Health Quality Ontario

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# ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

## Electrical Stimulation for Pressure Injuries: A Health Technology Assessment

### KEY MESSAGES

#### *What Is This Health Technology Assessment About?*

- This health technology assessment evaluates the effectiveness, cost-effectiveness, budget impact, and lived experience of adding electrical stimulation to standard wound care for pressure injuries.
- In particular, we compared rates for pressure injury (bedsore) healing, healing time, smaller wound surface area, complications, patient compliance, and health-related quality of life.

#### *What Did This Health Technology Assessment Find?*

- We are uncertain whether electrical stimulation improved healing rates, helped wounds heal faster, or reduced the size of wounds.
- We are certain electrical stimulation is safe.
- In Ontario, publicly funding electrical stimulation for pressure injuries could result in additional costs of $770,000 to $3.85 million yearly for the next 5 years.

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## HEALTH TECHNOLOGY ASSESSMENT AT HEALTH QUALITY ONTARIO

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## ABSTRACT

### Background

Pressure injuries (bedsores) are common and reduce quality of life. They are also costly and difficult to treat. This health technology assessment evaluates the effectiveness, cost-effectiveness, budget impact, and lived experience of adding electrical stimulation to standard wound care for pressure injuries.

### Methods

We conducted a systematic search for studies published to December 7, 2016, limited to randomized and non–randomized controlled trials examining the effectiveness of electrical stimulation plus standard wound care versus standard wound care alone for patients with pressure injuries. We assessed the quality of evidence through Grading of Recommendations Assessment, Development, and Evaluation (GRADE). In addition, we conducted an economic literature review and a budget impact analysis to assess the cost-effectiveness and affordability of electrical stimulation for treatment of pressure ulcers in Ontario. Given uncertainties in clinical evidence and resource use, we did not conduct a primary economic evaluation. Finally, we conducted qualitative interviews with patients and caregivers about their experiences with pressure injuries, currently available treatments, and (if applicable) electrical stimulation.

### Results

Nine randomized controlled trials and two non–randomized controlled trials were found from the systematic search. There was no significant difference in complete pressure injury healing between adjunct electrical stimulation and standard wound care. There was a significant difference in wound surface area reduction favouring electrical stimulation compared with standard wound care.

The only study on cost-effectiveness of electrical stimulation was partially applicable to the patient population of interest. Therefore, the cost-effectiveness of electrical stimulation cannot be determined. We estimate that the cost of publicly funding electrical stimulation for pressure injuries would be $0.77 to $3.85 million yearly for the next 5 years.

Patients and caregivers reported that pressure injuries were burdensome and reduced their quality of life. Patients and caregivers also noted that electrical stimulation seemed to reduce the time it took the wounds to heal.

### Conclusions

While electrical stimulation is safe to use (GRADE quality of evidence: high) there is uncertainty about whether it improves wound healing (GRADE quality of evidence: low). In Ontario, publicly funding electrical stimulation for pressure injuries could result in extra costs of $0.77 to $3.85 million yearly for the next 5 years.

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## OBJECTIVE

This health technology assessment looked at the effectiveness, cost-effectiveness, and patient perspectives of using electrical stimulation with standard wound care in treating pressure injuries.

## BACKGROUND

### Health Condition

A pressure injury (sometimes called a pressure wound or bedsore) is caused by localized damage to the skin or underlying soft tissue, from prolonged or intense pressure and often occurring over a bony prominence. The injury can present as intact skin or an open ulcer (wound) and is often painful. The tolerance of soft tissue for pressure can also be affected by microclimate, nutrition, perfusion (passage of fluid to a tissue), having multiple medical conditions, and condition of the soft tissue.[1]

Stages of pressure injuries[2] range from I to IV and are categorized as follows:

- Stage I: Intact skin with a localized area of redness (erythema), does not lighten when pressed, but can appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness can precede changes in appearance. Colour changes do not include purple or maroon discolouration; these can indicate deep tissue pressure injury.
- Stage II: In partial-thickness loss of skin with exposed skin, the wound is viable (able to heal), pink or red, moist. The injury can also present as an intact or ruptured fluid-filled blister. Fat and deeper tissues are not visible. New connective tissue and dead tissue are not present.
- Stage III: In full-thickness loss of skin, fat is visible in the ulcer and new connective tissue, and rolled wound edges are often present. Dead tissue is sometimes visible. The depth of tissue damage varies by where it occurs on the body; areas where there is a lot of fat can develop deep wounds. A wider area of the wound might lie beneath the wound opening and channels might extend into the subcutaneous tissue or muscle. Connective tissue, muscle, tendon, ligament, cartilage, and bone are not exposed. If dead tissue obscures the extent of tissue loss, this is an unstageable pressure injury.
- Stage IV: Full-thickness skin and tissue loss exposes the connective tissue or muscle, tendon, ligament, cartilage, or bone in the ulcer. Dead tissue might be visible. Rolled edges, a wider area of wound that lies beneath the wound opening, and channels extending into the subcutaneous tissue or muscle often occur. Depth varies by where the ulcer occurs on the body. If dead tissue obscures the extent of tissue loss, this is an unstageable pressure injury.

