

**Submission by Action on Pain to
NICE for the technology appraisal:
chronic pain of neuropathic and
ischaemic origin**

16th November 2007

Declaration:

This document constitutes the submission made by Action on Pain (registered charity 1088789) to the National Institute for Health and Clinical Excellence (NICE) on the subject of the technology appraisal being undertaken into spinal cord stimulation for chronic neuropathic and ischaemic pain.

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Executive summary

This document presents a fascinating insight into the lives of patients who have received a spinal cord stimulator implant. It highlights the long and frustrating journey that each patient had to endure before receiving their implant. In stark contrast since receiving their implant the positive impact on the patients and their families makes for compelling reading.

1. Background to Action on Pain

Action on Pain(AOP) is a national charity established in 1998 to provide support and advice for those affected by chronic pain. Pain is defined as chronic after three months with 1 in 7 of the UK population actually having chronic pain(Pain in Europe survey 2005) whilst overall 1 in 4 are actually affected by it(family, carers and friends).

Run entirely by volunteers the majority of whom are affected by chronic pain AOP operates "PainLine" – a dedicated telephone helpline that has taken over 27000 calls; a mobile information unit plus the only walk-in centre within the UK manned by volunteers providing access to advice and support for people with pain. AOP also produces a range of informative booklets as well as lobbying to improve access to effective pain management services within the NHS. The organisation is held in high regard with well established links with healthcare professionals as well as often being the first port of call for NHS Direct regarding pain issues.

2. Chronic Pain

Chronic Pain can be defined as pain that lasts for over three months. It is likely to remain with the patient for the rest of their life.

From the European Pain Survey a number of statistics around chronic pain were collected. Below is a summary of the most important points:

- On average patients have lived with chronic pain for 5.9 years
- Two thirds of patients report experiencing chronic pain all the time(70%)
- 1 in 4 reported losing their job because of their chronic pain
- Nearly two thirds of patients are worried about potential side effects of pain medication
- The majority of chronic pain patients(68%) feel their treatment is inadequate at times

3. Treatments for Chronic neuropathic & Ischaemic pain

Medication (pharmaceutical)

Advice & Education (ergonomics & postural advice, mattresses)

Exercise (stabilising, mobilising)

Physiotherapists, Chiropractors, Osteopaths – manipulation and mobilisation techniques

Pain relief through, electrical mechanisms e.g Ultrasound, TENS

Acupuncture

Massage

Hydrotherapy

Podiatry & orthotics

Alternative therapies

Pain management programmes which may include a psychological component (e.g. CBT)

Surgery including

4. Description of Spinal Cord Stimulation

Technology

Place in treatment pathway (see BPS guidelines)

5. Alternative Treatments to Spinal Cord Stimulation

Given that the patients eligible for spinal cord stimulation are either not responding to other treatments or not responding adequately there are few alternatives unless failed back surgery can be repeated successfully. If spinal cord stimulation was not available it is likely these patients would suffer indescribable pain, reduced mobility leading to an unnecessary and avoidable reduction their own quality of life and that of their family.

Patients report that once they have tried combinations of pharmacological treatments, physiotherapy and other non-surgical options they are effectively discharged as there appears to be no other option. In addition to more harmonised funding of the therapy an education programme of clinicians should be undertaken.

Patients also report significant variability in the provision and quality of specialised pain services across the NHS which indicates the clear need to provide increased financial support for such services within the health service.

Currently pain management provision is fragmented and variable in quality and accessibility. In order to resolve this unacceptable situation a complete review of the location and basket of services offered should be undertaken to eliminate the postcode variation within the NHS in England and Wales.

6. Action on Pain Research into Patient Experiences of SCS

Introduction:

For the purposes of the NICE technology appraisal of spinal cord stimulation a survey of patient experiences was undertaken by Action on Pain. Utilising pre-existing contact networks with NHS professionals working in pain management a number of patient recipients of spinal cord stimulation therapy were identified and interviewed.

Method:

Four pain management centres in England were contacted being asked if they would be willing to identify spinal cord stimulation patients and establish consent for a telephone interview, which would be conducted by Action on Pain Chairman, Ian Semmons during early November 2007. During the interviews notes were taken and then collated and written up by Action on Pain.

