Comments on the ACD Received from the Public through the NICE Website

Name	
Role	Other
Other role	Policy Lead, British Society for Rheumatology
Location	England
Conflict	No
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"The current appraisal is extremely thorough and inclusive of all relevant published literature on the techniques. The summary reflects published findings and consensus clinical opinion quite well. The BSR would be concerned that there is proposed limitation of access to the procedure, as advised by NICE, to within 6 weeks of the fracture?. Firstly, as indeed the document notes, there is weak evidence for such a stipulation on timing for intervention, and secondly the advice does not reflect the reality of clinical management where often patients present a late to clinicians, and may be delayed before ?optimal? pain management can be implemented, reviewed and changed accordingly (realistically a number of times ie to optimum). To accommodate the ?6-week rule? the general approach to assessment of acute back pain will need to be addressed ? imaging early, changes in referral triage processes all with implications for established clinical management pathways. To accommodate fast-track referral and assessment there may be extra cost. More pragmatic (and in keeping with the uncertainty in terms of reported optimum time to intervention) would be to relax the time to intervention by rewording to ?up to 3 months? perhaps then indirectly ensuring specialist assessment, enough time to optimise pain control, triage of non-fracture cases and the input of an experienced assessor who would conclude pain is arising directly from the relevant vertebral fracture and not elsewhere. It is in NICE?s interests to accommodate specialist assessment given that is the evidence base - ie patients in the studies reviewed, were all assessed by specialists! These comments would not apply if efficacy and/or cost-efficacy was robustly disproved for the time to intervention from fracture onset to procedure of >6 weeks to <3 months."
Section 2 (Clinical need and practice)	
Section 3 (The technologies)	
Section 4 (Evidence and interpretation)	
Section 5 (Implementation)	
Section 6 (Related NICE guidance)	
Section 7	

(Proposed date for review of guidance)	

Name	
Role	NHS Professional
Other role	
Location	England
Conflict	No
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	On balance I am happy/in support of the overall recommendations and content of the ACD
Section 2 (Clinical need and practice)	
Section 3 (The technologies)	
Section 4 (Evidence and interpretation)	
Section 5 (Implementation)	"It is important that clarification is provided as to Operative Placebo Local Anaesthesia (OPLA). This procedure may alleviate pain, as part of the optimal pain management described in point 1.1 of the appraisal committee?s preliminary recommendations, in the short term, but will not treat any progressive vertebral collapse/stablise vertebral body bone/micro movement. This procedure is more likely to be used downstream - for patients who have not had cement augmentation, and, as a result have persistent/chronic pain post fracture healing (sometimes in a deformed state). Based on my knowledge of the mortality database and NHS clinical experience, I am supportive of the assumption regarding incremental mortality gain cited in the ACD for patients treated with cement augmentation."
Section 6 (Related NICE guidance)	
Section 7 (Proposed date for review of guidance)	

Name	
Role	Private Sector Professional
Other role	
Location	US
Conflict	Yes
Notes	

Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There should not be a limit to acute fractures. There is ample evidence that even chronic painful fractures benefit from treatment. 1. Syed MI, Shaikh A. Does Age of Fracture Affect the Outcome of Vertebroplasty? Results from Data from a Prospective Multicenter FDA IDE Study. J Vasc Interv Radiol 2012; 23.1416-1422. 2. Brown DB, et al. Treatment of Chronic Symptomatic Vertebral Compression Fractures with Percutaneous Vertebroplasty. AJR:182;319-322. There is also evidence that VCF's may continue to be painful despite conservative treatment 1. Suzuki N, et al. The course of the acute vertebral body fragility fracture: its affect on pain, disability and quality of life during 12 months. Eur Spine J. 2008;17(10):1380-90.
Section 2 (Clinical need and practice)	Vertebroplasty should not be limited to patients who have failed conservative treatment. There is ample evidence that conservative therapy increases the risk of mortality in some patients. In the first longitudinal, population-based comparison of mortality risk between surgical and nonsurgical groups, a Medicare dataset from 2005 to 2008 containing 858,978 patients with vertebral compression fractures was analyzed (36). This included 119,253 patients treated with BKP, 63,693 patients treated with VP and the remainder treated with NSM. The findings at the 4 year follow-up showed that the VA treatment group was 37% less likely to die than the NSM group and that the adjusted life expectancy was 85% greater for the VA group. The adjusted life expectancy for the BKP was greater for that of VP and was increased 115% compared to the NSM group. Overall the median life expectancy was increased between 2.2 and 7.3 years across all treated groups as compared with nonsurgical management. 1. 36. Edidin A, et al. Mortality Risk for Operated and Non-Operated Vertbral Fracture Patients in the Medicare Population. JBMR, 2011: Feb 9. DOI: 10.1002/jbmr.353
Section 3 (The technologies)	
Section 4 (Evidence and interpretation)	
Section 5 (Implementation)	
Section 6 (Related NICE guidance)	
Section 7	

(Proposed date for review of guidance)	