



**Medical Services Review Board
January 17, 2008
Minutes**

Members Present:

Philip Bachman, M.D.
Beth Baker, M.D.
Barbara Baum, MS PT
Jeffrey Bonsell, D. C.
Sharon Ellis, R.N.
Michael Goertz, M.D.
Charles Hipp, M.D.
Rose Hatmaker
Greg Hynan, D.C.
Reed Pollack
Elizabeth Shogren, R.N.
Jon Talsness, M.D.

Members Excused:

Andrew Schmidt, M.D.

Members Absent:

Andrea Trimble Hart
Robin Peterson

Staff:

Kate Berger
Debbie Caswell
Penny Grev
William Lohman, M.D.
Phil Moosbrugger
Patricia Todd
Steve Sviggum

Visitors:

Natalie Haefner; WCRA
Jen Samuels; MAPS
Becky Schierman; MMA
Daniel Wulff; MNAJ

The meeting was called or order at 4:06 p.m. by Chairperson Beth Baker. A quorum was present. *Barbara Baum made a motion to approve the minutes from the July 19, 2007, meeting, as presented. Sharon Ellis seconded the motion. All voted in favor of the motion and it passed.*

Commissioner Steve Sviggum was introduced and thanked members for serving on the Medical Services Review Board (MSRB) and for reviewing policies for injured workers. He noted he is looking for a reform bill out of the Workers' Compensation Advisory Council (WCAC) this year aimed at the injured worker, with medical being part of that.

Members introduced themselves.

Assistant Commissioner Announcements and Update

Assistant Commissioner Patricia Todd said the WCAC is working on a legislative bill and she had strong confidence that there will be a bill this year. The employer and employee group are still discussing what they will bring forth.

Review of Comments Received on the Draft Rules
Long-term use of Opiates

Dr. William Lohman said the Department of Labor and Industry (DLI) received more comments about the draft rules and met with concerned citizens who had some good points. He noted the question of time frame was still on the table.

Lohman pointed out a copy of the draft rules for chronic management in members' packets and reviewed the comments. He proposed that members vote on each recommendation as a motion and all agreed. The comments received at the meeting and the actions to be taken are listed in the table below.

Proposed Rules for Long-Term Prescription of Narcotic Medication

12/13/07 Draft	Comment	Actions
p. 1, l. 6	What is the definition of "enduring"	<i>Change "enduring" to "intractable" as defined in MS 152.125. "... 'intractable pain' means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts."</i>
p. 1, l. 8	3 months seems too short a time; suggest 6 months or changing to "3 months after healing would have been expected"	<i>Set time period at 3 months.</i>
p. 1, l. 28-31	What do you do if the WC insurer refuses to allow the referral?	<i>No action needed. The provider and employee would have the legal recourse that currently exists for any denial of treatment.</i>
p. 1, l. 46- p. 2, l. 5	Why is this information needed?	<i>No action needed. Reviewing these possible contraindications is recommended medical practice.</i>
p. 1, l. 46- p. 2, l. 5	How does a non-psychiatrist use this information?	<i>No action needed. This information is used to determine if any further evaluation is needed before beginning treatment with long term opiates.</i>
p. 2, l. 3	Delete; impulse to use opiates is not an impulse control disorder	<i>Change "impulse control disorder" to "poor impulse control"</i>

p. 2, l. 22-25	Prescribing in 7 day increments does not make sense; tell the patient that prescriptions will not be filled on weekends or vacation days and let them bear the responsibility.	<i>Change "in multiples of seven day increments" with "in an amount sufficient" and add "holiday"</i>
p. 2, l. 22-25	Some patients vary their dosing or have a bad month.	<i>No action needed. This is why a plan for breakthrough pain is required.</i>
p.2, l. 28	This agreement should be part of the written agreement in subpart D	<i>No action needed. The department will review the drafting of sub items C and D and duplicate or rearrange items into the most user friendly format</i>
p.2, l. 35	This should be acknowledged in the written agreement	<i>No action needed. The department will review the drafting of sub items C and D and duplicate or rearrange items into the most user friendly format</i>
p. 2, l. 38	This seems redundant with subpart D 3	<i>No action needed. The department will review the drafting of sub items C and D and duplicate or rearrange items into the most user friendly format</i>
p. 3, l. 42	This seems redundant with subpart D 4	<i>No action needed. The department will review the drafting of sub items C and D and duplicate or rearrange items into the most user friendly format</i>
p. 3, l. 32	This should be in subpart C	<i>No action needed. The department will review the drafting of sub items C and D and duplicate or rearrange items into the most user friendly format</i>
p. 3, l. 47	Should a time-frame be added for accomplishing the goals of the treatment plan, for example 3-6 months	<i>No. The evaluation of the treatment plan and the time-frame for that evaluation should be left to the discretion of the prescribing health care provider.</i>
	It will be hard for physicians who don't see many of these patients to use a written agreement or comply with the rules	<i>The Department will create two forms as part of this rule whose use by the provider would be presumptive evidence of compliance with the rule – 1) a template for the requirements of items A and B 2) a standard written agreement meeting the requirements of items C and D</i>

[Shall we summarize the discussion brought up by Shogren about the WCAC consulting with the MSRB about "lollipop" drugs as stated below? Deb]

The MSRB members noted they considered the use of Fentanyl when they worked on the rules draft and suggested it might be helpful for the WCAC to get the MSRB's input regarding "lollipop" drugs. It was noted that the next WCAC meeting will be on January 29, 2008, from 9:00 a.m. to noon and it is a public meeting.