Pressure injuries can lead to shortening of muscles, tendons, or ligaments (contractures), to infection of bones (osteomyelitis), to loss of limbs, or to a life-threatening response to infection (sepsis). Pressure injuries affect the quality of a person's life, affect a person's family life, decrease mobility,[3] and are costly and difficult to manage.[4]

Factors that influence healing are pressure injury duration (how long a patient has had a pressure injury; pressure injuries of longer duration take longer to heal), initial surface area, and comorbidity.

## Clinical Need and Target Population

Pressure injuries are a consequence of immobility. They often occur in people with severe neurologic conditions (such as people with spinal cord injuries); in people with acute severe illnesses (who are unable to be mobile); or in people who are frail, elderly, and have difficulty moving (immobile).[5-7] People who are vulnerable to developing pressure ulcers often reside in long-term care homes or community care. Pressure ulcers affect up to 40% of people with spinal cord injuries and 32% of people admitted to hospital.[8,9]

Pressure injuries are common across health care settings.[10] In 2013, the breakdown of existing (and new) pressure injuries according to health care setting was as follows: 10.2% (4.3%) in acute care, 3.2% (1.6%) in home care, 8.4% (4.1%) in long-term care, and 2.2% (7.2%) in complex continuing care.

## Current Treatment Options

Standard wound care for patients with pressure injuries consists of four phases[11]:

- Assessment: plan treatment by assessing the wound, including examining the stage/depth, location, surface area, odour, if a wider area of wound lies beneath the wound opening and if channels extend into the subcutaneous tissue or muscle, if liquid is produced to respond to tissue damage, appearance of the wound bed, and condition of the surrounding skin (periwound). Continue to reassess pressure injuries weekly
- Debridement: remove the dead and damaged tissue from the wound if clinical and vascular assessment indicate debridement is necessary. Select the appropriate method considering the goals of the treatment; client's condition; type, quantity, and location of necrotic tissue; depth of lesion; amount of drainage; and availability of resources
- Control bacteria/infection: manage infection with wound cleansing, antibiotics, and debridement as necessary
- Wound cleansing: clean wounds with normal saline, Ringer's lactate solution, sterile water, or non-cytoxic wound cleansers at each dressing change

## Health Technology Under Review

Electrical stimulation is suggested for patients with pressure injuries as an adjunct therapy to standard wound care. In electrical stimulation, electrodes are applied directly to the wound bed of the pressure injury and connected to a stimulator that is designed to create a small electrical charge in tissues. It replaces the current that would be produced naturally when the tissue is broken.[12] At least two small electrodes are placed on the skin and are connected to a small battery-operated device.

Clinical experts from Ontario whom we consulted stated that, in general, electrical stimulation is used daily (minimum three times weekly) for 60-minute sessions. Available literature indicates electrical stimulation is generally administered for 30 to 120 minutes, once or twice daily, 5 to 7 times a week.

Delivery of electrical stimulation can be given either by direct or pulsed current. Direct current (DC) involves unidirectional continuous flow of current for longer than 1 second.[13] Pulsed current (PC) involves the brief unidirectional or bidirectional flow of electrons or ions in which each pulse is separated by a longer off period with no current flow.[13] In Ontario, the most common modality of electrical stimulation is biphasic pulsed current.

Other stimulus parameters of electrical stimulation can be varied and include frequency (low or high Hertz), polarity (negative, positive, or mixed), pulse type (monophasic or biphasic), duration of stimulation (time per sessions), and amplitude (low or high mA). Experts state that there are no standard ways of applying these parameters and that treatment can be customized to each patient based on assessment of the injury.

