

Dear Carol

Re: Comments on: TA reports on Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women and Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women

I am writing these comments in my capacity as a clinical expert to the Appraisal Committee. Since I have already had input into the comments on these TA reports submitted by the Guideline Development Group, I will limit this response to more general issues raised by the processes of guidance and guideline development in the context of prevention of osteoporotic fractures (primary and secondary).

The opportunity to participate in the development of a clinical guideline for osteoporosis is one that I welcome. In particular, the remit of the GDG to explore the use of risk factors together with BMD in the assessment of fracture risk provides a challenge and an opportunity to advance the field. I hope that it will be possible to do this within the NICE framework, but at present I have difficulty in understanding how this can be achieved.

The major barrier to further progress with development of the clinical guideline within the NICE framework is the edict, from NICE, that recommendations from their guidance must be included in the clinical guideline. Since the guidance, but not the guideline, has a statutory basis this effectively means that the role of the GDG to develop clinically appropriate guidelines becomes redundant, certainly as far as prevention of osteoporotic fractures in postmenopausal women is concerned. Furthermore, in view of the marked discrepancies between the recommendations generated by the guidance and guidelines, it is hard to see how the two sets of recommendations could be reconciled. These differences have mainly arisen from the use of different risk factors, the arbitrary lowering of T-score intervention thresholds by the Appraisal Committee, and a fundamentally different approach towards identification of high-risk individuals (quasi-RCP versus the WHO approach).

It is my understanding that the development of guidance and guidelines on osteoporosis was intended to be a parallel process but despite some overlap in representation between the two groups this has not been achieved. As set out in the GDG response, despite the fact that risk factors were clearly within the remit of the GDG, the Appraisal Committee chose to ignore the evidence that had been systematically gathered and which has been shared with them for over one year. Throughout the process, comments submitted by the GDG to the Appraisal Committee on various drafts have been largely ignored and there has never been any formal response to these comments. During my attendance at the Appraisal

Committee meetings, GDG responses were not discussed unless explicitly raised by Peter Selby or myself. Examples of some of the major issues that have been raised by the GDG but have not been addressed by the Appraisal Committee include the time period over which fracture probabilities are expressed, lack of comparability of NICE intervention thresholds with others published for the UK, and the different efficacy estimates for fracture reduction used in the re-analysis for secondary prevention. There are many other examples.

Whilst I understand that the deadlines imposed on NICE allowed insufficient time to develop fully the WHO approach in their guidance, this could have been (and still can be) successfully achieved by the GDG within a reasonable timescale. However, the decision taken by the Appraisal Committee to jettison this approach in favour of one akin to the present RCP recommendations, together with their insistence that guidance recommendations are included in the clinical guideline, means that inclusion of the WHO risk assessment approach would be at odds with the guidance recommendations and would become essentially redundant in terms of its impact within the NICE guideline.

Many of these concerns have been expressed previously in GDG feedback to the Appraisal Committee. I hope that some means will be found by which the GDG can fulfil their function of producing clinically appropriate guidelines against a background of health economic analysis. It is difficult to see how this can be achieved in the setting of the NICE process as it currently operates.