Treatment Parameters
Spinal Cord Stimulators and Morphine Pumps

Lohman referred to the draft rule for spinal cord stimulators in the meeting packets and reviewed information and references on the department's web page regarding spinal cord stimulators. He reviewed the comments and the department's recommendations. A list of specific contraindications will be brought to the next meeting by Lohman. Discussion occurred and the comments and recommendations from the meeting are in the table below.

	Comment	Recommendation
p. 1 l. 30	Change "and is not a candidate for any other surgical therapy" to "Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated". Use of SCS should not be limited to cases in which <u>all</u> other therapies are no longer available.	No action taken.
p. 1 l. 31	Who does the psychological evaluation?	Clarify that this is done by the treating health care provider.
p. 1, l. 31	What if the provider doesn't feel capable of making this determination?	Clarify that the provider can obtain a consult if desired.
	Added by Department	
p. 1, l. 35-37	What constitutes an appropriate trial period?	A minimum trial period of three days
p. 1, l. 35-37	When is a trial judged to be successful?	At least 50% relief of pain
p. 1, l. 29	Provide a definition of "intractable pain"	Use the definition provided in MS 152.125 "... 'intractable pain' means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts."

Old Business
Drug Rules

Lohman noted the drug rules are moving forward. It is a long process and DLI will solicit formal comments.

PPD Schedule

Lohman said technical changes have been proposed to the PPD schedule rules and they are also moving forward in the same fashion.

New Business

The 2008 meeting was schedule pointed out to members and approved.

Baker pointed out that there are several open positions on the MSRB and asked members to solicit applications and to contact Deb Caswell for information.

Lohman stated that the Treatment Parameters are being posted on a user friendly Website being built at DLI and did a demonstration. You can go to the Table of Contents and browse by condition, and look up specific treatments. Or, you can look up treatment options. At this point in time it is just a framework and will give people easy access to the Treatment Parameters when it is completed.

Bachman made a motion to adjourn the meeting at 5:10 p.m. Bonsell seconded the motion. All voted in favor of the motion and it passed.

Respectfully submitted,

Debbie Caswell
Executive Secretary

dc:s

Comments Received and Recommendations Re: Proposed Rules for Spinal Cord Stimulators

	Comment	Recommendation
p. 1 1. 30	Change "and is not a candidate for any other surgical therapy" to "Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated". Use of SCS should not be limited to cases in which all other therapies are no longer available.	
p. 1 1. 31	Who does the psychological evaluation?	Clarify that this is done by the treating health care provider.
p. 1, 1. 31	What if the provider doesn't feel capable of making this determination?	Clarify that the provider can obtain a consult if desired.
Added by Department		
p. 1, 1. 35-37	What constitutes an appropriate trial period?	A minimum trial period of three days.
p. 1, 1. 35-37	When is a trial judged to be successful?	At least 50% relief of pain
p. 1, 1. 29	Provide a definition of "intractable pain"	Use the definition provided in MS 152.125 "... 'intractable pain' means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts."

Spinal Cord Stimulators
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 01/17/08

1 **5221.6200 Low Back Pain**

2
3 Subp. 6. Surgery, including decompression procedures and arthrodesis. Surgery may only be
4 performed if it also meets the specific parameters specified in subparts 11 to 13 and part
5 5221.6500. The health care provider must provide prior notification of nonemergency inpatient
6 surgery according to part 5221.6050, subpart 9.

7
8 A. In order to optimize the beneficial effect of surgery, postoperative therapy with active and
9 passive treatment modalities may be provided, even if these modalities had been used in the
10 preoperative treatment of the condition. In the postoperative period the maximum treatment
11 duration with passive treatment modalities in a clinical setting from the initiation of the first
12 passive modality used, except bedrest or bracing, is as follows:

- 13
14 (1) eight weeks following lumbar decompression or implantation of a ~~dorsal column~~
15 ~~stimulator or morphine pump~~ spinal cord stimulator or intrathecal drug delivery system;
16 or
17 (2) 12 weeks following arthrodesis.

18
19 B. Repeat surgery must also meet the parameters of subparts 11 to 13 and part 5221.6500, and is
20 not indicated unless the need for the repeat surgery is confirmed by a second opinion obtained
21 before surgery, if a second opinion is requested by the insurer.

22
23 C. ~~The following surgical therapies~~ Spinal cord stimulators have very limited application as
24 provided in subitems (1) and (2). And require a second opinion that confirms that the treatment is
25 indicated and within the parameters listed, and a personality or psychosocial evaluation that
26 indicates that the patient is likely to benefit from the treatment.

27 (1) A trial screening period of these devices is indicated only if the treating health care
28 provider determines and a second opinion confirms that:

- 29 (a) the patient has intractable pain;
30 (b) the patient is not a candidate for another surgical therapy; and
31 (c) the patient has no psychological contraindications to this treatment. The
32 treating health care provider may refer the patient for a consultation if the provider
33 feels unable to assess the patient for psychological contraindications.

34
35 (2) Long term use of a spinal cord stimulator is indicated if the treating health care
36 provider documents that there has been at least a 50% improvement in pain during a trial
37 screening period of at least three days.