Electrical stimulation should not be used in people with certain medical conditions including osteomyelitis or cancer, or in people with implanted electronic devices or who have a blood clot in their leg. Electrical stimulation should also not be applied over the pregnant uterus, wound dressings containing metallic or ionic components, or certain body locations containing excitable tissue (e.g., perineum, anterior neck). Electrical stimulation treatment can result in minor skin irritation under the electrode, which usually resolves spontaneously within 24 to 72 hours.[14]

Timing for administering electrical stimulation is based on the clinicians' assessment of the patients' wound. The Registered Nurses' Association of Ontario,[14] the Australian Wound Management Association,[15] the US's National Pressure Ulcer Advisory Panel,[16] and the US's Institute for Clinical Systems Improvement[17] suggest providing electrical stimulation to promote healing installed Stage II pressure injuries and in Stages III and IV pressure injuries. The UK's National Institute for Health and Care Excellence[18] (NICE) recommends not offering electrotherapy to adults to treat a pressure injury. The expert panel for NICE decided there was no evidence to support its use. In clinical practice, pressure injuries that are "healable," late-stage, and recalcitrant are typically considered eligible for electrical stimulation treatment.

Health Quality Ontario's quality standard for pressure injuries includes an "Emerging Practice Statement" on electrical stimulation for pressure injuries.[19] The statement noted that no guidance can be provided at this time on the use of electrical stimulation as an adjunct therapy for treatment of pressure injuries, because of conflicting recommendations in the guidelines used to develop the pressure injury quality statements.

## Regulatory Information

In terms of the regulatory status of electrical stimulation for pressure ulcers, licence numbers 14753 (mini-Micro-Z) and 74189 (Quadstar) are both electrical stimulation Class 2 devices approved by Health Canada. The Micro-Z device was first issued in 1999, and the Quadstar devices were first issued in 2007. According to experts we consulted, these two devices are most often used.

The mini-Micro-Z is ideal for patient use in a self-management model (e.g., in home care). Electrical stimulus parameters are programmed by the manufacturer and cannot be adjusted by the patient or caregiver. Patients and caregivers can easily be trained to adjust intensity and turn the device off and on. Devices are designed to link with specialized garments (socks and gloves) to provide ongoing and overnight treatment for chronic pain and to improve circulation in the skin.

The Quadstar Elite is used in physiotherapy offices, where electrical stimulation protocols are designed by the clinician. The device uses a large rechargeable battery and can be plugged into a wall outlet. All stimulus parameters are fully adjustable. Once the machine is programmed, parameters can be "locked in" so that only the intensity dial and on/off switch are available to patients. The device can be cleaned and reused with multiple patients over several years.

Last, the GV-350 is strictly for health care professionals and should not be used by patients in a self-management model. This portable device has enough power (runs on 4 AA batteries or can be plugged into a 350-V outlet) to treat open, deep wounds. It delivers one form of electrical current that is known to stimulate healing of chronic wounds, called high-voltage pulsed current. Analog dials and switches are fully adjustable to select treatment parameters. The machine can be set to turn off automatically after 60 minutes of treatment.

## Ontario Context

Several health care organizations, including at least one Community Care Access Centre, provide electrical stimulation to eligible patients without charge. The device that appears to be most common (Micro-Z) in Ontario is pre-programmed, and patients using the device at home simply have to turn the device on and off. Experts shared a protocol that outlines the parameters to be used for electrical stimulation. The parameters include:

- Waveform: high-voltage pulsed current, monophasic or unbalanced pulsed current
- Polarity (+/−): alternate
- Frequency: High (80–120 Hz)
- Intensity: sensory or submotor
- Treatment time: minimum of 45 to 60 minutes daily

Pulsed-current electrical stimulation according to this protocol, specifically high-voltage pulsed current (HVPC), could be more clinically relevant to Ontario cases than other parameters. Even though a few guidelines recommend the use of electrical stimulation as adjunct treatment for pressure injuries, no recommendations specify standard parameters (waveform, polarity, frequency, intensity, treatment time and duration) for electrical stimulation.

Given the complexity of pressure injuries and their healing, patients should be treated outside acute care because hospital stays are typically too short for electrical stimulation. After speaking with multiple experts, we found that (along with home care), a continuing care centre and a few outpatient rehabilitation facilities also offer electrical stimulation.

# CLINICAL EVIDENCE

## Research Question

In adults with pressure injuries, what is the clinical effectiveness and safety of electrical stimulation plus standard wound care compared with standard wound care alone (+/− sham electrical stimulation) on complete pressure injury healing, healing time, reduced wound size (surface area), complications, patient compliance, and health-related quality of life?

## Methods

Research questions are developed by Health Quality Ontario in consultation with patients, health care providers, clinical experts, and other health system stakeholders.

### *Literature Search*

We performed a literature search on December 7, 2016, to retrieve studies published from inception to the search date. We used the Ovid interface to search the following databases: MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Health Technology Assessment, National Health Service Economic Evaluation Database (NHSEED), Database of Abstracts of Reviews of Effects (DARE); and we used the EBSCO host interface to search the Cumulative Index to Nursing & Allied Health Literature (CINAHL).

