WORKING GROUP ON ACUTE PURCHASING

Spinal Cord Stimulation in the Management of Chronic Pain

December 1997

GUIDANCE NOTE FOR PURCHASERS 97/07
Series Editor: Nick Payne

Trent Development and Evaluation Committee

The purpose of the Trent Development and Evaluation Committee is to help health authority and other purchasers within the Trent Region by commenting on expert reports which evaluate changes in health service provision. The Committee is comprised of members appointed on the basis of their individual knowledge and expertise, and includes non-clinically qualified scientists and lay members. It is chaired by Professor Sir David Hull.

The committee recommends, on the basis of appropriate evidence, priorities for:

- the direct development of innovative services on a pilot basis;
- service developments to be secured by health authorities.

The statement that follows was produced by the Development and Evaluation Committee at its meetings on 21 October 1997 and 20 January 1998 at which this Guidance Note for Purchasers (in a draft form) was considered.

SPINAL CORD STIMULATION IN THE MANAGEMENT OF CHRONIC PAIN

AUTHORS: Tomlinson J, McCabe CJ and Collett B, Sheffield: Trent Institute for Health Services Research, Universities of Leicester, Nottingham and Sheffield 1997. Guidance Note for Purchasers: 97/07.

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DECISION: The Committee did not feel able to recommend spinal cord stimulation in the treatment of chronic pain on the basis of the cost and clinical effectiveness information presented. The Committee did not discount individual reports of benefit and would like to see the treatment more rigorously evaluated. Because of the small numbers involved, this could not be conducted at a single centre, but should be carried out nation-wide.

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SPINAL CORD STIMULATION IN THE MANAGEMENT OF CHRONIC PAIN

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Trent Institute for Health Services Research
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The Trent Institute for Health Services Research is a collaborative venture between the Universities of Leicester, Nottingham and Sheffield with support from NHS Executive Trent.

The Institute:

- provides advice and support to NHS staff on undertaking Health Services Research (HSR);
- provides a consultancy service to NHS bodies on service problems;
- provides training in HSR for career researchers and for health service professionals;
- provides educational support to NHS staff in the application of the results of research;
- disseminates the results of research to influence the provision of health care.

The Directors of the Institute are: Professor R L Akehurst (Sheffield);
Professor C E D Chilvers (Nottingham); and
Professor M Clarke (Leicester).

Professor Akehurst currently undertakes the role of Institute Co-ordinator.

A Core Unit, which provides central administrative and co-ordinating services, is located in Regent Court within the University of Sheffield in conjunction with the School of Health and Related Research (ScHARR).

FOREWORD

The Trent Working Group on Acute Purchasing was set up to enable purchasers to share research knowledge about the effectiveness and cost-effectiveness of acute service interventions and determine collectively their purchasing policy. The Group is facilitated by The School of Health and Related Research (ScHARR), part of the Trent Institute for Health Services Research, the ScHARR Support Team being led by Professor Ron Akehurst and Dr Nick Payne, Consultant Senior Lecturer in Public Health Medicine.

The process employed operates as follows. A list of topics for consideration by the Group is recommended by the purchasing authorities in Trent and approved by the Purchasing Authorities Chief Executives (PACE) and the Trent Development and Evaluation Committee (DEC). A public health consultant from a purchasing authority leads on each topic assisted by a support team from ScHARR, which provides help including literature searching, health economics and modelling. A seminar is led by the public health consultant on the particular intervention where purchasers and provider clinicians consider research evidence and agree provisional recommendations on purchasing policy. The guidance emanating from the seminars is reflected in this series of Guidance Notes which have been reviewed by the Trent DEC, chaired by Professor Sir David Hull.

In order to share this work on reviewing the effectiveness and cost-effectiveness of clinical interventions, The Trent Institute's Working Group on Acute Purchasing has joined a wider collaboration, InterDEC, with units in other regions. These are: The Wessex Institute for Health Research and Development, The Scottish Health Purchasing Information Centre (SHPIC) and The University of Birmingham Institute for Public and Environmental Health.

Professor R L Akehurst,
Chairman, Trent Working Group on Acute Purchasing.

ACKNOWLEDGEMENTS

Comments and advice from Dr R Atkinson, Royal Hallamshire Hospital Sheffield; Dr R Marks, York General Hospital; and Professor D Rowbotham, Leicester Royal Infirmary in the preparation of this Guidance Note are gratefully acknowledged.