38
39 ~~(1) Dorsal column stimulator is indicated for a patient who has neuropathic pain, and is~~
40 ~~not a candidate for any other surgical therapy, and has had a favorable response to a trial~~
41 ~~screening period.~~

42 ~~(2) Morphine pump is indicated for a patient who has somatic pain, and is not a~~
43 ~~candidate for any other surgical therapy, and has had a favorable response to a trial~~
44 ~~screening period.~~

the use of spinal cord stimulators did not differ markedly in quality from those recommending their use but did tend to rely on a smaller base of data.

The conclusions drawn by the Department from the reviewed literature are:

1. There is limited evidence (predominantly from case series and two RCTs) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 60% of patients with chronic spinal conditions who have a positive response during a screening trial period.
2. There is limited evidence (predominantly from case series and one RCT) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 67% of patients with complex regional pain syndrome (reflex sympathetic dystrophy) who have a positive response during a screening trial period.
3. There is inconsistent evidence as to whether spinal cord stimulators improve other clinical outcomes in patients with either chronic spinal conditions or complex regional pain syndrome (reflex sympathetic dystrophy).
4. There is inconsistent evidence as to whether spinal cord stimulators are more effective than alternatives for relieving pain in patients with either chronic spinal conditions or complex regional pain syndrome (reflex sympathetic dystrophy).
5. Complications occur in 1/3 to 1/2 of cases, but are often mild and mostly involving problems with the equipment or local infection. But up to 1/3 of patients will require re-operation in the first two years due to complications.
6. Trial screening periods in the reported case series and clinical trials have lasted from 1 day up to 30 days, with most lasting from 3 to 7 days. There is no information to judge whether the length of the trial period influences the reported efficacy of spinal cord stimulation.
7. The most common measure of success in the trial period was relief of pain and the most common criteria was pain relief of at least 50%.

Recommendations

Based on the conclusions derived from the literature the Department proposes the following draft recommendations to the Medical Services Review Board, to be used as the basis for changes to the Permanent Treatment Parameters governing the use of spinal cord stimulators in workers' compensation claims.

I. Spinal cord stimulators can effectively relieve pain in some patients with chronic spinal pain or complex regional pain syndrome (reflex sympathetic dystrophy).

II. An adequate trial period of at least three days is needed to determine who might benefit from spinal cord stimulation.

III. Adequate pain relief of at least 50% during the trial period is needed to determine if a patient might benefit from spinal cord stimulation.

DRAFT REPORT

Spinal Cord Stimulators

December 18, 2007

The Department has prepared this report spinal cord stimulators in accordance with the guidelines and formats used in the MSRB Charge to its Medications Task Force (October 14, 2004 MSRB meeting). The overall clinical question considered in this review was:

1. What is the proper use of spinal cord stimulators in the treatment of chronic spinal pain and complex regional pain syndrome (reflex sympathetic dystrophy)?

This overall question was addressed by identifying and synthesizing the best available medical data on the following specific issues:

Are spinal cord stimulators *effective* in the treatment of chronic spinal pain and complex regional pain syndrome (reflex sympathetic dystrophy)?

Are spinal cord stimulators *safe*?

What is the appropriate trial period for determining if a patient will have a favorable response to treatment with a spinal cord stimulator?

What are the appropriate criteria for judging whether a patient had a favorable response during a trial period?

Department Work Plan

The Department used the same “evidence-based medicine” approach to spinal cord stimulators as had been employed by the MSRB’s Medications Task Force in preparing its report on non-steroidal anti-inflammatory drugs (NSAIDs)¹. Evidence-Based Medicine (EBM) “is the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.”² EBM replaces clinical intuition, observations from personal clinical experience, and hypothetical arguments based on pathophysiological principles, as the principle grounds for clinical decision-making. Instead evidence from systematic surveys and critical appraisals of peer-reviewed, methodologically-sound clinical research is gathered, reviewed and synthesized using standardized, objective protocols based on agreed rules of evidence.

Key components of the evidence-based medicine approach used by the Department are:

- a) the systematic search for, and retrieval of, all the relevant medical literature regarding the use of spinal cord stimulators that addresses one or more of the specific issues listed above;
- b) sorting the retrieved literature by level of evidence;
- c) critical appraisal of that literature to systematically examine its validity, results and relevance; and,
- d) synthesis of the findings, with a grade of recommendation.

1 Final Report. MSRB Task Force On Medications. Nonsteroidal Anti-Inflammatory Drugs, July 21, 2005

2 Rosenberg W, Donald A. “Evidence-based medicine: an approach to clinical problem solving” BMJ 1995; 310(6987): 1122-1126

Strauss SE, Richardson WS, Glasziou P, Haynes RB Evidence-based Medicine: How to Practice and Teach EBM Edinburgh; Churchill Livingstone, 2005

The search and retrieval of the medical literature was done using computerized search engines and on-line bibliographical databases of the medical literature. In order to maximize the efficient use of time and resources, the same strategies as used by the MSRB's Medications Task Force in its analysis on NSAIDs were adopted to target the searches to the best and most recent evidence by using a step-wise search process.