Centres contacted:

- John Radcliffe Hospital, Oxford
- Newcastle General Hospital, Newcastle
- Seacroft Hospital, Leeds
- The Walton Centre, Liverpool

Results:

The results which were collated and written up by Action on Pain are presented below. Of the four centres contacted, 3 were able to provide a total of 10 patients for participation in the survey.

Table 1: Participating centres and consenting patients

Centre Contacted	Consenting Patients
John Radcliffe Hospital	3
Newcastle General Hospital	2
Seacroft Hospital	0
The Walton Centre	5

Below is a summary of the profiles of the 10 consenting spinal cord stimulation patients identified to participate in the survey.

Table 2: Patient Profile

Age	Gender	Condition	Year of 1 st SCS Implant	Years with SCS therapy (total)	Patient Location
32	F	CRPS	2000	7	Merseyside
41	F	Foot Pain	2005	2	Northamptonshire
41	F	Leg Pain/CRPS	2003	4	Oxfordshire
43	F	Leg Pain/Loss of mobility ?CRPS	2005	2	Lancashire
47	M	Mid-Foot amputation	2006	1	Lancashire
52	F	Failed Back Surgery	2004	3	Cheshire
54	F	Ruptured Achilles Tendon	2006	2	Berkshire
60	M	4 Failed Back Surgeries and Damage to Neck	2004 (external in 2004 then implantable 2005)	3	Northumberland
65	F	Failed Back Surgery Syndrome	2000	7	Tyne and Wear
69	M	Multiple long bone fractures and crushed back of skull. Also TIA and MI.	2004 (1 st implant – removed due to hospital acquired infection and 2 nd in 2008)	1	Lancashire

Demographics Summary:

Age Range of participants: 32-69

Gender Ratio: 7 Female : 3 Male

Duration of spinal cord stimulation therapy range: 1-7 years

Analysis of Patient Interviews – key themes prior to treatment with spinal cord stimulation

Physical Health & Wellbeing

Physical health state

- On average patients reported their chronic pain symptoms had been inadequately managed for on average 6.8 years (range 2-20 years). Their exposure to various treatments had been unsuccessful

Mobility and activities of daily living:

- Every patient (n=10) reported considerable difficulty with their mobility which had significant negative implications on daily life
- One patient reported that aged 21 they were confined to bed as a result of the chronic neuropathic pain
- One person aged 69 reported they changed from an active to an inactive person due to the pain
- Two patients required a close family member to give up or take regular time off work to care for them
- 9 out of 10 patients reported they required family assistance with activities of daily living

Mental Health/Psychological Wellbeing (Emotional)

Depression

- 8 of 10 (80%) patients reported requiring treatment for depression over a sustained period because of their chronic pain

Frustration & Anger

- All patients (100%) experienced frustration and anger about the consequences of the pain on their life and the lack of effective treatments for their condition
- 9 patients (90%) reported frustration at having to stop their employment

Anxiety/Uncertainty

- All participants reported being uncertain and anxious about the future

Suicidal Thoughts

- Three patients (30%) of patients interviewed had suicidal thoughts as a direct consequence of the poorly managed chronic pain

Current Treatments

GP consultations (frequency and satisfaction)

- All participants reported a significant increase in accessing GP consultations
- All patients chronic pain remained unresponsive and hence uncontrolled /managed as a result of GP intervention
- 6 out of 10 (60%) patients reported their GP had difficulties understanding the complexities of chronic pain and felt dissatisfied with the treatment options

Pharmaceuticals for pain relief

- All patients received analgesics and other pharmacological therapies for their symptoms of chronic pain (usually GP prescribed):
 - Morphine (6 patients received this and 1 patient Oromorph)
 - Gabapentin (2 patients)
 - Methadone (1 patient)
 - Phentoni patches (1 patient)
 - Epeilin (1 patient)
 - Pregabalin (1 patient)
 - Amitriptyline (3 patients)
 - Antidepressants (8 patients)

Physiotherapy

- Three patients received physiotherapy which had not been successful in fully managing their pain

Others e.g. TENs

- Four patients reported limited success with TENs machines

Nerve Blocks

- Four patients received little or no benefit from nerve blocks

Response/Outcomes of treatment

Overall impact on pain relief

- All patients reported their pain was unsuccessfully managed with all combinations of pharmacological and other therapies. As a result they continued to suffer having exhausted all options presented to them (100% were refractory to treatment for chronic pain)

