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Coverage decisions by insurers: The evidence-to-decision framework, using the example of transcutaneous electrical nerve stimulation (TENS) for the treatment of neuropathic pain.

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Cochrane Corner

This Cochrane Corner illustrates how the GRADE[1] Evidence-to-Decision Framework can support insurers making coverage decision when research evidence is inconclusive, using a case study on pain management with transcutaneous electrical stimulation (TENS).

The case

As a cost manager at a health insurance, you have noticed a 30% increase in prescriptions for transcutaneous electrical nerve stimulation (TENS) machines for the treatment of neuropathic pain in the last 6 months. This increase could have an impact on your budget. You note that a pain center and two practice groups specializing in patients with lumbar radiculopathies and spinal cord injuries are mainly causing the increase in prescriptions. You organise a meeting with the organizations' doctors and your insurance company's chief medical officer in order to analyze the situation.

During the talk, the doctors justify their prescriptions by referring to current research findings and their good personal experience regarding the effectiveness of TENS for pain reduction. Your own search in the Cochrane Library revealed a systematic review on "TENS for neuropathic pain in adults" by W. Gibson and colleagues (1), which found less optimistic results. You ask the insurance expert panel to evaluate whether – based on the available evidence and using the GRADE Evidence-to-Decision (EtD) Framework - the insurer should continue to pay for TENS treatment for patients with neuropathic pain.

Background

Neuropathic pain is a common cause of chronic pain and functional impairment. It results from nerve damage or disease of peripheral nerves, such as post-traumatic injuries. Central neuropathic pain results from injuries affecting the central nervous system, including spinal cord injury. Medical treatment is difficult and often requires the simultaneous use of different treatments. TENS is often recommended for pain control. TENS machines use a weak electrical current through skin electrodes to trigger nerve stimulation. Common TENS machines differ significantly in terms of technical settings and therapy modes, e.g. high or low frequency, high or low intensity, treatment duration over several days or several months. Accordingly, research findings on the effectiveness of treatment with TENS are controversial.

[1] GRADE stands for Grading of Recommendations, Assessment, Development and Evaluations

Methods and main outcome

The 15 studies in the review - all randomized or quasi-randomized - used very different approaches to test the effectiveness of TENS for the treatment of neuropathic pain. They compared TENS with placebo TENS or with no treatment, with usual care - such as sensorimotor rehabilitation or manual therapy - or they compared usual care plus TENS with usual care alone. The only condition for inclusion in the review was that the TENS application had to produce a perceptible sensation in the patient. Otherwise, all types of technical settings or therapy modes qualified. The review examined the effectiveness for the endpoints pain intensity, health-related quality of life, analgesic use, and adverse effects.

A major limitation in almost all studies was that patients - and in some studies, medical staff - knew what treatment patients were receiving. Because pain intensity is a highly subjective experience, the lack of blinding of patients and staff complicates interpretation and lowers our confidence in the results.

Patients treated with TENS instead of placebo-TENS had slightly less pain. The joint analysis of five studies with pain measured on a visual analogue scale (VAS) ranging from 0 to 10 points found a mean reduction in pain intensity of 1.58 points (95% confidence interval: 2.08 points to 1.09 points). An improvement of this magnitude is generally considered to be patient-relevant. Most studies comparing TENS with usual care (there was substantial diversity of what constituted ‘usual care’) found no difference in pain outcomes compared to active treatment, or they preferred usual care. None of the studies reported on health-related quality of life or the use of analgesics. Side effects were minor and limited to mild skin irritation from the electrodes. However, overall confidence in the reported effects was considered very low due to multiple sources of bias, low number of studies and few participants in individual trials.

Conclusions of the review authors

Overall, it remains unclear whether TENS treatment is successful in alleviating pain. Thus, the role of TENS in the management of neuropathic pain also remains undecided. This conclusion is due to the very low quality of the studies. Future studies of high quality may lead to substantial changes in the current findings.

Evidence does not make decisions, people do: The GRADE Evidence-to-Decision Framework as an aid for coverage decisions by insurers

The GRADE Evidence-to-Decision Framework (2, 3) aims to support evidence users in evaluating studies in a structured and transparent way to make clinical recommendations and decisions for patient care and for public health or health system interventions. Today, many health insurers have an expert panel that prepares the content of recommendations and assesses the evidence required within the framework, and a panel of decision-makers that ultimately makes the decision.

Applying the framework involves three steps: First, posing the question (see box). Second, the assessment of the evidence required for the judgement of twelve criteria (Table 1) in the context of cost coverage by the insurer. Data pertinent to the criteria stem from research evidence and other considerations (Table 2). Third, the formulation of conclusions. In addition, the expert panel often provides considerations for implementation, monitoring, re-evaluation of the decision and need for further research.

Here we give a brief overview of the EtD framework and apply the twelve criteria to our case as an example (2, 3). All criteria have four to seven predefined response options. These are used to clearly communicate the expert panel's assessments to the decision-makers.

Table 1: The twelve criteria of the Evidence-to-Decision Framework for coverage decisions

• The priority of the problem
• Desirable effects
• Undesirable effects
• Certainty of the evidence
• Peoples values on the outcomes
• Balance between desirable and undesirable effects
• Resources required (costs)
• Certainty of evidence of required resources
• Cost-effectiveness of the intervention
• Impact on health equity
• Acceptability from key stakeholders
• Feasibility of the implementation

Application of the EtD framework to the case study of TENS for neuropathic pain

BOX: Formulating the coverage issue as a structured question with the most important aspects that specify the question

Question: Should a health insurance (continue to) cover the costs of TENS treatment for patients with neuropathic pain?
Patients: Insured individuals with neuropathic pain
Intervention**:** Treatment with transcutaneous electrical nerve stimulation (TENS)
Comparison: Care as usual
Main outcomes: Pain intensity, (health-related) quality of life, use of analgesics, adverse effects
Setting: Social insurance in Switzerland
Perspective**:** Health insurance

Table 2: Case study of the application of the EtD framework to a coverage decision about pain treatment with TENS machines.

