Dr Diana Dickson: Clinical Expert Statement Template

Thank you for agreeing to give us a personal statement on your view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them. Your statement can be as brief as you like, but we suggest a maximum of 8 pages.

If there are special reasons for exceeding this 8-page limit please attach an Executive Summary to your statement.

What is the place of the technology in current practice?

How is the condition currently treated in the NHS?

The two best indications for the use of Spinal Cord Stimulation are for neuropathic pain and for visceral pain (which may also in a significant proportion of cases, have neuropathic characteristics). Recommended indications also include specific neuropathic pain syndromes such as complex regional pain syndromes I and II (formerly classified as reflex sympathetic dystrophy and causalgia) and specific visceral pain syndromes such as intractable angina and pain due to peripheral vascular disease

Neuropathic pain is defined by the International Association for the Study of Pain as: **Pain initiated or caused by a primary lesion or dysfunction in the nervous system**. The other term commonly used, neurogenic pain is similar but suggests a more transient nature: **Pain initiated or caused by a primary lesion, dysfunction or transitory perturbation in the peripheral or central nervous system.** Both definitions tend to be used loosely for similar clinical entities. The pain for which spinal cord stimulation is recommended is neuropathic pain and I will use this definition throughout this article.

It is probably most helpful initially to look at the management of neuropathic pain in general. This falls into four categories.

i. **Interventions designed to "switch off" or attenuate the neuropathic pain-** either by relieving a part of the cause where this is inflammatory, or by modulating sympathetic nervous system contribution to the pain .

These are really only of use in the early stages of development of neuropathic pain. Subsequently they cease to be useful or at best only produce temporary relief or improvement of the pain. They are therefore not a long term solution to intractable neuropathic pain Historically permanent destructive nerve blocks were used for chronic pain even where this was the result of previous nerve damage. These proved to have short lived effects and in addition could be associated with significant morbidity.

ii. Medications from outside the group of analgesic drugs normally recommended for nociceptive pain which are capable of providing a degree of relief for neuropathic pain:

These included drugs such as the antidepressant Amitriptyline, and a number of anticonvulsant drugs the most commonly used are now Gabapentine and Pregabalin. Unfortunately all of these drugs have side effects which limit their use The side effects which most significantly limits the use of these drugs is, in my opinion sedation and associated impairment of mental function with forgetfulness. Many patients who are working make a conscious decision not to take such medication in order to be able to function effectively at work.

iii. **Stimulation techniques including TENS, Acupuncture and Spinal Cord Stimulation**. The most commonly used is TENS (Transcutaneous Electrical Nerve Stimulation)

UnfortunatelyTENS, unlike spinal cord stimulation(SCS) is less likely to be effective in neuropathic pain and in some patients can even exacerbate the pain. Acupucture is not effective in many patients with Neuropathic Pain.

Iv **Pain Management and Coping Strategies:** These exist at various levels and should always be a part of the overall management of a patient with neuropathic pain. They will include Cognitive Behavioural Therapy, and pacing skills together with a number of other pain management skills.

These skills are vital to optimising the pain patient's beliefs concerning their pain, their functional abilities and coping skills. They do not, however, do anything to diminish the pain except insomuch as they modify the patient's psychological and behavioural approach to the pain

As can be seen, there are limitations to all the above. Crudely speaking, if one excludes SCS the overall likelihood of a treatment being effective and being tolerated by the patient is around 30%. There is thus a need for some form of effective treatment for neuropathic pain without systemic side effects. Spinal cord stimulation has a relatively high success rate in the right group of patients and is without central nervous system side effects

Is there significant geographical variation in current practice?