Overall impact on quality of life

- All patients except one reported they were unable to function normally because of the impact of their chronic pain despite receiving various treatments for their pain.
- 9 out of 10 patients reported a significant negative impact on their quality of life and independence

Side effects of medication

- 9 out of 10 patients reported very severe side effects from pharmacological therapies
- One patient reported they felt unsafe to use machinery as a result of the medication (impaired alertness/sedating)
- Severe withdrawal symptoms lasting 1-6 months were reported by 3 patients interviewed after stopping
- One patient reported having "lost a year of their life" due to being so heavily medicated they were detached from reality
- One patient reported the combination of medication had caused stomach ulcers
- 4 patients questioned whether the combination of medications was excessive and may be more detrimental than beneficial

Inadequate clinical management

- Lack of awareness of impact of chronic pain by GPs and access to pain clinics and other potential treatments
- Once patients had tried any options offered by their GP (or in some cases pain clinics) they were "discharged" from care if their pain was not adequately managed (i.e. they fall out of healthcare system and suffer in silence)
- Patients reported inequality of access to treatment and in some cases a tertiary referral must be sought in order to progress to alternative treatment options

Family and Social Implications

Employment

- 9 out of 10 patients were unable to work as a result of their chronic pain (8 had to give up their employment and 1 had retired)
- 2 patients required a close family member to give up work to care for them

Financial impact

- All patients interviewed reported severe financial consequences as a result of the symptoms of their chronic pain and in many cases their inability to continue working.

Social dynamics and pressures

- 6 patients reported a strain on family life as a consequence of their reduced independence and pain symptoms
- 4 reported financial pressures which caused instability within the family and some degree of deprivation

- 7 patients highlighted tensions within the household driven by the family being unable to help the person resolve their symptoms and cope with the changes required in the daily routine within the household
- 4 patients reported either feeling inadequate or under-valued
- 4 patients felt there was a lack of understanding by those around them

Family quality of life

- 7 participants reported a significant impact on the family quality of life through a inability to engage in social events, hobbies, holidays and recreational activities
- 2 patients reported difficulties in their sexual activities as a result of their pain

Access to support services (financial and aids to daily living)

- 8 patients were totally unaware of any support services available to provide advice in relation to dealing with their chronic pain
- 6 patients were unclear about possible financial assistance (state benefits) which could maintain an income to support the family

Analysis of Patient Interviews – key themes following treatment with spinal cord stimulation

Physical Health & Wellbeing

Physical health state

- All participants have experienced a significant improvement in their health state following implantation of spinal cord stimulator (some have described this as “life-changing”)
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Mobility and activities of daily living:

- All participants reported an overwhelming positive impact on their overall mobility since receiving spinal cord stimulation implant
- Consistently more able to perform activities of daily living after treatment than before reported by all participants

- One patient reported they now have sufficient mobility and pain control to go skiing and another patient stated they cannot get out of bed without spinal cord stimulation being activated
- Another patient reported for the first time in 6 years they regained sensation in their arm once stimulation is activated

Mental Health/Psychological Wellbeing (Emotional)

Depression

- Patients who reported significant depression prior to implant, state this has generally been resolved since their pain is better controlled

Frustration & Anger

- No evidence was found of frustration or anger related to symptoms of chronic pain since acceptable management strategy was found

Anxiety/Uncertainty

- Participants reported significant reduction in anxiety once a suitable pain management programme was implemented

Suicidal Thoughts

- None of the participants highlighted a persistence of these thoughts since adequate management of their pain

Current Treatments

GP consultations (frequency and satisfaction)

- Overall there were considerably less GP episodes reported by all patients after receiving spinal cord stimulation

Pharmaceuticals for pain relief

- 9 out of 10 patients reported a considerable reduction in medication use post implant, however pharmaceutical therapies still play a role in 2 of the patient's long term pain management
- One patient reported a reduction from 18 tablets to 4 daily

Response/Outcomes of pain management (with spinal cord stimulation)

Overall impact on pain relief

- Patients report at least 90% reduction in pain severity

Overall impact on quality of life

- Without exception every patient has reported a high degree of improvement in their quality of life
- One patient stated "every day life is just amazing" comparing to

