RCGP COMMENTS ON THE ACD DOCUMENT

Alendronate, Etidronate, Risedronate, Raloxifene and Strontium Ranelate for the Primary Prevention of Osteoporotic Fragility Fractures in Post-Menopausal women.

1. Our perception was that the CQG had not been set in stone, and that some drugs with a higher CQG have been approved in the past.
2. In the cost effectiveness modelling no mention is made of the fact that Alendronate is now available generically.
3. The advice is that Primary Prevention is not cost effective under the age of 70. As GPs we need guidance on how to advise our patients in this age group.
4. I would like to see demonstrated what hip costs have been used and to know whether these include social services costs.
5. The use of a DXA at the hip has been advised. We need an explanation as to why lumbar bone mineral density has not been used. We also need advice as what to do in the absence of central DXA, as resources in the UK are limited. It may be useful to refer to the NOS Position Statement on Peripheral DXA.
6. We are advised that in women over the age of 75 with three or more clinical risk factors, there is no need for a DXA. However, it has been demonstrated that Bisphosphonates are less effective if T-scores are in the normal or osteopenic range. Many experts are unhappy about treating patients in the absence of more abnormal DXA results.
7. The risk factors now include parental hip fracture at any age. These changes need to be highlighted.
8. It is accepted that there are medical conditions independently associated with bone loss, such as rheumatoid arthritis. We need advice on what other conditions are associated with bone loss. These could be given within the document or a reference could be included, such as to the Royal College of Physician's Guidance on Osteoporosis.
9. For the purpose of this guidance intolerance of Bisphosphonates is defined as oesophageal ulceration, erosion or stricture. As symptoms of dyspepsia do not correlate well with oesophageal findings (NICE Clinical Guideline 17), this advice will increase the need for gastroscopy with its associated cost, morbidity and ultimately mortality. This needs to be included in the cost effectiveness modelling.
10. Many experts do not believe Etidronate is as effective as Alendronate nor Risedronate, as it does not have good hip fracture data. Strontium Ranelate, however, in the over 74 year old group does have good hip fracture data and so should be positioned above Raloxifene and Etidronate.
11. It would be useful to see the relative risks derived from the metaanalyses tabulated to make comparisons easier.

Alendronate, Etidronate, Risedronate, Raloxifene, Strontium Ranelate and Teriparatide for the Secondary Prevention of Osteoporotic Fragility Fractures in Post-Menopausal women.

1. I believe we need a clear definition of what is meant by Post-menopausal Osteoporotic Fragility Fractures. I have canvassed the opinion of several GPs and feel that there is a poor understanding of how to assess women in different age groups. This could be improved by giving examples of how management changes in different age groups even when the women experienced her fracture at the same age.
2. The advice is that hip DXA should be used to assess bone mineral density. It would be helpful to have an explanation as to why lumbar DXA is not advocated. Given the poor availability of central DXA in the UK it would be also useful to have advice on what alternatives should be used, perhaps a reference to the NOS Position Statement on the use of Peripheral DXA would be helpful.
3. I welcome the advice that Calcium and/or Vitamin D supplementation should be provided when clinicians are not confident that Calcium and Vitamin D levels are not adequate. We need advice on how to assess patients for this or at least references to other documents.
4. In the assessment of risk factors it is acknowledged that several conditions are associated with low BMD, such as rheumatoid arthritis. We need a more complete list than this or references to other documentation where we can find this advice.
5. It is unclear from this guidance as to whether or not all the Bisphosphonates are considered to be the same. Etidronate does not have good hip fracture data, whereas Strontium Ranelate does have this in the over 74 year old group. I therefore feel that Strontium Ranelate should be placed above Etidronate and Raloxifene.
6. In section 1.6 I welcome the reference to patients being fully adherent to treatment. However, I believe that we need an explanation as to what is meant by fully adherent (?80% medication possession ratio). I find it surprising that there is no comment made about the different adherence/persistence rates of the weekly versus daily Bisphosphonate dosing regimes. In this section I would also like to see some advice on what it considered to be a significant decline in bone mineral density.
7. Section 1.7 points out that intolerance of Bisphosphonates is defined as oesophageal ulceration, erosion or stricture. It is recognised that patient's symptoms do not correlate well with endoscopy findings (NICE Guideline 17) and so consequently to demonstrate intolerance patients will need to be referred for gastroscopy. This is obviously not satisfactory as it has a cost complication and associated morbidity and mortality. In any one year approximately 40% of the population have significant dyspepsia and this statement could unnecessarily lead to over investigation of patients.
8. In the cost effectiveness modelling it has not been pointed out that Alendronate is now available generically. Furthermore, it is not apparent whether social services costs have been included in this modelling.