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EXECUTIVE SUMMARY

Spinal Cord Stimulation (SCS) is '.... a reversible, non-ablative technique for the management of intractable pain'.[1] Over time there has been little agreement about the indications for the use of SCS. Clinical use has been based more on uncontrolled experience than controlled trials.

Although the volume of activity is not large (approximately 30 procedures were carried out in the Yorkshire Region in 1996) the treatment package, including testing, implant and follow-up, has been costed at between £7,500 and around £9,000. This level of expenditure can only be supported if there is strong evidence of clinical benefit.

This paper considers the evidence for the effectiveness of SCS in the following conditions: 'failed back surgery syndrome' (FBSS); peripheral vascular disease (PVD) with ischaemic pain; peripheral nerve injury (PNI); phantom limb or stump pain; spinal cord lesions with well circumscribed segmental pain; and angina pectoris.

The quality of evidence is generally weak. The best evidence of efficacy is for PVD and angina pectoris. The preliminary report of the RCT in FBSS suggests that there is potential benefit from SCS in this condition. For all other indications the existing evidence is very poor. The poor quality of the evidence is a reflection of the difficulties in carrying out RCTs; these difficulties include recruiting from a heterogeneous group of patients each with very low numbers and little agreement about best practice.

There is insufficient evidence to estimate the cost-effectiveness of SCS in any of these conditions. There is sufficient evidence to justify additional well designed research in most of them. However, it is difficult to justify purchasing SCS from mainstream NHS funds except for PVD, angina pectoris and possibly certain types of FBSS.

If SCS is to be purchased, it should be from a single designated provider, to maximise expertise, and should include proper assessment and collection of outcome data to inform future decision making.

1. INTRODUCTION

Spinal Cord Stimulation (SCS) is '.... a reversible, non-ablative technique for the management of intractable pain'.[1] First used in America in 1967, it involves the electrical stimulation of the spinal cord via a device which may be implanted by surgical or percutaneous procedures. These devices can be driven by an intracorporeal powered pulse generator or by an external transmitter and radio frequency coupling. Early designs consisted of monopolar electrodes, but modern equipment tends to have multiple electrodes which are more effective and optimise stimulation in varying body positions.

Over time there has been little agreement about the indications for the use of SCS. Clinical use has been based more on uncontrolled experience than controlled trials. Failure rates for pain relief have been high[1] as have complication rates.[2] Increasingly, there is agreement on the need to select patients carefully as certain types of chronic pain are proving more amenable than others to successful management using SCS.

The volume of activity is not large; approximately 30 procedures were carried out in the Yorkshire Region in 1996, (personal communication from Dr. R. Marks; York District General Hospital). However, the treatment package including testing, implant and follow-up has been costed at around £7,500 to £9,000. This level of expenditure can only be supported if there is strong evidence of clinical benefit.

The objectives of this paper are:

(a) to review the evidence on the effectiveness of SCS in the treatment of different types of chronic pain;
(b) to summarise what agreement there is on the most appropriate applications of SCS; and
(c) to outline possible options for purchasers to consider with regard to funding SCS in the future.

The terms 'Spinal Cord Stimulation' and 'Dorsal Column Stimulation' are used interchangeably in the literature. This paper will use the term 'Spinal Cord Stimulation' (SCS).

2. SPINAL CORD STIMULATION IN THE MANAGEMENT OF CHRONIC PAIN: SUMMARY OF EVIDENCE OF EFFECTIVENESS

2.1 Summary of Evidence of Effectiveness

North[3] gives the following list of conditions for which SCS has been recommended:

"... listed in decreasing order of frequency of application and reported success rates.

1. Lumbar arachnoid fibrosis or 'failed back surgery syndrome' (FBSS) with radiculopathic pain, ideally predominating over axial low back pain, in particular mechanical pain.
2. Peripheral vascular disease (PVD), with ischaemic pain.
3. Peripheral nerve injury (PNI), neuralgia, causalgia (including so called 'reflex sympathetic dystrophy').
4. Phantom limb or stump pain.
5. Spinal cord lesions, with well circumscribed segmental pain".

Simpson[1] gives a much more extensive list (See Table 1 below). However, there is only one condition, angina pectoris, which Simpson considers appropriate for SCS, which is not included in North's list. The remainder of the paper will therefore limit itself to considering the five conditions identified by North, plus angina pectoris.