First, the Department searched the medical literature by "level of evidence." The levels of evidence (Table 1) are a hierarchy representing the strength of the conclusion that can be drawn from a study of that type. Level I evidence is the most compelling, while Level VI evidence is the weakest. The Department restricted the initial search of the medical literature to Level I evidence – systematic reviews and meta-analyses. A systematic review is itself a review of the medical literature conducted using methods (including systematic search and retrieval of all the relevant primary source evidence and critical appraisal of the evidence found using standardized techniques) designed to minimize the likelihood of bias in the results. A meta-analysis is a systematic review in which quantitative methods are used to summarize the results of the review³. Not only are systematic reviews and meta-analyses the strongest evidence available but they have the additional property of representing the other levels of evidence.

Table 1: Levels of Evidence⁴

I	systematic reviews/meta-analyses of multiple randomized, controlled trials
II	randomized, controlled trials
IIIA	controlled studies without randomization
IIIB	other types of quasi-experimental study
IV	non-experimental descriptive studies
V	case series
VI	expert committee reports or opinions/clinical experience of respected authorities, or both

Using Level I evidence means that the Department could review efforts by other researchers who had already searched the medical literature for Level II and higher evidence, retrieved and reviewed these studies to determine their relevance and methodological quality, abstracted and evaluated their findings, and synthesized the results. This allowed the Department to leverage its resources to review a much larger body of evidence.

Second, the Department tried to focus the search on the most recent studies, so as to best represent the most current information.

The Department also searched for any already published, evidence-based guidelines for the use of spinal cord stimulators.

³ Guyatt G, Rennie D. *Users' Guides to the Medical Literature. Essentials of Evidence-Based Clinical Practice* AMA Press, 2002
 FOCUS "Critical Appraisal Tool" at <http://www.focusproject.org.uk/>

⁴ Adapted from Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, Dawes M "Levels of Evidence and Grades of Recommendation"
 Oxford Centre for Evidence-based Medicine, 1998 http://www.cebm.net/levels_of_evidence.asp

Prior to beginning the literature search, the Department adopted a set of guidelines for determining when and how the searches would be extended that were similar to those used by the MSRB's Medications Task Force in its analysis on NSAIDs. If at least 10 valid and unrelated references to systematic reviews were not found, the search would be extended to look for all articles in category II (randomized controlled trials) and for all articles in category I (systematic reviews) in the entire database.

The search for relevant medical literature was in fact extended to all levels of evidence. And the search was extended back in time to encompass all of the available literature in the on-line databases.

The Department conducted the literature searches in two electronic bibliographic databases:

1. Medline through the PubMed portal at <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi> ; and,
2. The Cochrane Library (The Cochrane Database of Systematic Reviews, Database of Abstracts of reviews of Effects, and The Cochrane Central Register of Controlled Trials) through the Lumina portal of the University of Minnesota Libraries at http://tc.liblink.umn.edu/sfx_local/a-z/default.

PubMed is a service of the National Library of Medicine (NLM) available via the National Center of Biotechnology's Entrez retrieval system. PubMed is a public access search engine for MEDLINE, NLM's premier bibliographic database for medical literature. MEDLINE contains bibliographic citations and author abstracts from more than 4,800 biomedical journals published in the United States and 70 other countries. The database contains over 12 million citations dating back to mid-1960.

The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases created by the Cochrane Collaboration, an international non-profit independent organization of health care providers and health care researchers. The Cochrane Library is a collection of evidence-based medicine databases, which is up-dated quarterly from the best available information about healthcare interventions found in both published and unpublished medical studies from around the world. The Cochrane Database of Systematic Reviews (CDSR) is the collection of systematic reviews done by Cochrane Collaboration work groups. The Database of Abstracts of Reviews of Effects (DARE) contains summaries of systematic reviews done by others, which have met strict quality criteria established by the Cochrane Collaboration. Included reviews have to be about the effects of interventions. The Cochrane Central Register of Controlled Trials (CENTRAL) includes details of clinical trials found in bibliographic databases (notably MEDLINE and EMBASE), and other published and unpublished sources.

The Department used the same inclusion criteria used by the MSRB's Medications Task Force in its analysis on NSAIDs to determine which of the studies found in the automated searches would be retrieved for further analysis. First, the title of the article was reviewed to confirm that the article was about the therapeutic use of spinal cord stimulators in humans. The abstracts and bibliographical data were then retrieved for articles meeting the first screening and reviewed to determine if:

- the article addressed one of the specific issues of relevance about spinal cord stimulators;
- the article represented a study of the appropriate level of evidence;
- it was a study published during the search time frame;
- the article was published in English; and
- the article was available on-line through the University of Minnesota Bio-Medical Library.

Articles selected for inclusion after a review of the article abstract were retrieved in electronic format from the University of Minnesota Bio-Medical Library through the Lumina portal. An electronic database was created listing the authors, the title of the article, and the journal reference. Each article's abstract and full text was then hyperlinked to its citation in the database. Retrieved articles were evaluated for their level of evidence and assigned a "relevance" category. Systematic reviews (and/or meta-analyses) and randomized controlled trials were considered to be of "high" relevance. Other types of controlled trials and economic evaluations were considered to be of "medium" relevance. Unsystematic reviews, editorials, case series, case studies and all other types of articles were considered to be of "low" relevance.

