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Whole person. Whole system.

IDSS 2023

12 – 14 November
Hobart

How evidence reviews can inform workers compensation scheme practice

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Institute for Safety, Compensation and Recovery Research

IDSS 2023 Actuaries Institute.

A unique collaborative partnership between WorkSafe VICTORIA and MONASH University


RESEARCH


BROKER


TRANSLATION


TRAINING

- 14 years of decision-informing research in the field of Australian worker health and safety
- Broad area expertise with skills in applied research for policy and practice

Prevention | Recovery | Mental Health

ISCRR

Exclusive National Science

This was published 1 year ago

To hell and back: Devices meant to ease pain are causing trauma

Liam Mannix
February 5, 2022 — 5.17am

Save Share A A A

A $35,000 treatment a
electric pulses into th
incontinent, unable to

Exclusive National Medicare

This was published 4 months ago

Insurers call for ban on spinal cord stimulator subsidies after new trial

Liam Mannix
October 27, 2022 — 12.30pm

Save Share A A A 6 View

"For people with low back pain…at 6 months, spinal cord stimulation probably does not lead to better function, or higher quality of life compared with placebo."

Traeger et al (2023)

"We rated the evidence as being of low, or very low certainty... our confidence in the results is limited."

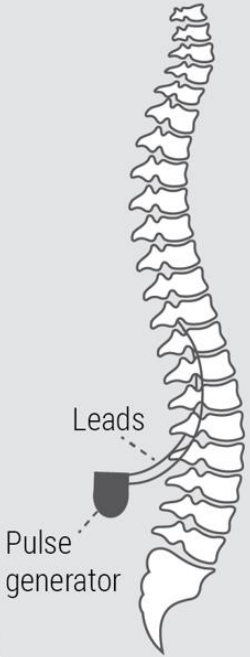
O'Connell et al (2021)

Overview

- What are Spinal Cord Stimulators (SCSs)?
- How do evidence reviews help inform practice?
- What is the current evidence base for SCS use?
- What is happening in the SCS's regulatory space in Australia?
- WorkSafe Victoria perspective

What are spinal cord stimulators?

What is a Spinal Cord Stimulator?



A Spinal Cord Stimulator (SCS) is a surgically implanted device used to treat persistent pain.

SCSs block pain signals to the brain using electrical impulses via leads into the spine.

WorkSafe Victoria funds SCSs for injured workers based on clinical advice.

SCS is used to treat chronic or persistent pain in a range of conditions. Most commonly:

- Failed Back Surgery Syndrome
- Complex Regional Pain Syndrome

What are the other benefits?

Improvement in disability and function

Reductions in the use of pain medications

Improvements in quality of life

Improvements in return to work capacity

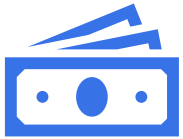
How do evidence reviews help inform practice?

Evidence reviews contribute to evidence-based decision-making.

In areas of rapid technological advancement, up to date evidence reviews are vital for getting the best outcomes for patients.

Key issues with SCS

Financial implications



- $30k to $40k
- Maintenance costs
- Revisions and replacements

Technological advances

- Rapid advances in technology
- Less replication
- Lack of long term outcome studies