Table 1: Simpson's Review of Success with SCS Based on Reports Published between 1981-1994

GROUP LEVEL OF SUCCESS		
A	***Success almost certain***	
	Angina pectoris	Ischaemic limb pain
B	***Success very likely***	
	Causalgia	Cauda equina damage
	Reflex sympathetic dystrophy	Nerve root avulsion
	Peripheral nerve lesion	Amputation stump pain
	Brachial plexus damage	
C	***Success reasonably likely***	
	Failed back surgery syndrome (leg pain more than back pain)	Phantom limb pain
	Partial spinal cord lesion	Post herpetic neuralgia
D	***Success unlikely***	
	Nociceptive pain, including cancer	Vaginal, penile, rectal, perianal pain
	Thalamic syndrome (central post-stroke pain)	Other mid-line pains
	Intercostal neuralgia	
E	***Success very unlikely***	
	Facial anaesthesia dolorosa	Abdominal pain
	Atypical facial pain	Complete cord lesion

The criteria which Simpson uses to categorise these conditions are not made clear in the paper.

1. Lumbar Arachnoid Fibrosis - 'Failed Back Surgery Syndrome' .

Failed back surgery syndrome (FBSS) is not a single disease entity, and a fundamental distinction exists between FBSS with purely back pain, and FBSS with back and leg pain. Simpson suggests that the outcome (in terms of pain relief) of SCS for FBSS with back and leg pain is superior to that when used for back pain alone.[2] The evidence on the efficacy of FBSS is generally from data reported as part of case series containing patients with various conditions.[2] There is an on-going randomised controlled trial (RCT)[3] which has reported initial results. This study is a randomised cross-over trial of somewhat unusual design. Patients are randomised between re-operation and SCS for the management of FBSS. Six months after the initial intervention, the patients are offered the opportunity to choose to switch to the alternative intervention. Preliminary results indicate that more of the patients who underwent surgery as the initial intervention chose to switch to SCS after six months. This suggests that FBSS has better patient perceived outcomes with SCS than re-operation. However, at the present time, there is no definitive evidence for the efficacy of SCS in treating FBSS.

2. Peripheral Vascular Disease

A number of case series have reported improvements in the pain and functioning of people suffering from PVD, specifically critical limb ischaemia.[2,4,5] Other reported benefits include healing of ulcers and improved microvascular blood flow.

As before, the datasets on which these reports are based tend to be small and have often been collected over a number of years, during which time the technology and the level of clinical expertise has changed, making it difficult to view them as a single sample.

Simpson[1] reports two studies on-going in the United States and Sweden which are designed to provide clear evidence on the effectiveness or otherwise of SCS in treating PVD. They were due to have reported at the end of 1994, but no published results have been identified in the literature. A personal communication from Professor Jacobs in Amsterdam, the lead clinician for the Swedish Study, indicates that the initial results suggest a benefit from SCS. However, the Dutch authorities are asking for outcome data at two years before making a definitive decision on re-imbursment.

3. Peripheral Nerve Injury

Simpson[1] identifies nine papers, published between 1981 and 1991, which he claims report good outcomes for SCS in the treatment of PNI with SCS being particularly effective with regard to reducing pain and immobility. However, these conclusions do not appear to be consistent with the evidence presented.

As with the rest of the literature on SCS, the literature on its use in PNI does not include RCTs, nor even particularly large case series. The evidential basis for using SCS in PNI, therefore, remains poor.

4. Phantom Limb or 'Stump' Pain.

Simpson[1] identified 69 papers reporting the use of SCS for chronic pain. It is quite telling that in his review of the efficacy of SCS in phantom limb pain, he does not cite a single paper in support of his arguments. The authors of this paper have managed to identify one paper by Krainick et al reporting the outcome of SCS for pain reduction in amputees.[6] This paper states that 42.6% of the 64 patients studied, had pain relief of 25% or more at five year follow-up. What the authors do not make clear is how pain relief was measured and, therefore, what 25% means.

Once again, the evidence for the efficacy of SCS must be considered poor.

5. Spinal Cord Lesions, with well Circumscribed Segmental Pain

The literature on the use of SCS for the management of pain related to spinal cord lesions tends to report failure. Simpson[1] suggests that this may be because spinal cord lesions are a heterogeneous group of conditions, none of which is sufficiently well understood to allow the effective use of SCS.