An additional computerized search for guidelines, using the key words "pain" and "spinal cord stimulation" was conducted at the websites of organizations known to be active in guideline development, appraisal, or cataloging:

Country	Name of organization	Website
Netherlands	Dutch Institute for Healthcare Improvement	http://www.cbo.nl
New Zealand	New Zealand Guidelines Group	http://www.nzgg.org.nz
	Accident Compensation Corporation	http://www.acc.co.nz/index.htm
Scotland	Scottish Intercollegiate Network	http://www.sign.ac.uk
Sweden	Swedish Council on Technology Assessment in Health Care	http://www.sbu.se
UK	National Library of Guidelines	http://www.library.nhs.uk/guidelinesfinder
USA	National Institutes of Health Consensus Development Program	http://consensus.nih.gov
	National Guideline Clearinghouse	http://www.guideline.gov
	Agency for Healthcare research & Quality	http://www.ahrq.gov/

Finally, the computerized searches were supplemented by hand searches of the bibliographies of key articles (particularly systematic reviews and guidelines) and with articles submitted by interested parties.

Articles chosen for analysis were then assessed for their quality using criteria that were appropriate to the study type.

For systematic reviews, the quality criteria chosen were:

1. Study Identification	
Multiple electronic databases	
Unbiased explicit searching strategies	
Hand searches	
Attempts to include "gray" literature	
Estimation of potential publication bias	
2. Study selection	
Only randomized controlled trials included	
Explicit inclusion/exclusion criteria	
Selection criteria applied uniformly	
Rationale for excluding studies	
3. Appraisal of studies	
Described in detail	
Uniformly applied to all studies	
Important parameters addressed	
<ul style="list-style-type: none"> • random allocation • double blinding • relevant outcome measures • follow-up of at least 80 per cent of participants • analysis consistent with the study design 	<hr/> <hr/> <hr/> <hr/> <hr/>
Effect of study quality on conclusions assessed	
4. Data Collection	
Was missing information considered?	
5. Data synthesis	
Assessment for heterogeneity	
All valid studies used	
Sensitivity analysis performed	
Variations between studies considered	

For randomized controlled trials, the quality criteria were:

Random allocation	
Minimal dropouts (< 15%)	
Blinding of patient	
Blinding of the assessor	
Co-treatments have been used in an equivalent manner among treatment groups.	
Assessment of the extent of patient adherence to the prescribed therapy	
No unintended crossovers from one study treatment to the other.	
Adequate consideration of statistical and clinical significance of findings.	
Adequate demographic description of patients, including at least age, gender, and referral source.	
Adequate clinical description, including pain duration, neurologic deficits, sciatica, previous surgery, and other inclusion or exclusion criteria.	
Adequate description of treatment in terms of dosage, duration, frequency, and technique.	
Reporting of all relevant outcomes, which may include symptoms, physiologic changes, functional ability, costs of care, and psychological measures.	

These criteria were adapted from recommendations for critical appraisal of systematic reviews and randomized controlled trials found in the peer-reviewed literature and textbooks of evidence-based medicine.⁵

For guidelines, the quality criteria were derived from the instrument developed by The AGREE Collaboration started in 1998 as a research project under the Biomedicine and Health Research (BIOMED 2) Programme, funded by the European Union⁶:

Scope and purpose	
Objective(s) of the guideline are specifically described.	
The clinical question(s) is specifically described.	
The patients to whom the guideline is meant to apply is specifically described.	
Stakeholder involvement	
The guideline development group includes individuals from all the relevant professional groups.	
The patients' views and preferences are sought.	
Rigour of development	
Systematic methods are used to search for evidence.	
The criteria for selecting the evidence are clearly described.	
The methods used for formulating the recommendations are clearly described.	
The health benefits, side effects and risks are considered in formulating the recommendations.	
There is an explicit link between the recommendations and the supporting evidence.	
The guideline was externally reviewed by experts prior to publication.	
A procedure for updating the guideline is provided.	
Clarity and presentation	
The recommendations are specific and unambiguous.	
The different options for diagnosis and/or treatment of the condition are clearly presented.	
Key recommendations are easily identifiable.	
Applicability	
The target users of the guideline are clearly defined.	
The potential organizational barriers in applying the recommendations are discussed.	
The potential cost implications of applying the recommendations were considered.	
The guideline is supported with tools for application.	
The guideline presents key review criteria for monitoring and audit purposes	
The guideline was piloted among end users.	
Editorial independence	
The guideline is editorially independent from the funding body.	
Conflicts of interest of guideline development members are recorded.	

Articles were scored "yes", "no", "can't tell" on each item. A summary score was determined by adding together the "yes" responses, dividing by the total number of criteria. This scoring system is a short hand way of indicating overall study quality and is similar to systems used in many systematic reviews for evaluating primary source literature.

⁵ Oxman AD, Cook DJ, Guyatt GH "Users' guides to the medical literature. VI How to use an overview" *Journal of the American Medical Association* 1994; 272(17): 1367-1371

Guyatt GH, Sackett DL, Cook DJ "Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid?" *Journal of the American Medical Association* 1993; 270(21): 2598-601.

Crombie IK *The Pocket Guide to Critical Appraisal: A Handbook for Healthcare Professionals* London; BMJ Publishing Group, 1996

⁶ <http://www.agreecollaboration.org/>

In addition, the author's conclusions regarding spinal cord stimulator were abstracted, and, in the case of the systematic reviews, the primary literature relied upon by the author(s) in reaching their conclusions was identified and tabulated. The results of the quality review, the author's conclusions, and, if relevant, the bibliography of the primary source literature were entered into a "Summary Sheet" for each article. These Summary Sheets were then also hyperlinked to the Department database.

