*Comment on Technology Assessment Report for NICE*

[redacted]
**On behalf of NHS Quality Improvement Scotland**

**Simpson, EL, Duenas, A, Holmes, MW, Papaioannou, D Spinal cord stimulation (SCS) for chronic pain of neuropathic or ischaemic origin *Health Technol Assess* March 2008**

The investigators have focussed on well-conducted randomized controlled trials for a clinical analysis and have adapted a Canadian cost-effectiveness analysis for UK costs. They could only find 11 suitable randomized controlled trials and some had small numbers of participants. Just 160 in total in the 2 failed back surgery RCTs (PROCESS and North) and only 54 for the Kemler RCT for CRPS Type1. Follow-up time has been short for all studies (6 weeks to 5 years).

<u>"Failed back surgery"/spinal neuropathic pain</u>
Only 2 RCTs have been found suitable for analysis. They have both shown a benefit from SCS when compared to reoperation for nerve exploration (North) or when compared to physical therapy alone (PROCESS). Other studies have not been included because of methodological failings. The bulk of the literature tends to support the use of SCS for spinal neuropathic pain.

<u>CRPS Type1</u>
The data as presented for CRPS amount to a single RCT of patients with CRPS Type1 refractory to other treatments. The results show an improvement in pain over physical therapy alone for up to 2 years but with no additional benefit thereafter. Limb function did not appear to improve with SCS.

<u>Critical limb ischaemia</u>
The 4 RCTs presented failed to show any long term advantage in pain relief, quality of life or limb salvage from treatment with SCS.

<u>Angina</u>
Four RCTs were eligible and these showed a similar efficacy between SCS and CABG in reducing angina attacks but otherwise SCS held no real advantage against other coronary artery symptoms.

**Comment**

The presence of only a few good studies for this treatment considering the many thousands of SCS devices implanted annually confirms the need to explore the clinical indications for SCS more effectively. The evidence as it stands shows a clinical benefit for "failed-back"/neuropathic pain in the short to medium term. There is some short-term benefit in pain relief, but not limb function, in CRPS type1 but no discernable benefit for

patients with critical limb ischaemia. SCS for angina due to coronary artery disease may give some benefit to patients for whom CABG is too dangerous. There may be further benefits due to some trials analysing patients for pain relief while their SCS was switched off.

**Comment on Cost Analysis**

In the ScHARR economic model the actual cost of the device has been hidden. There are price differences between the device manufacturers and this may also vary from hospital to hospital if prices/discounts are negotiated locally. This makes it difficult to attach a true cost to the equipment.

Device longevity is the key to cost-effectiveness, which is nicely shown in the models presented by ScHAAR. However this is unpredictable as at the outset of treatment the current delivery required for effective stimulation and the daily duration of such stimulation will vary between patients. Therefore cost-effectiveness cannot be used as the sole indicator for implementation of policy for SCS. Most patients continue to take analgesia while having SCS so there are no real savings from the drug budget. Newly-marketed rechargeable systems may become a more cost-effective solution for some patients but their current initial cost is significantly more than standard pulse generators. The average costs presented for revision surgery seem reasonable.