At present the geographical distribution of activity in spinal Cord Stimulation is probably a little patchy although I do not have a precise up to date picture of this distribution. All the large teaching centres will offer this treatment as part of their overall range of treatments. Smaller centres are only likely to offer it if the local pain service includes a pain clinician who has experience in undertaking SCS. Commissioning and regional issues also play a part. In the Yorkshire region the smaller centres were not funded to undertake a technique which was deemed to be better undertaken in a regional centre with the requisite yearly activity level and departmental support system for the whole process. (This is notwithstanding the fact that many of the consultants in the smaller centres were trained in this technique at senior registrar level). Some regions have been less keen to fund SCS than others thus also producing an imbalance between regions. The reasons for this are not necessarily because it is not believed to be effective. It is one of the most expensive procedures undertaken in Pain Management, a specialty which can otherwise be regarded as extremely inexpensive (cheap and cheerful). When compared to cardiology or vascular or orthopaedic surgery SCS is no more expensive than many procedures performed with a good deal less preparation and forethought

Different departments will have different biases regarding interventional and non interventional pain management which is likely to reflect the experience and enthusiasms of the Pain Clinicians in that department. This may well be reflected in the numbers of Spinal Cord Stimulators implanted in any one department or region.

Are there differences in opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Although there may be maverick individuals who do their own thing almost all pain clinicians are members of the British Pain Society. A group, of which I was a member, published "**Recommendations for best clinical practice for Spinal Cord Stimulation in the management of pain"** in 2005 on behalf of the British Pain Society and the British Society of Neurological Surgeons. These covered the background to and process of Spinal cord stimulation from assessment and selection to long term aftercare. The document can be viewed and downloaded from the website (The British Pain Society.org). It covers the range of indications from good to poor and notes the conditions for which it is not recommended.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

Overall, if patients are well selected the long term success rates are in the order of 50%. There are however potential risks, although these can be minimised by following the recommendations, they cannot be eradicated. All patients will require battery replacement every few years. There is a separate patient information leaflet explaining the benefits, burdens and risks of SCS. It is important that patients have a realistic view of what SCS will and will not do regarding their pain

A worrying subgroup are patients in whom only short term success can be obtained with SCS. Some of these are the "seekers after solutions" who have perhaps been too influenced by media claims and promises concerning medical treatment. They believe that there "must be something" which can be done to cure or further improved their pain. Others may be patients for whom SCS is only transiently effective or who are not happy with the level of effectiveness. It is difficult to know how much if this is physiological and how much is due to unrealistic expectations. In both groups there may be excessive pressure on the clinician to revise or reposition the system on more than one occasion. Although this can, and has been done, it does increase the risks.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

I believe that this technique is best undertaken in specialist units within secondary care, where the clinicians are able to maintain an adequate level of competence, where there is adequate 24 hour cover, good long term follow up and the availability of a full multidisciplinary pain service to manage the patients pain in an holistic way.(see 2005 Recommendations)

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

The technology is available, and as stated above there are some variations in the use of SCS for neuropathic pain. As we speak, there are still many more patients who fulfil the criteria for SCS implantation than who receive it. In general if they can cope without they are left to do so. SCS has in the past been used outside the list of definite indications in the pain society document. In Leeds we undertook a trial series of implantations for chronic intractable abdominal pain on the basis that it was already recognised to be effective in visceral pain in the chest and lower limbs. . Many of this group of patients had had multiple hospital admissions and negative laparotomies. An audit of the first 15 patients treated in this way demonstrated a decrease of opioid medication in 11 patients, some of whom were able to stop entirely, and a reduction of inpatient hospital admission time of two patient years. SCS continues to be used for some of this group of patients. However, equally important was the recognition and management of this subgroup of abdominal pain patients whose pain had a neuropathic pain component.

At the present time I am unaware of other uses.

*Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.*

The British Pain Society and Society of British Neurological Surgeons recommendations for best clinical practice in Spinal Cord Stimulation is a consensus document. Nevertheless, it took into account the available publications including systematic reviews in it's recommendations.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology in clinical practice reflects that observed under clinical trial conditions. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting?

Many of the previous reported series of SCS especially for Failed Back Surgery Syndrome (FBSS) were in the USA,. From the information available it is difficult to ascertain whether all the patients in these series would have had neuropathic pain or indeed whether the patients would have fulfilled the UK selection criteria since the US operates a privately funded healthcare system which influences patient selection. If all the patients did not have neuropathic pain then this is likely to have produced poorer outcome results than would be expected. Conversely a privately funded group of patients might have been better motivated which would have biased the results in the opposite direction. IT is therefore difficult to extrapolate such results to a UK setting.

