Osteoporosis stakeholder workshop, 26th May 2011
Notes from the Discussion groups

Scope section	Question
4.1 Population • Adults	**Is the population appropriate?**
• Only include people above the age of 50, as the risks were deemed very low below this age. Also include high risk sub-groups, like people on steroids. However information on young patients would be helpful. • Specify adults over the age of 18 years • Should we define the group to whom you apply the tool at the outset or is it a question? Who should have assessment of fragility fracture risk?	
Clinical Management **4.3.1 Key clinical issues that will be covered** a) Evaluation of fracture risk assessment tools: • WHO-FRAX • ORAI (Osteoporosis Risk Assessment Instrument) • SCORE (Simple Calculated Osteoporosis Risk Estimate) • OSIRIS (Osteoporosis Index of Risk) • WHI hip fracture risk factor • FORE (Foundation for Osteoporosis Research and Education) • GARVAN • ABONE (Age Body Size No Estrogen) Score • NOF guideline (National Osteoporosis Foundation, USA) • SOFSURF (Study of Osteoporosis Fractures—Study Utilizing Risk Factors) • DOEScore (Dubbo Osteoporosis Epidemiology Study) • EPESE (the Established Populations for Epidemiologic Studies of the Elderly) • Qfracture score • Minimum data set b) Special consideration will be given, if appropriate, to the performances of the tools in the following groups: • Premature menopausal women • Men • People with frequent falls • Ethnicity • Populations with Long-Term • Glucocorticoid Use (≥3 months)	**Are the assessment tools listed commonly used?** **Are there any other assessment tools not listed?** **Are there individual parameters that need to be examined?** **Is combination of risk factors an issue that needs to be examined?**

• Add the Qfracture tool (for primary prevention)
• Need to be aware of what generation people of ethnic groups are from
• We should use just 2: WHO-FRAX (but look separately at the tool when includes BMD and BMI) and Q Fracture, as these are the only 2 routinely used in the UK. Also used is DEXA+age (clinical judgment), fracture+ age
• Need to include:
  ○ people who have had treatment for breast or prostate cancer
  ○ people who have a fragility fracture despite already being on treatment.
  ○ people in care homes
• It is unclear how you can evaluate the “fracture risk assessment tools”. It is assuming that you will find validation data on these tools. A study where they compared FRAX vs usual care is the Scoop
• We need to pay special attention to the populations used to create the assessment tools. A lot of them used healthy women.
• It needs to be clear if these tools will be used for primary or secondary prevention of those at risk of fracture i.e. have they already had a fracture or is it mass screening of the population?
• It was suggested to look at combinations of tools
• Few tools on list have longitudinal follow up; there is a longitudinal study from the Osteoporosis	

society of Canada.

- Different populations would need different tools to be used, therefore it would be a good idea to come up with a risk assessment for different populations and stratify the patients according to their risk of fracture pathway.
- Need to describe those who need screening i.e. those who fall are good predictors of those likely to fracture. i.e. age?
- Discussed the importance of a Falls Risk Tool being included in guideline.
- Discussed the need to define what a fragility fracture is. Also, the need to define what the different risks of fracture is (high, moderate, low).
- Identify fracture risk and how many people will benefit from treatment: for the guideline to have validity, this needs to be addressed
- Questioned whether this guideline will be able to assess long-term risk.
- The FRAX tool leads to a web site that recommends treatments. However, this is potentially biased given pharma links by the group who designed FRAX.
- Another issue with FRAX is that although it asks you about your fracture history, it doesn't incorporate the different levels of risk certain fractures have on your future risk of fracture.
- It was felt that people who have received treatment for cancer are a very important sub-group who should be included.
- The group felt that prognostic accuracy of the tools is generally poor. It is important to look at whether each tool had been validated, where (in community?) and when it was done.
- Tools may be good at predicting non-vertebral fractures but vertebral fractures are ones for which there is most evidence about prevention
- It was suggested that one way of looking at the tools is by stratification:
    - Aspect of fracture targeted- e.g. bone remodelling/balance/activity
    - Population developed in
    - Ease of use
    - BMD included in the tool?
    - Validation including test/retest
    - Incidence/prevalence
- The stakeholders agreed that the WHO-FRAX, Q-fracture and DoeScore are the main risk assessment tools and we should look at BMD on its own as a predictor.
- Qfracture includes components of co-morbidities and FRAX do not include groups that are at high risk – look at whether co-morbidities are included in other tools. A paper that is due to be published found FRAX and Q fracture gave similar results.
- Age, previous fracture and BMD could be the more important parameters in predicting fracture risk.
- The group suggested that a few tools could be recommended for GPs, depending on the outcome(s) and whether it fits best with the target group.
- There are some simple clinical measures/indicators that could be potentially effective and cheaper in cost (this could be done as self-assessment prior to FRAX or other risk assessment tools by e.g. physiotherapists), such as:
    - Change in height
    - Age
    - Grip strength
    - Balance (balance reduces fall risk, but not fracture risk)
- Different measurements of bone density:
    - Bone marker test might be more important for monitoring compared to doing repeated bone scans; could be useful for specific subgroups as they are relatively easy to do. The two main bone remodelling markers are C-terminal peptides and PIMP. These biomarker studies, however, are not often validated/ replicated.
    - Heel ultrasound
    - Vertebral X-ray – just as good as DEXA?
- Other subgroups suggested are:
    - People with eating disorder (anorexia/bulimia) – would fit under "premature menopausal women" as this group is associated with hormone (oestrogen) depletion
    - People with gastro-intestinal problems
    - Young men
    - People with renal failure
    - People with epilepsy – would fit under "people with frequent falls" (There are some data

supporting it being an independent risk factor, may be not a priority)
    - People who received treatment for cancer – a risk factor in itself
    - People with visual problems (e.g. cataract, post-surgery), associated with increased fall risk
    - People who received thyroid treatment
    - People who received hormone replacement therapy
    - Ethnicity/race – often not well validated
    - Should practices screen for people with previous fracture?

