

NICE and Osteoporosis Treatments: Secondary Prevention

As clinician members will be aware, NICE's return to this topic continues (see history at <http://www.nice.org.uk:80/guidance/index.jsp?action=byID&o=11704>). NICE, at our winter joint appeal (with NOS, SfE and BSR) were found to be proposing discrimination against patients who, through no fault of their own, could not take alendronate. Since then the English Court of Appeal, to whom a pharmaceutical company had recourse on behalf of patients requiring Aricept, has overturned NICE's earlier ruling that NICE could withhold economic models from interested parties such as patient's organisations, scientific societies and pharmaceutical companies (see separate posting on this web-site). In its ruling the Court determined that such models, paid for as they were by the Public Purse, could not be held confidential from the tax-paying public because there was no over-riding duty of confidentiality.

Although SCHARR has been asked to prepare revised economic models according to various specifications (see link above), I believe that in its next iteration NICE will have to recommend equality of access to treatments regardless of whether alendronate causes side-effects for the individual patient.

There remains however the vexatious issue of the strong apparent conflict between what NICE is likely to recommend and what appears reasonable to prescribe based on the use of the FRAX model in our clinics (www.shef.ac.uk/FRAX/). This conflict is made more striking because of the similar mathematical methodology and risk factors underlying the WHO-FRAX and the NICE-SchARR models. Where they differ is in the assumptions concerning how medical history, age, anthropometric measurements etc impact on fracture risk. In part this is because NICE have allowed SchARR to ignore the literature published in the last three years (particularly the series of meta-analyses of risk factors for fracture across the world's data-bases published by John Kanis et al) but maybe also for other reasons.

We need to determine why these differences have emerged and to have a frank and open discussion as to how best to proceed for the benefit of our patients. NICE and the NHS have been accused of operating rationing by subterfuge by adopting a too-low value for a quality-adjusted life year; but it is not my purpose here to query this value (currently either £20,000 or £30,000) since the allocation of resources between health and other choices for public spending is a political decision. The BRS's mission is in education and research – ie to throw light on important things where there is currently darkness or obscurity. The BRS needs to bend every sinew to ensure that the model used to determine who gets anti-osteoporosis treatment is based on the most up to date published scientific data. Currently the WHO document "Assessment of Osteoporosis at the Primary Health Care Level – WHO Scientific Group Technical Report 2007" is up to date and NICE-SchARR have done little to update their evidence base since 2004-5.

<http://www.nice.org.uk/nicemedia/pdf/OsteoporosisPrimaryMar08DSUreport.pdf>).

I therefore on behalf of the Society and in consultation with the Committee wrote to NICE a month ago explaining my concerns about the scientific quality of the evidence NICE was using. I pointed out that the lay person would be thoroughly confused by any apparent conflict between the NHS and WHO recommendations and would suspect a raw deal if the NHS proposed less than whatever the WHO FRAX model suggested was reasonable. Since then, the Court of Appeal has ruled that Economic Models used by NICE should be made available to interested parties and may therefore be critiqued for scientific accuracy. It is now my principal aim for the Society or its trusted allies to get hold of the NICE model and examine its concordances and discordance with the FRAX model. This critique will be an arduous job, involving the translation of computing code for comparison with published data. Once this is done the BRS should be in a better position to advise members and the Public concerning the benefits of using, or not using, anti-osteoporosis treatments in any common circumstance for which evidence has been collected.