Search strategies were developed by medical librarians using controlled vocabulary (i.e., Medical Subject Headings) and relevant keywords. The final search strategy was peer-reviewed using the PRESS Checklist.[20] Database auto-alerts were created in MEDLINE, Embase, and CINAHL and monitored for the duration of the health technology assessment.

We performed targeted grey literature searching of health technology assessment agency sites and clinical trial registries. See Appendix 1 for Literature Search Strategies, including all search terms.

### *Literature Screening*

A single reviewer reviewed the abstracts and, for those studies meeting the eligibility criteria, we obtained full-text articles. We also examined reference lists for any additional relevant studies not identified through the search.

### *Types of Studies*

- We considered systematic reviews, meta-analyses, randomized controlled trials, and non–randomized controlled trials that compared electrical stimulation plus standard wound care with standard wound care (+/− sham electrical stimulation)
- Systematic reviews that did not include primary outcomes of interest were excluded
- Studies that applied any type of electrical stimulation parameters were included
- Studies where electrodes were placed somewhere on the body other than the ulcer or periulcer were excluded

- Studies that combined other wounds (e.g., venous leg ulcers, diabetic foot ulcers, and surgical wounds, where data on just pressure ulcers could not be extracted) were excluded
- Studies where outcome data could not be extracted were excluded
- Studies that administered electrical stimulation after plastic surgery were excluded
- Studies that examined multiple interventions were excluded (e.g., electrical stimulation and another treatment)
- Studies with fewer than five participants in each treatment group were excluded
- Studies that had duplicate data (from other included studies) were excluded
- Animal or in vitro studies were excluded

We did not include observational studies, editorials, case reports, or commentaries.

### *Types of Participants*

People with severe neurologic conditions (people with spinal cord injuries) and older adults who are frail and immobile (people in long-term care homes, complex continuing care, and community care) are at high risk of developing pressure injuries.

### *Types of Interventions*

In electrical stimulation electrodes are applied directly to the wound bed or on the periulcer of the pressure injury and are connected to a stimulator designed to create a small electrical charge in tissues.

Standard wound care should consist of four phases: assessment, debridement, controlling bacteria/infection, and wound cleansing.

If available, comparators to electrical stimulation include ultraviolet C light, warming therapy, growth factors, skin equivalents, negative pressure wound therapy, and hyperbaric oxygen therapy.

### *Types of Outcome Measures*

Health outcomes of interest include:

- Complete pressure injury healing
- Healing time (if available)
- Reduced wound surface area
- Complications (such as pain, dermatologic complications, bleeding, and infection)
- Patient adherence (if available)
- Health-related quality of life (if available)

### *Data Extraction*

We extracted relevant data on study characteristics and risk-of-bias items using a data form to collect information about:

- Source (i.e., citation information, contact details, study type)

- Characteristics of participants, intervention, and comparator (i.e., age, sex, injury duration, injury severity, details on electrical stimulation, and standard wound care)
- Methods (i.e., study design, study duration in years, participant allocation, allocation sequence concealment, blinding, reporting of missing data, reporting of outcomes, and whether or not the study compared two or more groups)
- Outcomes (i.e., outcomes measured, number of participants for each outcome, number of participants missing for each outcome, outcome definition and source of information, unit of measurement, upper and lower limits [for scales], and times at which the outcome was assessed)

We contacted authors of the studies to clarify methods and results.

### *Statistical Analysis*

Quantitative synthesis of individual studies was performed using Review Manager, version 5.3.[21] Summary measures were expressed as the mean difference for continuous data and risk difference for dichotomous data using the Mantel-Haenszel method. Statistical heterogeneity was assessed using the $I^2$ value. The pooled estimate was not reported in the forest plots owing to moderate to high heterogeneity ($I^2 < 65\%$). A random effects model was used if studies were heterogeneous. Graphs of the forest plots were also examined. A *P* value ≤ .05 was considered statistically significant for overall effect estimate.

Where outcomes could be meta-analyzed and where appropriate (based on clinical and statistical heterogeneity), we performed subgroup analysis for the following considerations:

- Type of electrical stimulation (pulsed current vs. direct current)
- Wound severity (by National Pressure Ulcer Advisory Panel stage[1,2])
- Length of follow-up

### *Quality of Evidence*

The level of quality of the body of evidence for each outcome was evaluated according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Handbook.[22] We started with the assumption that randomized controlled trials are high quality, whereas observational studies are low quality. We then rated the studies based on the following considerations: risk of bias, inconsistency, indirectness, imprecision, publication bias, magnitude of effect, dose-response gradient, and any residual confounding factors. The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology. The quality level determination reflects our certainty about the evidence.