Finally, the abstracted conclusions from each article were transferred to a separate spreadsheet. There, the conclusions were first sorted onto different pages based on the clinical population addressed in the study (Failed back Surgery Syndrome (and other spinal pain problems), Complex Regional Pain Syndrome, and Mixed Chronic Pain Patients); then they were arranged thematically into columns for comparison across articles.

Results

The first PubMed search used a search string published in the medical literature that has been validated as both sensitive and specific for retrieving systematic reviews.⁷ The search string was combined first with the key words "spinal cord stimulator" and "neurostimulator." Because a search done limiting articles to those published since 1990 yielded less than 10 unique references, this search was expanded to the entire Pub Med database. Expanding this search to the entire PubMed database still did not yield more than 10 unique references, so the search was eventually expanded to include other types of articles. Separate searches were done for articles reporting on the use of spinal cord stimulator in low back pain patients and in patients with complex regional pain syndrome (reflex sympathetic dystrophy). The results of the searches can be found in the documents "SCS and LBP.doc", "SCS and RSD.doc", "Neurostim and LBP.Doc", "Neurostim and RSD.Doc", "SCS-CT.doc", "SCS-meta_analysis.doc", and "SCS-RCT.doc" (Available at: <http://www.doli.state.mn.us/msrb/scs/>).

These searches retrieved 161 titles, some found more than once. Of these, 63 articles were presumed relevant based on their title and retrieved for further review.

The searches of the Cochrane Database of Systematic Reviews (CDSR) of the Database of Abstracts of Reviews of Effects (DARE) were done using the key word "spinal cord stimulator" and did not yield any new references not found in the PubMed search.

The hand search added 4 articles which were considered potentially relevant (their ID# marked with a suffix "h" in the database) and 2 articles were submitted by interested parties (their ID# marked with a suffix "s" in the database).

⁷ "((meta-analysis [pt] OR meta-analysis [tw] OR metanalysis [tw]) OR ((review [pt] OR guideline [pt] OR consensus [ti] OR guideline* [ti] OR literature [ti] OR overview [ti] OR review [ti]) AND ((Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw]))) OR (handsearch* [tw] OR search* [tw] OR searching [tw]) AND (hand [tw] OR manual [tw] OR electronic [tw] OR bibliographi* [tw] OR database* OR (Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw]))))) OR ((synthesis [ti] OR overview [ti] OR review [ti] OR survey [ti]) AND (systematic [ti] OR critical [ti] OR methodologic [ti] OR quantitative [ti] OR qualitative [ti] OR literature [ti] OR evidence [ti] OR evidence-based [ti])) BUTNOT (case* [ti] OR report [ti] OR editorial [pt] OR comment [pt] OR letter [pt]) " found in Shojania KG, Bero LA. "Taking advantage of the explosion of systematic reviews: an efficient MEDLINE search strategy" *Eff Clin Pract* 2001;4(4): 157-62.

The search for guidelines on the World Wide Web found 9 and another was submitted by an interested party.

References for all the articles chosen for further review were combined in an Excel database, [spinal-stim.xls](#) (see Appendix 3). Of the 79 articles (9 systematic reviews, 6 randomized controlled trials, 12 guidelines, 3 clinical trials, 6 economic evaluations, 11 unsystematic reviews/editorials, and 32 case series/studies), the full article was available electronically for 44 of them through the Lumina portal at the University of Minnesota (9 systematic reviews, 5 randomized controlled trials, 2 guidelines, 2 clinical trials, 6 economic evaluations, 6 unsystematic reviews/editorials, and 14 case series/studies). Ten guidelines were available through the World Wide Web or were made available by an interested party. When available, the full article was hyperlinked to the database. The article's abstract was then reviewed to determine level of evidence and the relevance of the article.

In all, 14 articles met the inclusion criteria (9 systematic reviews, 5 randomized controlled trials, 12 guidelines) and were entered into a second Excel database, [spinal stim - review.xls](#) (see Appendix 4). A quality review was then performed for each article.

The retrieved articles varied in quality. The systematic reviews had summary quality scores ranging from 5/22 to 20/22. However, 5 of the 7 systematic reviews had quality scores greater than 15/22. The randomized controlled trials had summary quality scores ranging from 8/12 to 10/12. The guidelines had summary quality scores ranging from 7/23 to 20/23; however, 5 had scores greater than 13/23.

Overall, all of the systematic reviews and RCTs addressed the question of effectiveness. Five of the systematic reviews and three of the RCTs addressed issues of safety. Two systematic reviews focused on the use of spinal cord stimulators in patients with low back pain, two focused on their use in patients with complex regional pain syndrome (reflex sympathetic dystrophy) and five assessed the effectiveness of spinal cord stimulators in general. Two RCTs included only patients with low back pain and the others included only patients with complex regional pain syndrome (reflex sympathetic dystrophy). Five of the systematic reviews reported on the criteria used for judging whether a patient had a favorable response during a trial period; four reported on the appropriate trial period.

