Analyses of the cost-effectiveness of pooled alendronate and risedronate, compared with strontium ranelate, raloxifene and teriparatide.
Response of the Osteoporosis Guideline Development Group (GDG) to the assessment report

Additional Comment from

1. I am in complete and wholehearted agreement with the collective response provided on behalf of the osteoporosis Clinical Guideline Development Group and will not reiterate the points made in that response.

2. The original GDG terms of reference as laid out by NICE (and in keeping with the NSF for Older People) included a requirement to achieve an integrated and cohesive set of recommendations with respect to the NICE Guidelines for the prevention of falls and the management of osteoporosis. This is the principal reason for my membership of both groups.

3. The revised model as presented by the DSU report raised concerns about the needs of older women (in particular those over 75) for anti-resorptive therapy. The concerns with respect to the application of the model to the over-75's with self-identified or opportunistically assessed low-trauma fracture history are fully addressed in the GDG response, and I wholeheartedly endorse that response. If agreed, the clinically reasonable approach proposed should achieve adequate access to treatment for this high-risk group, including those determined under NICE Guideline 21 to be at high risk of falling.

4. There remains, however, some concern about the model as it affects those in this category below this age of 75, for whom it would still incorporate clinical decision making based on (1) universal BMD measurement and (2) the presence or absence of WHO-identified clinical risk factors (CRF's). This is because it has not been possible for the WHO CRF categories to quantify risk of falling for the purpose of the algorithm. Risk of falling is therefore excluded from the algorithm.

5. The contribution of falling from standing height or less to low-trauma fracture in older people is unquestioned. It's directly causative in over 90% of proximal femoral, distal radial and humeral fractures. The contribution of this risk relative to other fracture risk factors is, however, inadequately quantified in the literature (perhaps almost because it appears so self-evident?). It has not been systematically measured because of an exclusive (albeit in itself appropriate) preoccupation with pharmacological interventions for osteoporosis and a broad failure of investigators in pharmacological trials to detect and quantify its contribution and make this evidence available for epidemiological analysis.

6. Therefore, for example, under the current model (if I understand it correctly - Table 25) it would still be possible for a 70-74 yr old woman with a history of self-identified or opportunistically ascertained low-trauma fracture, a measured T-score of <-2.5, gross irreversible ataxia and macular degeneration, but no WHO-listed risk factors to be ineligible for treatment with pooled alendronate/risedronate.

7. I think this anomaly is clinically unacceptable and felt I should draw the problem to the attention of the TA Committee. While it might be reasonable to be hope the clinical anomaly would resolve with the anticipated pricing of generic alendronate, I still feel uncomfortable with the rationale as it stands.

8. One suggestion I have made is that a pragmatic weighting equivalent to perhaps two or three WHO CRF's might be attached to individuals found after multifactorial assessment under NICE Guideline 21 to be at very high risk of falling. This would, however, be a pragmatic

(rather than strictly evidence-based) strategy, and I think that is one reason why the GDG have felt reluctant to raise it collectively, and why I am writing individually.

9. Perhaps an important consideration here is that the assessment of fall risk has been costed separately for Guideline 21, so that there is no need to incorporate these detection costs within the present model.

I would be encouraged if the TA Committee could consider this issue in the forthcoming meeting.

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