Adverse events

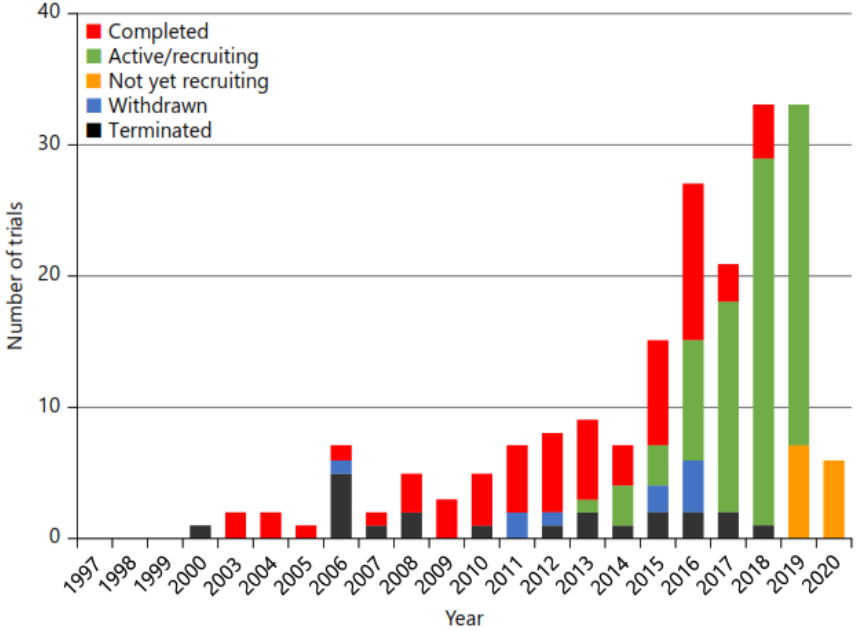
- Range of complications
- Under reporting

Rapid advances in technology and investment

The spinal cord stimulators market size is US$2,702 million in 2023. For investors, the expectation is of 7.2% growth to 2033 with a market size of US$5,441 million.

https://www.futuremarketinsights.com/reports/spinal-cord-stimulator-market

Rapid increase in clinical trials



Approximately two-thirds of all clinical trials commenced within the last 5 years.

Figure 1. Trials by status of completion.

Harmsen et al. Trends in Clinical Trials for Spinal Cord Stimulation. Stereotact Funct Neurosurg. 2021;99(2):123-34.

The evidence review process

Search criteria

- Published between April 2014 and August 2022
- Evidence-based guidelines, systematic reviews, randomised controlled trials, controlled clinical trials
- spinal cord stimulation OR spinal cord stimulator OR spinal neuromodulation OR implantable pulse generator

Systematic search

- Searched: Medline, Cochrane, Embase
- Reference lists scanned for additional studies
- Supplementary searches in the most recent issues (2022) of relevant journals

Quality appraisal

- McMaster's Health Evidence Checklist (systematic reviews)
- Quality Assessment Tool for Quantitative Studies (randomized control trials)

What did our evidence review find?

21
Systematic reviews

- One Cochrane systematic review (2021)
- 12 with a primary outcome of pain
- 9 with other primary outcome (e.g., opioid use)

10
Randomised control trials

- 7 with a primary outcome of pain
- 3 with other primary outcome (e.g., opioid use)

20
Prospective cohort studies

- 19 with a primary outcome of pain
- 1 with a primary outcome of quality of life

What did our evidence review find?

Effect on persistent pain

- ✓ Effective in short & medium term
- ✓ Lack of evidence in long term

Secondary effects

- ✓ Disability & functioning
- ✓ Quality of life
- ✓ Medication use

Evidence base

- ✓ Low quality
- ✓ High risk of bias (industry funding)
- ✓ High heterogeneity

Adverse events

- ✓ Still issues with reporting
- ✓ High rates
- ✓ TGA investigating

Evidence base for adverse events

Adverse events reported to the TGA 2012-2019

- 26,786 devices implanted and 10,702 devices removed
- 520 reported adverse events
- Device malfunction was the most common event (56.5%).
- Most were rated as severe (79%) or life-threatening (13%).

> "Our results raise questions about the safety and utility of this approach to treating chronic intractable pain"
>
> Jones et al (2022)

What is happening in the regulatory space?

- TGA announced it is undertaking a post-market review of Spinal Cord Stimulators.
- The purpose of the review is to reassess the safety and performance of the devices, with the current real-world evidence that is now available for the intended purposes for which they are to be used.

How do our evidence reviews inform workers compensation scheme practice?

What are the next steps for the spinal cord stimulator work?

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Thank you

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