The expert panel addresses the coverage issue using medical evidence from the Cochrane review Transcutaneous electrical nerve stimulation (TENS) for neuropathic pain in adults (1), internal analyses of use and resource consumption, and trade-offs regarding the acceptability of the decision options by the various stakeholders, and justifies the decisions made.

The setting of the case study – a social insurance in Switzerland – has implications for considerations on resource requirements, health equity, acceptability of decisions, or feasibility of implementing the decisions which are likely to vary across countries.

Evidence to Decision Criteria Conclusion	**Reasoning:** **Findings from research and other considerations**
1. Problem Is the problem a priority? • Probably YES	The treatment of neuropathic pain is challenging as patients often do not achieve satisfactory pain control. The intensity of the pain often requires the use of pharmacological and non-pharmacological measures to manage the pain.
2. Desirable effects How substantial are the desirable anticipated effects? • Do not know	Given the low quality of the studies identified and contradictory effects, the systematic review could not reliably conclude whether or not TENS is effective for the treatment of neuropathic pain. Neither the effectiveness nor the non-effectiveness has been established.
3. Undesirable effects How substantial are the undesirable anticipated effects? • Trivial	The review found only mild skin irritation as an adverse effect.

4. Certainty of evidence What is the overall certainty of evidence of anticipated effects? • Very low	Due to the methodological limitations of the studies and inconsistent effects, confidence in the evidence is very low. Future high quality studies are likely to find effects that are substantially different from the effects found in this review.
5. People's values on the outcomes • No important uncertainty	Patients with neuropathic pain often have severe pain. All patients value at least satisfactory pain control and improved quality of life. One can reasonably assume that these endpoints are of great importance to all patients.
6. Balance of effects Does the balance between desirable and undesirable effects favor the intervention or the comparison? • Do not know	According to the review, the adverse effects are trivial (skin irritation by electrodes), even though not all studies reported on side effects. Yet, as it is unclear whether there is a benefit for the patients with regards to pain reduction, quality of life, reduced use of analgesics, the balance of effects cannot be judged.
7. Resources required How large are the resource requirements (costs)? • It varies, overall it is about modest costs or savings	The prices for TENS on the market range between 16 € and 250 €. Cost absorption for purchased machines is about 180 € per case, for rented machines about 32 € per case. Overall, significantly more machines are rented than purchased.
8. Certainty of evidence of required resources • Low	Internal analyses show that the treatment method is gaining in importance. However, the effective use of this treatment method is difficult to estimate due to different billing methods and a substantial share of self-payers.
9. Cost-effectiveness of the intervention • Don't know	With unclear effectiveness, no formal cost-effectiveness analyses are currently available for neuropathic pain. If there were an urgent need to do so in the absence of effectiveness data, such an analysis could be done using different assumptions on effectiveness and costs, and different clinical scenarios, e.g. options of paying for versus renting a TENS machine.
10. Impact of health equity • Probably no impact	As long as the clinical effectiveness of the measure has not been clarified, neither of the two decision options (cost coverage yes or no) would impact on distributive justice in the health care system.
11. Acceptability from key stakeholders • It varies	A decision to discontinue coverage would probably not be acceptable to injured persons, pain therapists, patient representatives, manufacturers, possibly certain medical societies. A decision to continue to cover these costs might not be acceptable to insurers and would have to be balanced against other advantages (cost savings, but only marginal) and disadvantages (reputational damage).

12. Feasibility of the implementation • Yes, in case of full coverage or case-by-case decision • Probably no, in case withdrawal of coverage results in reputational damage for insurers with very little savings in resources	**Maintaining cost coverage:** This decision would not need to be implemented. **Options: Case-by-case** decisions by case manager or insurance physician; administrative costs for case-by-case decisions could be higher than simply covering the cost of a rented machine. **Withdrawal of coverage** on the grounds of strict application of legal criteria for coverage (e.g. non-compliance of effectiveness, judiciousness, economic efficiency) could lead to protest from stakeholders and reputational damage for insurers, with potentially very little savings in resources. Stakeholders could point out that due to the uncertainty regarding the clinical effectiveness, injured persons may be deprived of an effective measure.

Resolution of the case

After going through the criteria, the expert panel recommends that decision-makers continue to cover the costs of TENS. The main considerations are: Neuropathic pain can affect quality of life, daily activities and even the ability to work of injured people; the benefit of TENS in relieving pain intensity is unclear, but some patients may experience positive effects. There are no serious adverse events. Coverage costs for purchasing a TENS machine are modest; rental is a viable and already well-accepted alternative. Overall, the supply should not have a significant impact on your budget.

Implementation and provision of TENS do not pose challenges, while discontinuing coverage of TENS could lead to reputational damage for insurers with very little gain. However, the expert panel recommends that TENS should only be prescribed by pain specialists. Furthermore, patients with neuropathic pain should be informed about the uncertainties regarding the effectiveness of TENS. The Medical Expenses Division will continue to monitor TENS prescriptions and their impact on the budget and review the evolving evidence.

Literature

1. Gibson W, Wand BM, O'Connell NE. **Transcutaneous electrical nerve stimulation (TENS) for neuropathic pain in adults**. Cochrane Database Syst Rev. 2017;9:CD011976.
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Abbreviations

TENS: Transcutaneous electrical nerve stimulation

EtD Framework: Evidence-to-Decision Framework

GRADE: Grading of Recommendations, Assessment, Development and Evaluations