Risk of bias in randomized controlled trials was evaluated by the Cochrane Collaboration's tool for assessing risk of bias.[23] Risk of bias in non–randomized controlled trials was evaluated by the Methodological Index for Non-Randomized Studies (MINORS).[24]

### *Expert Consultation*

From November 2016 to March 2017, experts on electrical stimulation for pressure injuries were consulted. Members of the consultation team included physicians, surgeons, nurse specialists, and physiotherapists in the specialty areas of wound care. The role of the expert advisors was to contextualize the evidence, teach us about the technology, provide context for wound care in Ontario, and advise on methods.

## Results

### *Literature Search*

The literature search yielded 1,179 citations published until December 7, 2016 after removing duplicates. We reviewed titles and abstracts to identify potentially relevant articles. We obtained the full texts of these articles for further assessment. Nine randomized controlled trials and two non–randomized controlled trials met the inclusion criteria. We found nine systematic reviews that had the potential to meet our inclusion criteria; however, none fully addressed the research question (e.g., examined electrical stimulation only in spinal cord injury patients, examined all adjunct therapies for pressure injuries, or addressed the exact clinical questions of this health technology assessment). We hand-searched the reference lists of the included studies, along with health technology assessment websites and other sources, to identify additional relevant studies. No other relevant studies were identified.

Figure 1 presents the flow diagram for the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA).