Clinical management **4.3.1 Key clinical issues that will NOT be covered** • Pharmacological intervention for prevention of fractures • Risk assessment of people who have received treatment for cancer • Fracture and post-fracture management • Information and support for patients and carers	**Is the list of appropriate?**

- Need to exclude:
    - assessment of calcium and vitamin D
    - dietary advice
    - patients with an eating disorder
    - patients on current long term progesterone injections
- This suggests that the users of guideline needs to consider other factors before they use the fracture risk tools, i.e. race, osteomalacia, Vit D, diet
- It was highlighted that the usefulness of the tools may depend on whether the questionnaires are self administered or not. A lot of patients think there is a difference between fracture and a break. For this reason, we should include patient information on fractures and what the risk of fracture means. Also, a clinician or health carer should help the patient understand what their risk assessment means.
- It was suggested that we should exclude the issues relating to Vitamin D intake and nutrition and eating disorders.
- It was suggested that we should look at the NICE 2004 guideline on risk of falls.
- It was suggested that the guideline should include cancer patients or patients who are currently receiving treatment for osteoporosis.
- It was agreed that people who have already had previous assessments should be excluded.

4.4 Main outcomes
• Fracture incidence over a period of minimum 1 year:
    - vertebral
    - hip
    - forearm
    - all fractures
	Are there any outcomes not listed that should be included?

- Should include all Fragility fractures, rather than all fractures.
- Regarding vertebral fractures – a lot of vertebral fractures are missed. Questionable whether DXA can detect hidden fractures.
- There was confusion because of the term “outcome”, which suggested that the efficacy (specificity and sensitivity) of the assessment tools would be assessed in terms of their ability to prevent these outcomes. A better term would be reference standard/target condition/validity of tool.
- Add acceptability of the tool. Need to specify if fracture confirmed clinically or by imaging
- The group felt that fracture incidence measured over minimum 1 year is too short – should replace it with 2-3 years (trials are usually studied over 3 years). Fracture incidence after a year is most commonly found in high risk groups such as people >75years.

4.5 Economic aspects	**Given that the guideline does not cover treatment, is it important to look at cost-effectiveness of the assessment tools?**

- It was agreed that economic aspects should be looked at, because the issues of sensitivity and

specificity have cost implications in themselves.
- Need to do costing of different tools

GDG Constituency	**Do we have the right expertise on the group?** **Are there any expertise we are missing from the group?**
• Specialist bone metabolism (x2) • Care of elderly specialist • GP • Rheumatologist • Specialist nurse with an interest in prevention of fragility fractures • Expert of risk assessment (Epidemiologist/ /Statistician) • Patient/carer members (x2)	

- Should include: an endocrinologist, community health carer in primary care, geriatrician – specialist in osteoporosis, patient/carer (especially for dementia patients).

- Rheumatologist/endocrinologist
- Community nurse
- Pharmacist
- Geriatrician with special interest in fragility fracture rather than care of elderly specialist

- Specialist bone metabolism (x2) (1 could be an endocrinologist)
- Care of elderly specialist
- GP (x2) (1 with interest in osteoporosis and 1 general GP)
- Rheumatologist
- Osteoporosis nurse practitioner
- Physiotherapist (Nurses do not always carry out bone assessments)
- Service manager or commissioner
- Expert of risk assessment (Epidemiologist/statistician)
- Patient/care members (x2)
- Somebody from care home organisation (?)
- Radiologist with special interest

General	**Were there any other issues raised during the discussions that should be noted?**

- Definitions: 3.1 b) Fractures of the digits, skull, face and scaphoid are excluded as fragility fractures
- Epidemiology: 3.2 d) More recent figures available from the National Hip Fracture database
- Guideline under development: 5.2 Add patient experience
- General – Are we interested in modifiable risk? What is the tool being use for? To start treatment (some treatments don't work for some risk factors). Are the tools being used to triage people for treatment? Are we looking at primary or secondary prevention? We don't currently do risk assessments for primary prevention. Primary prevention patients don't get expensive treatments. Those at high risk need to be assessed. People who fall are at high risk: the guideline needs to include falls risk assessment tool. It would be helpful to be able to tell people what their risk is. Would be helpful to develop similar tool to Sheffield tables on cardiovascular risk. There is currently a trial on FRAX vs usual care called the *Scoop* trial
- Unclear what the point of the tool is – is it to detect those who need to start treatment or those at risk of fracture?
- It was discussed that there is not much use in detecting those at risk of fracture if treatment is not going to be offered. Keeping in mind, secondary prevention treatment is more aggressive. It was later discussed that this guideline will assess risk but not discuss treatments, since the TA will take over from this point.
- Need to produce something which translates the questions the tool uses in to language the patient can understand
- It was discussed if we wanted an intervention threshold (a number but set in the context of sound clinical advice)
- It was suggested that interaction effects should be looked at