British Pain Society

Comments on the Assessment Report for the Health Technology Appraisal of Spinal Cord Stimulation for Chronic Pain of Neuropathic or Ischaemic Origin

The British Pain Society wishes to comment upon the Assessment Report from three perspectives: general comments on the process and methodology used to inform the report, specific comments on the recommendations within the report, and other information we believe the Appraisal committee should consider.

General

1. The role of spinal cord stimulation in a pain management care pathway is not fully considered. It is important that first line therapies are more clearly detailed i.e. what should have usually been tried before a stimulator is inserted. Most importantly, whilst the importance of psychological assessment is mentioned in many of the trials the use of psychological therapies to manage pain is not discussed despite extensive evidence to their effectiveness.

a. C. Norrbrink Budh, J. Kowalski and T. Lundeberg, A comprehensive pain management programme comprising educational, cognitive and behavioural interventions for neuropathic pain following spinal cord surgery, J Rehabil Med **38** (2006), pp.172-180.

b. Lewin RJ, Furze G, Robinson J, et al. A randomized controlled trial of a self-management plan for patients with newly diagnosed angina. Br J Gen Pract 2002;52:194–201.

c. G.L. Moseley, Graded motor imagery for pathologic pain. A randomized control trial, Neurology 67 (2006), pp. 2129–2134.

2. Trial inclusions: there is no mention of Medtronic's involvement in sponsorship of the North trial. Tables should include whether the trial was sponsored by industry, as the majority have been. (Pages 24, 121, 139.)

Specific

1. We are pleased to note that the report supports SCS versus re-operation or CMM for FBSS both for clinical and cost effectiveness. However, the executive summary (p5, 2.5) omits to highlight the clinical effectiveness of SCS over re-operation in FBSS.

2. We note the situation for CRPS over CMM is a little less certain. The report seems to support its efficacy but there are concerns on the cost effectiveness. What they are doing is using available literature and assumptions, plugging into their economic model and then stressing it. Our UK health economy will support the cost of a QALY at less than

£30,000. They use the concept of the Incremental Cost Effectiveness Ratio which is the incremental additional cost of the treatment under investigation over and above the cost of normal care divided by the incremental improvement in utility (efficacy) over and above that achieved by normal care. SCS has high start up costs and moderate maintenance costs. The economic model will vary according to the time horizon of the disease (estimated as 15 years in this model).

Please note that average age at insertion in CRPS was 40 years old. This can be a lifelong condition, so a more realistic time horizon may be 25 to 30 years. The report also examines device longevity and initial costs of device for CRPS. Depending upon how the model is stressed then the cost per QALY will increase above the £30,000 threshold. However this does not take into account the improvements in device technology such that we assume lower lead displacement and fracture rates and longer IPG duration due to rechargeability.

3. The cost effectiveness for SCS in Angina versus CABG and PCI is dominant for SCS although the report is slightly less forthcoming due to the fact that the methodology of the published studies makes it more difficult to plug into the economic model.

4. The report accepts that it cannot determine an ICER and QALY for SCS in CLI. However this is where clinically if an elephant looks like an elephant then it is an elephant. It has been demonstrated that if microcirculation responds to SCS then there is a high chance of preserving a limb intact (Amann W, Berg P, Gersbach P, Gamain J, Raphael JH, Ubbink D. Epidural spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia – results of the European Peripheral Vascular Disease Outcomes Study (SCS-EPOS). *European Journal of Vascular and Endovascular Surgery*), which has got to be better than amputation which is the standard of care in many NHS hospitals.

5. Transferability of SCS evidence to other neuropathic pain states of peripheral origin has not been addressed in the report. Identifying these groups in sufficient numbers with similar aetiology is difficult. Many of the reported series are of mixed neuropathic pain aetiology, albeit most "FBSS". Separately analysed, the FBSS group showed no difference in outcome to the whole group. EFNS guidelines include SCS in refractory neuropathic pain as a treatment option. Many other case series include other neuropathic pain indications with apparent success. Consensus view on SCS already determines that SCS is less likely to be successful in neurogenic central pain.

6. Guidelines. The musculoskeletal framework is not mentioned and is highly relevant for Failed Back Surgery Syndrome (page 11).
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4138413]

7. Minor points

a. There is a case report of tolerance to a device because a patient's needs were not fully addressed (page 108). Eric Parisod, Robin F. Murray, Michael J. Cousins**.**

Conversion Disorder After Implant of a Spinal Cord Stimulator in a Patient with a Complex Regional Pain Syndrome. Anesth Analg 2003;96:201-206.

b. HES statistics. Until 2007, the capability to code procedures related to spinal cord stimulation was very limited (page 13).

Other Information

1. Trial designs. The Appraisal committee should acknowledge that, given the complex nature of chronic pain, where a wide variety of factors affect pain reporting, the true impact of spinal cord stimulation can never be fully explored by a single randomised controlled trial. Even within a randomised trial patients are likely to have multiple interventions to help pain. In future, it would be better to place testing of spinal cord stimulation within the context of a complex intervention framework. http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372

2. Turner et al make two important points in an editorial that accompanies the PROCESS trial [doi:10.1016/j.pain.2007.07.029]. Firstly, evidence based approaches to manage back pain in the early stages would decrease the amount of back surgeries and obviate the need for many stimulators. Secondly, industry ties make it difficult to assess the trials.

3. The Dutch Healthcare Insurance Board carried out a very similar review just prior to the publishing of the PROCESS trial, although angina was not considered. They highlighted difficulties regarding the economic modelling. The Appraisal committee should consider the points raised in this review. [http://www.cvz.nl/resources/rpt-Kleijnen%20SCS-spinalcordstimulation_tcm28-22555.pdf]