- Another patient stated they are "now very independent"
- One patient is happy now that they are in control of their own pain management (using the patient controller for spinal cord stimulation)

Side effects of spinal cord stimulation

- One patient reports that at high intensity of spinal cord stimulation they have to lie down
- Most patients report the surgery to implant spinal cord stimulators is somewhat uncomfortable and takes some time to recover
- One patient had to have the lead repositioned as it have moved
- Two patients required repositioning of their stimulator device itself, one of which was "rubbing on the hip"

Inadequate clinical management

- All patients reported inequality of access to treatment and in some cases a tertiary referral must be sought in order to progress to alternative treatment options
- One patient reported they were initially denied treatment with spinal cord stimulation because the pain clinic "did not believe in it"
- All patients report there remains a lack of education of GPs around issues of chronic pain
- One patient report an extreme lack of awareness as their GP did not know what a spinal cord stimulation device was

Family and Social Implications

Employment

- Since receiving spinal cord stimulation 5 of the patients interviewed have returned to work, 1 is actively doing voluntary work and another patient is considering retraining

Financial impact

- Those patients returning to paid employment (5 in total) report financial pressures on their family have reduced
- One patient reported the close family member who had ceased employment to provide care had returned to work as the intense level of care was no longer required

Social dynamics and pressures

- 7 of the patients highlighted they had received considerable support from their families for the implantation of spinal cord stimulation

- 9 out of 10 stated the tensions and pressure on the household had reduced dramatically since receiving adequate treatment for their pain.

Family Quality of Life

- All patients stated their quality of life has improved and had a knock-on effect with the wider family
- One patient claimed they "would cry if it was taken away" from them and another claimed they "could not cope without it"
- Another patient reported they had not missed a days work since receiving spinal cord stimulation and that their pain "does not drag them down anymore"

7. Overview of patient expressions

Patient stories

It is highly appropriate to present an overview of patient stories given that they present a unified picture of radical and at times potentially life-saving outcomes. Although highly experienced in talking to people with chronic pain the interviewer (who has chronic pain himself) was overwhelmed by the impact that receiving a spinal cord stimulator implant had made to the patients interviewed. After years of frustration and despair they were able to move forward in a positive way not only in terms of their health but also in their domestic and social environments. There was talk of the relief of not being overwhelmed by the impact of side – effects of medication; that they could play football with the children; that they could work and feel valued; that they were no longer a "burden" on their friends; that they no longer felt angry and isolated.

There was overall frustration that the journey to getting a spinal cord stimulator implanted was long and hard. The impact of that journey had led to undue pressures on families and friends as well as compromising their health. There was considerable bitterness that the money spent with failed treatments; GP and consultant episodes and benefit payments could and should have been spent on implementing a spinal cord stimulator. There was overall confusion and anger that given that pain becomes chronic after three months why does it take years for effective treatment to be provided. The staggering lack of continuity in the provision of pain management services within the NHS frequently came to the surface during the interviews.

8. Two patients are put forward to give oral evidence to the panel

- a) Mrs K Murch 2 Shadsworth Road Blackburn BB1 2AV Tel: 01254 264668
- b) Mr J Moffatt Badgers Nook Slaey Hexham NE47 0AA Tel: 01434 673958

9. Conclusion

After interviewing a number of patients who have received considerable benefit from spinal cord stimulation for up to 7 years it is clear there is a clinical rationale for this treatment being made available as part of the strategy for the timely delivery of effective and cost efficient pain management services across the whole of the NHS.

Spinal cord stimulation is not suitable for all patients with chronic pain as many will respond adequately to medications or physical therapy. In common with all interventions for chronic pain treatment should be individually suited to the particular needs of the patient and delivered by a well structured and resourced pain management service.

Spinal cord stimulation should be considered a highly effective and viable option for patients unresponsive to other treatments which may be available.. It is important there is equal access to this technology across the NHS to facilitate timely access for all patients needing treatment for chronic pain.

Patients feel very strongly about this technology as it has such a positive impact on their lives. Despite the occurrence of complications and the need for surgery to implant the device initially, many still consider the technology a very valuable treatment.

It is felt there are many positive cost implications to the NHS with spinal cord stimulation in cases where patients can reduce pharmacological therapies and GP consultations. Furthermore there is clearly considerable cost savings associated with individuals returning to work based on a reduced state subsidy.