6. Angina Pectoris

SCS for intractable angina was first used by Murphy and Giles in 1987,[7] since when many other reports have been published.[2] Murphy and Giles' consistently repeated finding was that SCS reduced both the frequency and the severity of attacks in all 10 patients studied. Other reports have reported improvements in exercise tolerance, reduced pain from angina and decreased recovery time.[8]

Extensive experimental work has failed to identify any negative side effects of SCS in the treatment of angina pectoris.[9,10]

The weight and quality of the evidence for the effectiveness of SCS in the treatment of angina pectoris is greater than for any other proposed use. This said, there is still no definitive RCT of SCS in angina pectoris published to date.[11]

Table 3 describes, from a small review of the literature, the type of study reported and the quality of the evidence contained therein. The scoring system is set out in Table 2.

2.2 Conclusion on the Quality of Evidence

The overall quality of evidence is generally weak. Although all the papers cited in Table 3 are categorised as either III or IV, the best evidence of efficacy is for PVD and angina pectoris. In these two indications, there is laboratory confirmation of improved micro-vascular supply and improvement in more objective outcome measures such as stress tests, recovery time and healing of ulcers. The preliminary report of the RCT in FBSS suggests that there is potential benefit from SCS in this condition, but this trial has not yet reported fully. For all other indications the existing evidence is very poor.

A recent Health Technology Assessment of Chronic Pain Control offered in an out-patient setting concluded that - for back pain: “there is a lack of evidence supporting the use of spinal cord stimulators. Case series are of poor quality and do not provide evidence of effectiveness, although at least 50% pain relief at five years is reported in over 50% of patients.”[12]

The poor quality of the evidence must be judged in the context of the difficulties of setting up RCTs in this area:

- The number of patients suitable for SCS in any one condition is small;
- There are significant variations in practice with regard to assessment and trial stimulation, making pooling of data from different centres difficult;
- There are relatively few well validated measures for assessing pain, the main outcome of treatment;

- The hardware has developed significantly over time. Thus, the long time period required to recruit sufficient patients carries the risk of the results being obsolete by the time they are available.

Given the poor quality of evidence for benefit from SCS in most of these conditions, and that most of the conditions have case series reporting some benefit, it is reasonable to conclude that further research can be justified. However, it is probably difficult to argue that the money should come from main stream NHS funding for any conditions other than PVD and angina pectoris.

Table 2: Classification of the Quality of Evidence[13]

I	Evidence obtained from at least one properly designed randomised controlled trial.
II-1	Evidence obtained from well designed controlled trials without randomisation.
II-2	Evidence obtained from well designed cohort or case controlled analytic studies, preferably from more than one centre or research group.
II-3	Evidence obtained from multiple time series with or without the intervention, or from dramatic results in uncontrolled experiments.
III	Opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees.
IV	Evidence inadequate owing to problems of methodology, e.g. sample size, length or comprehensiveness of follow-up, or conflict in evidence.

Table 3: Quality of Published Evidence on the Effectiveness of SCS for Different Types of Chronic Pain

PAPER	TYPE OF STUDY	QUALITY OF EVIDENCE (see Table 2 above)
North RB. The role of spinal cord simulation in contemporary pain management. *APS Journal* 1993; 2: 91-99.	**Narrative review of the literature on SCS for chronic pain relief.**	**III**
Simpson BA. Spinal cord stimulation. *Pain Reviews* 1994; 1: 199-230.	**Narrative literature review of SCS in chronic pain management.**	**III**
Urban BJ, Nashold BS. Percutaneous epidural stimulation of the spinal cord for relief of pain. *Journal of Neurosurgery* 1978; 48: 323-328.	**Reports results of SCS for chronic pain in 20 patients at up to 2 years post implantation.**	**III**
North RB, Kidd DH, Lee MS et al. A prospective RCT of spinal cord stimulation versus reoperation for FBSS: Initial result. *Stereoatactic and Functional Neurosurgery* 1994: 62; 267-272.	**Reports initial results, for the first 27 patients, of a RCT for SCS in FBSS.**	**IV at present, but when full trial reports this may improve the quality of evidence**
Jacobs MJHM, Jorning PJG, Beckers RCY et al. Foot salvage and improvement of microvascular blood flow as a result of epidural spinal cord electrical stimulation. *Journal of Vascular Surgery* 1990; 12: 654-60.	**Reports effect of SCS on microcirculatory blood flow for case series of 20 patients.**	**III**
Krainick J, Thoden U, Riechart T. Pain reduction in amputees by long term spinal cord stimulation. *Journal of Neurosurgery* 1980; 52: 346-350.	**Reports effects of SCS on pain relief for 64 amputees at two year follow-up.**	**IV**