Three of the guidelines were specific to the use of spinal cord stimulators in patients with complex regional pain syndrome (reflex sympathetic dystrophy); one addressed only use in patients with failed back surgery syndrome, while three addressed their use in chronic pain patients without concern for the underlying condition. The others provided guidance regarding both complex regional pain syndrome (reflex sympathetic dystrophy and failed back surgery syndrome cases). The evidence used in developing the recommendations was referenced in the available text for 10 of the 12 guidelines. Those guidelines all relied, at least in part, on systematic reviews and RCTs; in most cases those systematic reviews and RCTs were the same ones identified in the searches done for this report (as noted in columns K and L of [spinal stim - review.xls](#)).

The conclusions made by the article's author(s) were then abstracted and entered into a third database, spinal stim - analysis.xls (see Appendix 4). There, the conclusions were first sorted onto different pages based on the clinical population addressed in the study (Failed back Surgery Syndrome (and other spinal pain problems), Complex Regional Pain Syndrome, and Mixed Chronic Pain Patients); then they were arranged thematically into columns for comparison across articles. Themes were identified inductively from the abstracted conclusions by arranging them into the fewest mutually exclusive categories.

The themes identified were:

<i>theme</i>	<i># articles</i>	<i>summary quality scores</i>
Sources of data	SysRev: 9 RCT: 5 Guidelines: 10	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 7/23 – 20/23
Comments on data	SysRev: 7 RCT: 5 Guidelines: 10	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 7/23 – 20/23
Quantitative results	SysRev: 9 RCT: 5 Guidelines: 6	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 10/23 – 20/23
Reported complications	SysRev: 6 RCT: 4 Guidelines: 1	SysRev: 5/22 – 18/22 RCT: 9/12 – 10/12 Guidelines: 14/23
Study design issues	SysRev: 7 RCT: 5 Guidelines: 0	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12
Author's overall conclusions	SysRev: 8 RCT: 5 Guidelines: 11	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 10/23 – 20/23
Comments on length of trial period	SysRev: 3 RCT: 1 Guidelines: 0	SysRev: 5/22 – 20/22 RCT: 10/12
Comments on judging trial success	SysRev: 3 RCT: 5 Guidelines: 0	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12

Conclusions

The Department found considerable agreement of published opinion on each issue. While the individual articles varied in quality, this variation does not significantly affect the conclusions reached by the authors. Articles of higher quality most often reached the same conclusions as those of lower quality.

Nine of the 12 guidelines recommended the use of spinal cord stimulation in at least some clinical situations (5 of 6 guidelines with recommendations for back pain patients; 7 of 8 guidelines with recommendations for complex regional pain syndrome patients; 2 of 3 guidelines for recommendations for chronic pain patients in general).⁸ The guidelines not recommending

⁸ Some guidelines had recommendations for more than one clinical situation.

the use of spinal cord stimulators did not differ markedly in quality from those recommending their use but did tend to rely on a smaller base of data.

The conclusions drawn by the Department from the reviewed literature are:

1. There is limited evidence (predominantly from case series and two RCTs) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 60% of patients with chronic spinal conditions who have a positive response during a screening trial period.
2. There is limited evidence (predominantly from case series and one RCT) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 67% of patients with complex regional pain syndrome (reflex sympathetic dystrophy) who have a positive response during a screening trial period.
3. There is inconsistent evidence as to whether spinal cord stimulators improve other clinical outcomes in patients with either chronic spinal conditions or complex regional pain syndrome (reflex sympathetic dystrophy).
4. There is inconsistent evidence as to whether spinal cord stimulators are more effective than alternatives for relieving pain in patients with either chronic spinal conditions or complex regional pain syndrome (reflex sympathetic dystrophy).
5. Complications occur in 1/3 to 1/2 of cases, but are often mild and mostly involving problems with the equipment or local infection. But up to 1/3 of patients will require re-operation in the first two years due to complications.
6. Trial screening periods in the reported case series and clinical trials have lasted from 1 day up to 30 days, with most lasting from 3 to 7 days. There is no information to judge whether the length of the trial period influences the reported efficacy of spinal cord stimulation.
7. The most common measure of success in the trial period was relief of pain and the most common criteria was pain relief of at least 50%.

Recommendations

Based on the conclusions derived from the literature the Department proposes the following draft recommendations to the Medical Services Review Board, to be used as the basis for changes to the Permanent Treatment Parameters governing the use of spinal cord stimulators in workers' compensation claims.

I. Spinal cord stimulators can effectively relieve pain in some patients with chronic spinal pain or complex regional pain syndrome (reflex sympathetic dystrophy).

II. An adequate trial period of at least three days is needed to determine who might benefit from spinal cord stimulation.

III. Adequate pain relief of at least 50% during the trial period is needed to determine if a patient might benefit from spinal cord stimulation.

Appendix 1

The Department's website for this project is: <http://www.doli.state.mn.us/msrb/scs/>

All of the Department's work products are available on the website.

Appendix 2

The Word files “SCS and LBP.doc”, “SCS and RSD.doc”, “Neurostim and LBP.Doc”, and “Neurostim and RSD.Doc”, “SCS-CT.doc”, “SCS-meta_analysis.doc”, “SCS-RCT.doc” (Available at: <http://www.doli.state.mn.us/msrb/scs/>) list all of the articles found in the literature searches.

