Network) guidelines for the Management of Osteoporosis state that the risk of gastrointestinal symptoms can be lessened by using the once weekly preparations. (SIGN Guideline 71, 2003). In Thompson et al, the frequency of administration of bisphosphonates is also well recognised as being an additional factor for compliance. We therefore wondered whether a recommendation on the frequency of dosing might also be appropriate. - In section 7.3.3, we wondered whether the likelihood of compliance might be added to the considerations made by the patient and their physician when choosing a bisphosphonate - In relation to the Proposed Recommendation for Further Research, we wanted to point out that there are already head-to-head trials on-going in this area such as the MOTION Study. We would be more than happy to share data recently collected on compliance and persistence with bisphosphonates if this would be helpful to the Committee. We also noticed that the titles of Appendices B and C are incorrect.
Patient Group	The guidelines only address primary and secondary prevention of fractures in postmenopausal women with osteoporosis and so do not address specific requirements for people with osteoporosis or reduced bone density due to coeliac disease. The guidelines should state that recommendations are not relevant for people with coeliac disease. [Comment also made for Primary]
Pharmaceutical industry	Following our review we would like to raise the following concerns with respect to this proposed guidance: The guidance acknowledges the significant morbidity associated with osteoporotic fragility fractures. Primary prevention measures provide an opportunity to intervene prior to the onset of a clinically apparent osteoporotic fracture. As such, [we] believe that establishing such restrictive entry criteria runs counter to a public health remit whereby preventative strategies are seen to be of equal value to curative strategies. With regard to the economic modelling, we would like to query the rationale behind selecting £20 000/QALY as the maximum acceptable ICER. The guidance as it stands does not appear to provide provide any justification to support this assumption. The rationale put forward that the target population for this intervention consists of women who are well and asymptomatic does not seem rational given the morbidy associated with osteoporotic fragility fractures in previously asymptomatic osteopaenic or osteoporotic patients. The reference case as advocated by NICE takes into account that benefits and costs of a given health technology occur at various time points and this is taken into account by the application of discount rates. It therefore is fundamentally against NICE's recommended approach to assessing cost-effectiveness of technologies to bias against those whose benefit occurs in the future. Furthermore, It seems prejudicial at this stage to state a cost per QALY threshold. It is our understanding that these thresholds are not explicit and that the cost effectiveness of interventions is considered alongside other factors when formulating NICE guidance. By setting a lower threshold, the assessment group could be seen to imply that women in this age group have a lower level of need when compared to patients with other medical conditions. This would seem to place a lower value on this particular patient population. We are sure that this was not the intention of the writers however, it is understandable that patients with this condition, which can severely impair quality of life, could take issue with this. We would like to question the rationale behind excluding the protective effect that raloxifene demonstrates against breast cancer. It would seem appropriate to include all benefits delivered by a given health technology as this impacts the overall mortality and morbidity of the patient. The secondary prevention guideline indicates that experts acknowledge that the possibility of preventing vertebral fractures and breast cancer simultaneously could be attractive to many women. The Appraisal Committee also agreed that in principle the side effects of using a technology should be considered but concluded that the breast cancer benefit should not be the sole factor in deciding whether raloxifence is a cost effective option for the treatment of osteoporosis. The Appraisal Committee does not seem to have accounted for patient choice in an appropriate manner. We believe that the risk benefit should be explained to patients and they should be given this option as an informed choice.