What, in your view, are the most important outcomes and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

Outcomes will vary according to the indication for which the SCS system is inserted. In a caring society "Relief of Pain and Suffering" must be one of the outcome parameters, regardless of whether this confers any functional improvement. Nevertheless in real and utilitarian terms important outcomes are a decrease of a patient's needs for treatment or external support and an increase in their ability to return to previous activities of daily living are the desired outcomes. Usually only aspects of these are measured.

In my experience the individuals who stand to benefit most in terms of "returning to a normal life" are highly motivated people who use SCS as part of a management plan to enable them to continue working. Unfortunately, neuropathic pain often continues to be interpreted in terms of organic pathology for which other clinicians continue searching. Patients can often be referred relatively late in the evolution of the pain. Even after referral, because of funding limitations we tend to try the least expensive treatments first, which may mean that by the time we get round to SCS they have lost their jobs and become demotivated. Although return to work is a desired outcome, it cannot, on the balance of probabilities be predicted after SCS. This is in significant part due to the delays inherent in the system bt also due to the fact that while it s likely to improve the pain, the pain will tend to me aggravated by an increase in activity

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

Side effects of SCS are rare. They relate to stimulation of other parts of the nervous system. If this cannot be improved by adjustment of the electrode parameters the electrode position will usually have to be modified.
Complications:
Dural puncture can occur during electrode insertion. This will produce the classical post spinal headache which may delay a patient's early recovery.
Infection is a **complication** of SCS implantation This varies from minor superficial infection of the stimulator pocket, to epidural abcess(which is rare). Careful neurological and infection monitoring is essential to avoid serious sequelae.
Direct nerve damage can occur but is rare, secondary damage can occur as a result of haematoma formation and again careful neurological mentoring is essential.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, if already available, compares with current alternatives used in the UK.
Is the technology easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its use?

As can be seen from comments earlier in this clinical presentation SCS is a valuable adjunct to current methods of managing Chronic neuropathic pain. It is undoubtedly quite complex to implant and electrode positioning requires the conscious cooperation of the patient to correctly identify the painful site. It is also relatively expensive compared to other pain treatments, although less so compared to cardiac pacemakers. Patients who have a stimulator

implanted make a commitment to its ongoing maintenance. In some patients this merely amounts to a battery replacement every 3-10 years (usually 4), in others the systems may need more frequent revisions.
Costs of the implantable equipment will vary from £9-£15 (probably averaging £10-11). The fully implantable systems are the most acceptable and are most commonly used unless the patient exhausts the batteries very rapidly In such cases external induction coil systems can be used. While these are less acceptable to patients it is a tribute to their positive evaluation of the SCS that they almost universally take it in their stride.

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

I have nothing to add to previous comments.

Any additional sources of evidence?

Only the series we undertook in Leeds !998-2003 of abdominal pain patients. There was no control group. The patients' behaviour and medication was assessed before and after treatment. Clearly other factors in their management could have contributed to their improvement. In support of improvement being SCS related is the fact that two patients whose SCS batteries subsequently became exhausted reverted towards previous behaviours in regard to hospital admissions and medication requirements. More recent patients with |SCS for Abdominal Pain are being audited by my successor.

Implementation issues

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

Please note: The NHS is required by the Department of Health and Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.
If the technology is unlikely to be available in sufficient quantity or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and Welsh Assembly Government to vary this direction.
Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

Were NICE to recommend this technology it would be likely to produce pressure for the implantation of more SCS systems in those existing patients who are known to be eligible. Although hospital stays are relatively short it is likely that some overall increase in funding would be required not only to provide the systems but also the staff to support this. If the publication of NICE Recommendations produced a flood of new referrals from other specialties then this might need to happen within a few months. Otherwise it is likely that the change would occur over time and would be dependent upon adequate staffing and resources to allow it to occur- as is the present situation

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