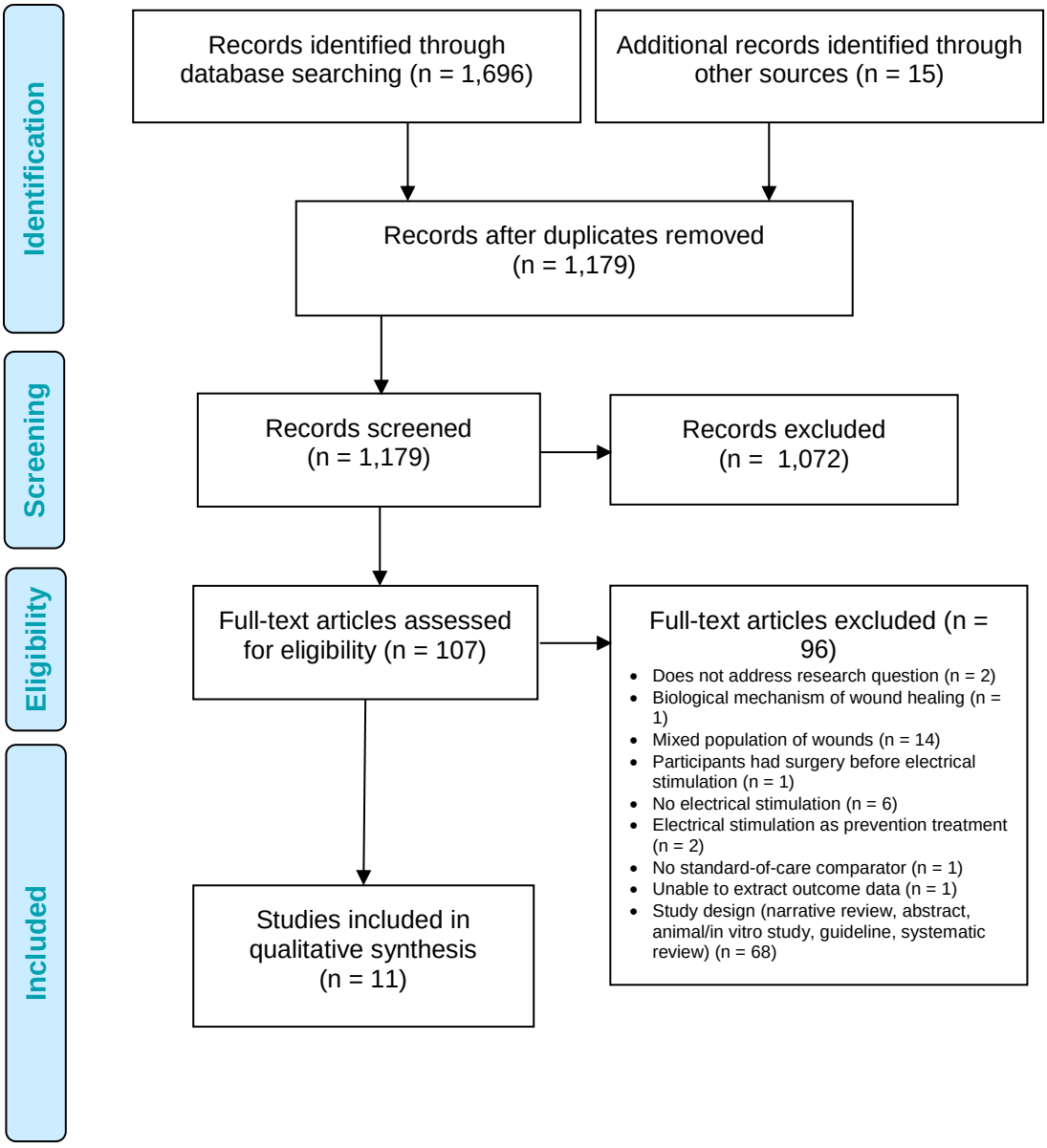


**Figure 1: PRISMA Flow Diagram for Clinical Review**

Abbreviation: PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.
*Source: Adapted from Moher et al.*[25]

## *Characteristics of Included Studies*

Eleven studies were included (9 randomized controlled trials[26-34] and 2 non-randomized controlled trials[35,36]). Two randomized controlled trials used a crossover design.[29,33] Six studies examined the effectiveness of electrical stimulation for pressure injuries in patients with spinal cord injuries.[27,30,31,33,35,36] Five studies examined the effectiveness of electrical stimulation for pressure injuries in older adults.[26,28,29,32,34] Studies took place in various health care settings from inpatient acute care to rehabilitation to home care (Table 1). While eight studies compared electrical stimulation with standard wound care (+/− sham electrical stimulation), three studies compared types of electrical stimulation (direct current vs. pulsed current),[36] contrasting polarity

(a parameter of electrical stimulation),[35] and duration of treatment (45 min vs. 60 min vs. 120 min) with standard wound care.[27]

The six studies that focused on patients with spinal cord injuries (Tables 2–4) had on average younger (26–50 years of age) patients than the five studies examining electrical stimulation in a general population (Tables 5 and 6) (55–80 years of age).

Clinical and methodologic characteristics were similar among the included studies. Seven studies applied pulsed current,[27-33] three studies applied direct current,[26,34,35] and one study applied both pulsed and direct current.[36] However, other parameters (frequency, amplitude, voltage, and duration of treatment) varied across studies.

Standard wound care also varied across studies. Some studies only partially followed directions for standard treatment. Seven of eleven studies administered sham electrical stimulation.[26,27,29,30,32,34,35]

Outcomes of wound healing also varied across studies. Complete wound healing was measured in six studies, but only two studies had this as the primary outcome. Seven studies measured wound surface area reduction at various times. Three studies calculated the relative rate of healing per day through either linear or exponential methods. Using an exponential equation means that authors assumed healing was not linear (that wounds do not consistently reduce in size), but wounds can reduce and increase in size even when treated.

Follow-up also varied across studies, from 20 days to 6 months. One limitation of primary studies examining the effectiveness of treatments for pressure injuries is that the follow-up is not long enough to capture complete healing.

We found no studies that evaluated health-related quality of life, nor any studies where the comparator was standard wound care plus another adjunct treatment for pressure injuries.

**Table 1: Randomized Controlled Trials and Non–Randomized Controlled Trials**

| Author, Year | N (Participants and Ulcers) | | Therapies | | Outcome | Follow-Up |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | | |
| **Spinal Cord Injury** | | | | | | |
| **Griffin et al, 1991[30]** | N = 8<br>No. of ulcers = 8 | N = 9<br>No. of ulcers = 9 | Device: Intelect 500 HVPC stimulator<br>Waveform: PC. Produces a twin peaked pulse with about 75-µs spacing between pulses<br>Frequency: set at 100 pps, with continuous mode. Intensity was slowly increased to 200 V<br>Duration: ES 60 min, daily for 20 consecutive days (20 h total) | Sham ES. Ulcers were cleansed twice daily, followed by gel application and dry dressing. Wounds were mechanically debrided as necessary. All ulcers were cultured before treatment began. All possible efforts were made to keep pressure off ulcer. A routine 2-h turning schedule was followed when patients were in bed. Nutritional status of patients was evaluated. Regular diet planned | WSA on Days 5, 10, 15, and 20 calculated as percentage of change (%) from baseline WSA | 20 d |
| **Stefanovska et al, 1993[36]** | PC group (N = 42)<br>No. of ulcers = 42<br>DC group (n = 12)<br>No. of ulcers = 12 | N = 34<br>No. of ulcers = 34 | Group 1<br>Waveform: DC<br>Amplitude: 600 µA<br>Duration: 120 min daily<br>Group 2<br>Waveform: PC<br>Frequency: Pulse duration of 0.25 ms and a repetition rate of 40 Hz. 4-s stimulation trains were rhythmically alternated with pauses of the same duration (low frequency)<br>Amplitude: 15–25 mA<br>Duration: 120 min, once daily (56 h total) | No details on standard treatment<br>Authors stated participants received standard treatment for 1 mo | Relative healing rate using exponential trajectory | 4 wk |