North RB, Kidd DH, Zahwak M et al. Spinal cord stimulation for chronic intractable pain: experience over two decades. *Neurosurgery* 1993 ;32: 63-67.	**Reports the effects of SCS for chronic pain management in 320 patients over 20 years.**	**III**
Augustinsson LE, Holdm J, Carlsson CA et al. Epidural electrical stimulation in severe limb ischaemia. Evidence of pain relief, increased blood flow and a possible limb saving effect. Annals of Surgery 1985; 202: 104-111.	**Reports effect of SCS in PVD for 34 patients over 7 years. Follow-up up *to* 16 months.**	**III**
Eliasson T, Augustinsson LE, Mannheimer C. Spinal cord stimulation in severe angina pectoris - presentation of current studies, indications and clinical experience. *Pain* 1996; 65: 169-179.	**Narrative review of literature from 1980s and 1990s on use of SCS in angina pectoris.**	**III**
de Jongste MJL Hautvast RWM Hillege HL Lie KI Efficacy of Spinal Cord Stimulation as Adjuvant Therapy for Intractable Angina Pectoris: A prospective RCT. *Journal of the American College of Cardiology* 1994; 23: 1592-7.	**Reports a RCT of SCS in the management of angina pectoris with 8 week follow-up, for 17 patients.**	**IV**

2.3 Patient Selection and Effectiveness

Initially, patients were selected for SCS on the basis of the severity and/or the chronicity of their condition. However, the low success rates, the invasive nature of the treatment and the difficulty in obtaining funding, focused attention on ways of identifying those patients with the greater probability of successful outcomes.

A large body of work has looked at the possible role of psychiatric screening to exclude patients with ‘psychiatric disturbance’ or ‘serious mental disability’. However, this body of work has failed to produce a definitive conclusion as to its value, and it is by no means standard practice. [2]

Some researchers have suggested that success is related to the ‘quality’ of the pain. North et al. have shown that success is positively related to pain being described as ‘sharp’; and that a poor outcome is related to pain being described as ‘pounding’ or ‘sickening’.[14] Despite this, the actual use of validated instruments which describe the type of pain, (e.g. McGill Pain Questionnaire) in relation to SCS, is surprisingly rare. The effect of this is that the hypothesis has never been properly tested. However, it is important to note that outcome for patients with chronic pain may be poorly assessed by monitoring pain and disability alone. Measurements of quality of life and return to work, for example, may be better indicators of successful treatment.

Trial cord stimulation, where a temporary percutaneous system is used to assess the efficacy of SCS for the individual patient, was initially expected to become a routine part of the treatment process.[2] However, significant variation in the published results on the efficacy of trial stimulation has meant that this has not been the case. Failure rates in series using trial stimulation appear little different from failure rates in series which do not use trial stimulation.[2]

2.4 Complications

The most common complications have been associated with hardware failure, electrode migration and dislodgement, lead fracture and current leakage. These have become less common as the equipment has developed and clinicians have gained experience in the implantation procedures.

Infection rates vary enormously, with variations between temporary and permanent systems and the type of system. The incidence of reported infection is between 3% and 5%.[3] Infections are either (a) superficial around the pulse generator, or (b) more serious in the epidural space e.g. epidural abscess.

Post-operative pain is also a well recognised, but poorly documented, complication of surgical implantation. On the basis of personal communications with surgeons using the procedure, Simpson estimates that 5-10% of patients experience post-operative pain after thoracic laminectomy, which can last for several weeks. Percutaneous implantation is less painful.

Cord compression was reported in the early series, however, the numbers reported were small and the deficits usually reversible. Transient or reversible neurological deficit, not due to compression, has also been reported, but again not in large numbers.