Appendix 3

The Excel workbook [spinal-stim.xls](#) (Available at: <http://www.doli.state.mn.us/msrb/scs/>) lists all of the articles that were selected by the Department for further review.

Column A is an ID number

Column B lists the authors of the article.

Column C is the title of the article.

Column D gives the abbreviated citation as found in Medline and is an active link.

Clicking on the journal citation will call up the abstract and/or article

Column E identifies the type of article:

“SysRev” is a systematic review,

“RCT” is a randomized controlled trial

“CT” is a nonrandomized trial

“CE” is an economic evaluation

“Guide” is an evidence-based treatment guideline

“Review” is an unsystematic review

“Editorial” is a statement of a single physician’s opinion

“CaseSer” is a case series

“CaseRep” is a single case report

Column F indicates whether the article was determined to be relevant for the purposes of this study based on the levels of evidence hierarchy.

Column G indicates the availability of the article.

Column H indicates the patient subgroup(s) discussed in the article.

Appendix 4

The Excel workbook [spinal stim - review.xls](#) (Available at: <http://www.doli.state.mn.us/msrb/scs/>) lists the results of the quality review of the articles that were selected by the Department for this analysis.

Column A is an ID number

Column B lists the authors of the article.

Column C gives the abbreviated citation as found in Medline and is an active link.

Clicking on the journal citation will call up the abstract and/or article

Column D identifies the type of article:

“SysRev” is a systematic review,

“RCT” is a randomized controlled trial

“Guide” is an evidence-based treatment guideline.

Column E is marked with an “X” if the article discusses efficacy.

Column F is marked with an “X” if the article discusses safety.

Column G indicates the patient subgroup(s) discussed in the article.

Column H is a hyperlink to the summary sheet for the article

Column I is the summary quality score of the article

Column J includes any comments about the article

For guidelines only:

Column K lists the ID# for any systematic reviews included in this analysis that were used by the authors of the guideline.

Column L lists the ID# for any randomized clinical trials included in this analysis that were used by the authors of the guideline.

Column M lists the ID# for any guidelines included in this analysis that were used by the author's of the guideline.

Appendix 5

The Excel workbook [spinal stim -analysis.xls](http://www.doli.state.mn.us/msrb/scs/) (available at: <http://www.doli.state.mn.us/msrb/scs/>) lists the author's findings and conclusions regarding the efficacy and safety of spinal cord stimulators, and any other information relevant to the questions posed for this analysis. Wherever possible, the conclusions are stated in the authors' own words.

This workbook has 3 spreadsheets or pages:

The **first page** lists the results for articles that addressed the use of spinal cord stimulators in patients with low back pain.

- Column A** gives the abbreviated citation as found in Medline and is an active link. Clicking on the journal citation will call up the abstract and/or article
- Column B** identifies the type of article: "SR" is a systematic review, "RCT" is a randomized controlled trial, and "Guide" is an evidence-based treatment guideline.
- Column C** lists the sources of information used.
- Column D** lists any comments made by the authors regarding the sources of information.
- Column E** lists the quantitative results of the study.
- Column F** lists any information regarding complications.
- Column G** lists any comments made by the authors regarding the study design or other methodological issues.
- Column H** lists the authors' overall conclusions on the use of spinal cord stimulation.
- Column I** is intentionally blank.
- Column J** lists any information given regarding the conduct of a trial period.
- Column K** lists any information given regarding the criteria for judging a trial as successful.

The **second page** lists the results for articles that addressed the use of spinal cord stimulators in patients with complex regional pain syndrome.

- Column A** gives the abbreviated citation as found in Medline and is an active link. Clicking on the journal citation will call up the abstract and/or article
- Column B** identifies the type of article: "SR" is a systematic review, "RCT" is a randomized controlled trial, and "Guide" is an evidence-based treatment guideline.
- Column C** lists the sources of information used.
- Column D** lists any comments made by the authors regarding the sources of information.
- Column E** lists the quantitative results of the study.
- Column F** lists any information regarding complications.
- Column G** lists any comments made by the authors regarding the study design or other methodological issues.
- Column H** lists the authors' overall conclusions on the use of spinal cord stimulation.
- Column I** is intentionally blank.
- Column J** lists any information given regarding the conduct of a trial period.
- Column K** lists any information given regarding the criteria for judging a trial as successful.

The **third page** lists the results for articles that addressed the use of spinal cord stimulators in chronic pain patients in general.

Column A gives the abbreviated citation as found in Medline and is an active link.

Clicking on the journal citation will call up the abstract and/or article

Column B identifies the type of article: “SR” is a systematic review, “RCT” is a randomized controlled trial, and “Guide” is an evidence-based treatment guideline.

Column C lists the sources of information used.

Column D lists any comments made by the authors regarding the sources of information.

Column E lists the quantitative results of the study.

Column F lists any information regarding complications.

Column G lists any comments made by the authors regarding the study design or other methodological issues.

Column H lists the authors’ overall conclusions on the use of spinal cord stimulation.

Column I is intentionally blank.

Column J lists any information given regarding the conduct of a trial period.

Column K lists any information given regarding the criteria for judging a trial as successful.

Appendix 6

The Excel workbook spinal stim –primary sources.xls (available at: <http://www.doli.state.mn.us/msrb/scs/>) lists all of the original studies referenced by the authors of systematic reviews and evidence-based guidelines.