| Author, Year | N (Participants and Ulcers) | | Therapies | | Outcome | Follow-Up |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | | |
| **Jercinovic et al, 1994[33]** | N = 42<br>No. of ulcers = 61 | N = 31<br>No. of ulcers = 48 | Waveform: PC<br>Biphasic, asymmetric, charge-balanced pulses<br>Frequency: 40 pps and a pulse duration of 250 µs were used<br>Amplitude: up to 35 mA<br>Duration: ES 120 min, once daily, 5 times/wk (40 h total) | Standard treatment included initial selective debridement, application of new standard dressing to ulcer twice daily or more, as needed, and a broad-spectrum antibiotic in cases of infection. SCI patients included were lying on dry-floatation mattresses and were turned to a new position every 4 h during the night | Rate of healing using linear and exponential trajectory | 4 wk |
| **Karba et al, 1997[35]** | DC + (n = 16)<br>No. of ulcers = 16<br>DC +/− (n = 18)<br>No. of ulcers = 18 | N = 16<br>No. of ulcers = 16 | Device: Encore TM Plus<br>Waveform: DC<br>Amplitude: 0.6 mA<br>Duration: ES for 120 min, daily<br>Group 1<br>Electrode placement: DC + positive stimulation electrode overlaid ulcer; other 4 were on periulcer<br>Group 2<br>Electrode placement: DC +/− 2 electrodes were positioned on periulcer (1 positive and 1 negative) | Sham ES. Standard treatment (daily cleaning and dry gauze dressing exchanges) | Relative healing rate using exponential trajectory | NR |
| **Ahmad, 2008[27]** | N = 15 in all groups (45 min, 60 min, 120 min)<br>No. of ulcers = 15 in each group | N = 15<br>No. of ulcers = 15 | Waveform: PC, twin monophasic pulses at interphase interval of 50 µs<br>Frequency: 120 Hz<br>Voltage: 100–175 V<br>Duration: 3 treatment groups receiving treatment for 45, 60, and 120 min daily, 7 d/wk | Sham ES. Standard treatment (wet dressing and whirlpool therapy 4–5 times weekly). All wounds were debrided before admission | WSA on Weeks 3 and 5 | 5 wk |

| Author, Year | N (Participants and Ulcers) | | Therapies | | Outcome | Follow-Up |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | | |
| **Houghton et al, 2010[31]** | N = 16<br>No. of ulcers = 16 | N = 18<br>No. of ulcers = 18 | Device: Micro-Z<br>Waveform: PC, monophasic pulse duration of 50 µs<br>Voltage: 50–150 V<br>Frequency: 20 min at pulse frequency of 100 Hz followed by 20 min at 10 Hz and then 20 minutes off cycle each hour<br>Duration: 8 h daily, 7 d/wk (treatments were done typically at night) (672 h total) | Standard treatment (evaluation by multidisciplinary team, assessment of nutritional issues, assessment of appropriate dressing protocol with respect to moisture control, bacterial burden, and debridement). Also received comprehensive pressure management | WSA reduction measured as percentage change at end of 3 mo | 3 mo (full follow-up 6 mo) |
| **Older Adults** | | | | | | |
| **Gentzkow and Miller, 1991[29]** | N = NR<br>No. of ulcers = 21 | N = NR<br>No. of ulcers = 19 | Device: Dermapulse<br>Waveform: PC<br>Amplitude: 35 mA<br>Frequency: 128 pps<br>Duration: ES 30 min, twice daily (28 h total) | Sham ES. Standard treatment was prescribed by physician according to needs of individual patients, and was recorded. In all patients, wounds were kept hydrated with saline-moistened gauze between treatments | WSA reduction expressed as percent change over study period | 4 wk |
| **Wood et al, 1993[34]** | N = 41<br>No. of ulcers = 43 | N = 30<br>No. of ulcers = 31 | Device: MEMS CS 600<br>Waveform: DC<br>Frequency: 0.8 Hz<br>Amplitude: 300–600 µA<br>Duration: ES 3 d/wk with no information on length of treatment | Sham ES. Wound cleansing, simple moist dressings, and whirlpool baths | Complete wound closure | 8 wk |
| **Adunsky and Ohry, 2005[26a]** | N = 35<br>No. of ulcers = 35 | N = 28<br>No. of ulcers = 28 | Waveform: DC (microcurrent)<br>No other ES parameters provided<br>Duration: ES for 20 min, thrice daily, 7 d/wk reduced to 2 daily sessions after 14 d (42 h total) | Sham ES. Standard treatment of wounds included surgical debridement, if deemed necessary, followed by application of hydrocolloid or collagen dressings | 1. Complete healing (closure of ulcer), 2. Speed of wound closure, 3. WSA reduction, 4. speed of healing (rate of WSA reduction reflected by change from baseline of ulcer area, percentage) | 8 wk (full follow-up 12 wk) |

