

Eloise Saile
Technology Appraisals Project Manager
National Institute for Health and Clinical Excellence (NICE)
MidCity Place
71 High Holborn
London
WC1V 6NA

21 April 2008

Dear Ms Saile

Re: Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin

P1-P10: It appears that only pharmacotherapy is considered as an alternative management of neuropathic pain. As part of the process the review should consider inclusion of a biopsychosocial approach to assessment and management for all of the pain conditions under review.

P 11: The musculoskeletal framework is not mentioned and is highly relevant for Failed Back Surgery Syndrome

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4138413]

P13: It is important that first line therapies are clearly stated. A care pathway to spinal cord stimulation would be helpful i.e. what has commonly been tried before they had a stimulator 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.

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

Thus spinal cord stimulation's place in a pain management care pathway is not fully considered.

P21: HES statistics are inaccurate as until 2007 the capability to code procedures related to spinal cord stimulation was very limited. Thus the activity related to spinal cord stimulation in the NHS is most probably undercaptured.

P24, 121, 139: 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. With regard to trial design there should be consideration given to better trial designs rather than just consideration of the quality of placebos etc. 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. It would be better to place testing of spinal cord stimulation within the context of a complex intervention framework. [www.mrc.ac.uk/complex_packages.html].

P108: As the nervous system is plastic and pain is controlled by a variety of processes, including psychosocial factors, then pain levels will rise no matter whether a stimulator is inserted if other processes are ignored. Tolerance to a device may occur because a patient's needs have not been fully addressed.

[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].

Other reviews: Judith Turner makes two important points in an editorial that accompanies the PROCESS trial [[doi:10.1016/j.pain.2007.07.029](https://doi.org/10.1016/j.pain.2007.07.029)]. Firstly evidence based approach 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. The current draft guidelines do not make it obvious that these concerns have been considered.

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 guideline group should consider the points raised in this review

[http://www.cvz.nl/resources/rpt-Kleijnen%20SCS-spinalcordstimulation_tcm28-22555.pdf]

I trust these comments are of use.

Yours sincerely,

A black rectangular redaction box covering the signature area.