Response to NICE appraisal document; 4 Jly 08

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Expert Consultee Nominated by Society of British Neurological Surgeons

I would like to make a number of observations regarding the SCS appraisal.

- 1. I welcome the conclusion that SCS can be supported as a therapy for neuropathic pain consequent upon failed back surgery syndrome. However I think that the result obtained from the RCT evidence for this specific indication can be extrapolated to other neuropathic pain conditions, given that there is much other evidence that corroborates this finding in other neuropathic pain conditions. An almost identical situation pertains in respect of "failed neck syndrome", as well as a number of other conditions. Evidence is to be found in the various papers listed in the literature search performed by SCHARR. I would therefore ask that the committee allow extrapolation of the recommendation in respect of FBSS to all neuropathic pain. It will be unrealistic to attempt RCT for each individual category of neuropathic pain.
- 2. The recommendation regarding CRPS be re-examined. The 5 year Kemler results are not readily interpreted, and only the 2 year data represents an RCT. I am aware of many criticisms of this and to be fair these were aired at the appraisal committee meeting. I am also aware of submitted critique of the cost effectiveness. Again I think the committee should give more weight to the evidence that exists outwith RCTs. Perhaps there should be some consideration as to how the different levels of evidence can be quantified relative to each other; if this cannot be done then I cannot see good justification for discarding large volumes of lower levels of evidence, especially in the circumstance – as here - that it is consistent with RCT based evidence. You have asked specifically whether all relevant evidence has been taken into account; I would contend that it has not because of the decision to discard non RCT evidence. The solution should be to devise a quantification of the levels of evidence relative to each other – though to be fair it is most difficult to see how this might be done. The practical effect of this is that it will be almost impossible to design a trial (consider how patient information document would need to appear) that could recruit patients as the majority would refuse randomisation or demand cross-over if randomised to the stimulator negative arm of the trial, remembering that all such patients would have filed other treatments.
- 3. The area I think is contentious is that of trial stimulation. I do not think the false positive and false negative rates are established for this, as I commented to the appraisal committee. In particular a false negative may arise because the technology used for the trial is not as sophisticated a may be a permanent surgical lead. I think therefore this would be a suitable topic for research.
- 4. I do not have sufficient experience of the indications wrt angina or critical limb ischaemia to contribute too much to this aspect of the debate but would observe that pain responses for vascular claudication were extremely good in the small number that were done in Liverpool for this indication.

5. Another area for research is the issue of back pain; controversy exists as to whether SCS might be effective for this indication – for example when treating FBSS the usual recommendation is that SCS will be very likely to improve the neuropathic leg pain component, but success for the low back pain may or may not be relieved. Again this is an issue that might be affected by the introduction of newer technologies.

I hope these comments are of help.

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