3. COST AND BENEFIT IMPLICATIONS OF ADOPTING INTERVENTION

The Royal Hallamshire Hospital, Sheffield, charges £9,000 for SCS treatment, which includes testing, implant and follow-up. The Leicester Royal Infirmary and Guy's Hospital, London charge £7,500 for a similar package of care. Cost savings will predominantly be in relation to analgesia prescriptions. For angina pectoris there may be savings from a reduction in in-patient admissions as a result of the reduction in the number of angina attacks. A key determinant of the relative cost of SCS and traditional analgesia treatment is likely to be the effective life-time of each implant. The more frequent the need for replacement, the less likely it is that SCS will be a net cost-saving intervention. Manufacturers currently estimate the lifespan of SCS hardware to be five years. However, this will vary between components and is also dependent on the amount of usage.

The paucity of high quality evidence on the effectiveness of SCS has been documented above. At the present time, the published data do not allow a quantitative comparison of the costs and benefits of SCS.

4. OPTIONS FOR PURCHASERS AND PROVIDERS

Option 1 Stop/do not purchase.

Option 2 Purchase SCS for angina pectoris and PVD. Await the result of the RCT for FBSS before purchasing SCS for this indication.

Option 3 Purchase SCS for angina pectoris, peripheral vascular disease and FBSS.

Option 4 Option 3 but purchase SCS for FBSS on a case by case basis, using strict patient criteria for selection and assessment.

Option 5 Purchase any of the options above only within a properly designed trial incorporating an economic evaluation.

Option 6 Purchase all categories on request.

5. DISCUSSION AND CONCLUSION

There are no UK trials of SCS presently on-going. The primary option would be for purchasers to push for the establishment of such a trial (or programme of trials), and possibly to purchase SCS treatment only within the context of such a trial(s).

The evidence base for purchasing SCS is weak. The use of SCS should ideally be part of a well designed trial. The poor quality of the evidence is, however, a reflection of the difficulty of carrying out RCTs in small patient groups, and where there is little agreement about what should be the exact intervention to be evaluated.

If purchasers are to fund SCS there is a need to agree patient criteria. These could possibly include criteria for the quality of pain and the success of the trial stimulation. In addition, instruments to measure outcome should be adopted by the provider and complications monitored.

Permanent SCS should be implanted by a limited number of designated providers as the number of patients who might be suitable for SCS is very small, even when they are aggregated to a regional level. Therefore, it seems sensible to limit the number of provider units, so that the skills of the provider unit can be developed and thereby the complication rates minimised. A further benefit of limiting the number of provider units is that it will make evaluation easier.

Although there is slightly stronger evidence for use in PVD and angina pectoris, FBSS patients are likely to be the largest patient category for which SCS is requested. Patients with FBSS have often had a number of previous interventions to relieve their pain. The role of SCS in this group could be considered a possible option, but only in the context of a ***'last resort' treatment***. If purchasers wish to consider SCS for this group of patients, specific patient criteria may include:

- FBSS patients should have leg pain, not spinal pain alone;
- Patients should have prior assessment by spinal and pain specialists to consider/exclude other options. This should include an assessment of the quality of pain;
- Trial of stimulation by the designated provider should always be performed and be successful to warrant a permanent SCS.

These criteria should be revised following the report of the RCT referred to earlier in the text.

The purchase of SCS for peripheral nerve injury, phantom pain, and spinal cord lesions in well circumscribed segmental pain, is hard to justify on the basis of expected health gain predicted from the published evidence.

6. SPINAL CORD STIMULATION IN THE MANAGEMENT OF CHRONIC PAIN : SUMMARY MATRIX

PATIENT GROUP	PATIENT CRITERIA (GUIDELINES NOT PROTOCOLS)	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVING	AUDIT POINTS	EFFECTS THAT COULD BE EXPECTED IN RELATION TO STARTING POINT	COST-EFFECTIVENESS
Angina Pectoris	Not responding to medication and not suitable for surgical treatment		Reduced analgesia Reduced admissions	1. The number of procedures per specialist. 2. Compliance with patient criteria. 3. Complication rate. 4. Monitor success by measuring outcome for quality of life, pain and disability using validated instruments as well as measures of: i) successful trial of treatment; ii) successful permanent implant.		Not available
PVD	As above (Review following report of RCT)		Reduced analgesia Reduced admissions			
FBSS	Patients with: leg pain; sharp quality of pain; prior assessment by spinal and pain specialists Trial successful Review criteria following reporting of RCT		Reduced analgesia Reduced surgery Restrict number of providers			
TOTAL		~5 for a HA of 500,000				

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