Health Technology Appraisal of Spinal Cord Stimulation for Chronic Pain of Neuropathic or Ischaemic Origin (HTA 07/08): Comments on the Appraisal Consultation Document

The comments contained in this document have been made on behalf of the Pain Relief Foundation (PRF) and the Walton Centre for Neurology and Neurosurgery (WCNN) in Liverpool. The PRF is a charitable organisation set up to facilitate research into the causes and treatment of chronic pain. It is closely associated with the Pain Clinic at WCNN and the team are directly involved in the work of the PRF.

[redacted]
Pain Management & Neuromodulation
The Walton Centre for Neurology & Neurosurgery
Liverpool

---

i) Do you consider that all of the relevant evidence has been taken into account?

We have grave concerns that the international wealth of clinical experience in this area is not being given enough weight in the decision making process. Surely when there is not enough RCT evidence available it is appropriate to use clinical experience and non-RCT evidence to support the existing RCT evidence. It is appropriate to recommend further research, but we strongly believe that patient care will be compromised if the HTA concludes that SCS cannot be used for any condition, except FBSS, unless it is in the context of research as part of a clinical trial. The evidence for SCS, as a surgical procedure for the treatment of a range of pain conditions, is actually very good. There are few other surgical procedures that are supported by several well designed RCTs.

As discussed in our original submission, it is essential that the full range of evidence is taken into consideration and that treatment with SCS is not reserved solely for those conditions with RCT evidence. It is reasonable that further research is recommended, as long as treatment with SCS is not withheld from the wider range of neuropathic pain conditions known to respond to it in clinical practice. RCTs are not straightforward for this type of therapy and it is extremely difficult to provide any reasonable type of placebo control. However, comparison to standard treatment is not unreasonable; although this in itself proves a problem in many cases. For example, in the case of phantom limb pain there is no consensus as to the standard treatment and a wide range of therapies have been advocated over the years. A survey in 1980 identified 68 different methods, of which 50 were still in use (Sherman et al, 1980). As with pharmacological research, it may be that the results of RCTs in certain key conditions are then extrapolated to other similar

conditions. For example, many of the studies of the newer anticonvulsant drugs were focussed on the treatment of painful diabetic neuropathy and post-herpetic neuralgia, but the drugs are licensed for the general treatment of neuropathic pain. Therefore, it could also be argued that if SCS has been demonstrated to be effective in certain key neuropathic pain conditions, the results could be extrapolated to other similar neuropathic pain conditions. This again strengthens the argument for carrying out trials of SCS before permanent implant, especially in those conditions without RCT evidence.

ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?

We would strongly support the view that individual patients' battery usage can vary greatly in relation to the area of pain distribution and the complexity of the pain condition.

We would also agree with the general consensus that there are significant statistical flaws in the Kemler (2006) paper in relation to the five year follow up outcomes, which may lead to an underestimate of the long term outcomes. This loss of effect does not reflect our own clinical experience of the long term effectiveness of SCS in CRPS patients.

iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

No, we have grave concerns that provisional recommendations on the guidance for the NHS would have a significant and detrimental impact on patient care.

As stated in our original submission, in the NHS chronic neuropathic pain is currently primarily treated using a pharmacological approach. Despite a considerable increase in randomised placebo-controlled trials in neuropathic pain over recent years, the medical treatment of neuropathic pain is still far from satisfactory, with less than half of the patients achieving significant benefit with any pharmacological drug (Attal et al, 2006). Efficacy is limited in the drugs used to treat chronic neuropathic pain. Drug-related adverse effects are common, not only because of the specific medications used, but also because many of the patients with this condition are older, take multiple medications, and have co-morbid illnesses (Dworkin et al, 2003). Many patients fail pharmacotherapy because they are unable to tolerate the side effects.

At the WCNN, SCS has been used since the early 1990s and approximately 600 - 700 patients have been implanted since that time. The WCNN has successfully treated a large number of patients with SCS for some of the conditions identified in the RCTs, but also for other conditions that do not have RCT evidence. These conditions include: neuropathic pain secondary to peripheral nerve damage (related to trauma or surgery), traumatic brachial plexopathy: (partial, not avulsion), post-amputation pain (stump and phantom pain), diabetic neuropathy, facial pain, neuropathic pain associated with MS, and post-herpetic neuralgia. It is essential that such patients are not denied treatment with SCS purely on the basis that an RCT has not been carried out for a particular condition, when there is strong clinical evidence to support its use.

We are also extremely concerned about the potential reaction from PCTs if the guidance is released with its current conclusions and how this would impact on patients who currently have SCS for conditions other than FBSS. If funding for revision surgery or IPG replacements is then refused, a huge number of patients who are currently being successfully treated with SCS on a long term basis could be denied ongoing pain relief. This has serious ethical and humanitarian implications.

In a recent WCNN audit (2006) a large number of the successful SCS trials that were carried out were for CRPS and post surgical neuropathic pain. In fact, the success rate of the trials for CRPS was actually slightly higher than for FBSS (90.9% vs 90%). The WCNN has successfully managed a large case load of patients with SCS for a range of conditions for over 15 years. Surely this huge wealth of clinical experience must count for something. We plan to carry out further research on the other conditions that respond to SCS. However, we sincerely hope that our ongoing and future treatment of patients with SCS for complex pain problems (that have often been refractory to an array of other treatments) is not curtailed by the outcome of the HTA, when SCS has been shown to be so effective in our hands for so many years.

FBSS and CRPS are two examples of neuropathic pain conditions. We believe that if NICE conclude that there is a good evidence base for the use of SCS in the treatment of FBSS, then the results should be extrapolated to other neuropathic pain conditions. This is seen to be appropriate in many pharmacological studies, as stated earlier in the text. Such drugs are licensed for the treatment of neuropathic pain in general and not restricted to solely the conditions studied in the RCTs. Surely it is appropriate for NICE to adopt the same approach for SCS when there is significant RCT evidence for two neuropathic pain conditions.

iv) Are there any equality related issues that may need special consideration?

No specific comments.

References

Attal N, Cruccu G, Haanpaa M. et al (2006) EFNS guidelines on pharmacological treatment of neuropathic pain. *European Journal of Neurology.* **13**: 1153-1169

Dworkin R, Backonja M, Rowbotham M. (2003) Advances in Neuropathic Pain: Diagnosis, Mechanisms and Treatment Recommendations. *Archives of Neurology.* **60**: 1524-1534

Kemler M, Barendse G, Van Kleef M. et al (2000) Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *The New England Journal of Medicine.* **343**: 618-624

Kemler M, De Vet H, Barendse G. et al (2006) Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy – five-year follow up. *The New England Journal of Medicine.* **354**: 2394-2396

Sherman R, Sherman C, Gall N. (1980) A survey of current phantom limb treatment in the United States. *Pain.* **8**: 85-99