| Author, Year | N (Participants and Ulcers) | | Therapies | | Outcome | Follow-Up |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | | |
| **Franek et al, 2012[28]** | N = 26<br>No. of ulcers = 26 | N = 24<br>No. of ulcers = 24 | Device: Ionoson<br>Voltage: 100 V<br>Waveform: PC, twin monophasic pulses lasting 100 µs in total<br>Frequency: 100 Hz<br>Duration: ES 50 min, once daily, 5 times/wk (25.2 h total) | Standard treatment, including cleansing with potassium permanganate followed by covering ulcer base with dressing. Dressings were tailored to meet needs of each subject and to promote moist interactive healing. If wound infection was suspected, it was appropriately treated. Sharp debridement was performed in relatively few participants | Relative and percent change in wound area, volume, longest length and width, and granulation tissue area were calculated<br>Gilman method was used to calculate wound size based on WSA and length of perimeter | 6 wk |
| **Polak et al, 2016[32]** | N = 25<br>No. of ulcers = 25 | N = 24<br>No. of ulcers = 24 | Device: Intelect Advanced Combo unit<br>Waveform: PC, twin monophasic pulse (154 µs) consisting of two 77-µs exponential pulses<br>Frequency: 100 pps<br>Amplitude: usually 0.24 A<br>Voltage: 100 V; charge was 250 µC/s<br>Duration: ES 50 min, once daily, 5 times/wk (25.2 h total) | Sham ES. Standard treatment consisted of evaluation by multidisciplinary team. All patients received pressure redistribution surface, devices, and pillows as needed; nutritional assessment; debridement; infection and inflammation control; maintenance of moisture balance; and monitoring of wound edges and of epithelization | Percentage reduction in WSA in relation to baseline, Week 4, and Week 6 | 4 wk (full follow-up 6 wk) |

Abbreviations: A, ampere; DC, direct current; ES, electrical stimulation; HVPC, high-voltage pulsed current; µC, microcoulombs; NR, not reported; PC, pulsed current; pps, pulses per second; SCI, spinal cord injury; WSA, wound surface area.

[a]Included 54 older adults and 9 spinal cord injury patients.

**Table 2: Patients With Spinal Cord Injuries Treated With One Electrical Stimulation**

| Patient Characteristics | Griffin et al, 1991[30] | Jercinovic et al, 1994[33] | Houghton et al, 2010[31] |
|---|---|---|---|
| Age (y) | 32.5[a] (17–54) | NR | 50.3 ± 17.3 (23–74) |
| Sex (m:f) | All male | NR | 8:8 |
| SCI level | Cervical spine: 4<br>Thoracolumbar disc: 4 | NR | Quadriplegia: 7<br>Paraplegia: 6<br>Spina bifida: 3 |
| SCI duration | 156 wk given as median (4–1,820) | NR | 18 y ± 16 (1–51) |
| Wound location | Buttocks-ischium: 5<br>Sacrum-coccyx: 3 | Sacrum 14<br>Trochanter: 16<br>Legs: 18<br>Buttocks: 5<br>Other locations: 8 | Ischial tuberosity: 8<br>Sacrum, coccyx, hip: 4<br>Leg (foot, ankle, knee) 4 |
| Wound duration | 4.5 wk given as median (2–116) | 158 d ± 284 | 1.2 y ± 1.0 (0.3–4.1) |
| Wound severity | Stage II: 2<br>Stage III: 5<br>Stage IV: 1 | NR | Stage II: 1<br>Stage III: 6<br>Stage IV: 7<br>Stage X: 2 |
| Initial WSA | 234.1 $mm^2$ given as median (126–1,027) | 10.6 $cm^2$ ± 13.33 | 3.38 $cm^2$ ± 3.44 (1.2 ± 12.0) |

Abbreviations: NR, not reported; SCI, spinal cord injury; WSA, wound surface area.
[a]Age is given as median.

**Table 3: Control Group of Patients With Spinal Cord Injuries Given Standard Care Only**

| Patient Characteristics | Griffin et al, 1991[30] | Jercinovic et al, 1994[33] | Houghton et al, 2010[31] |
|---|---|---|---|
| Age (y) | 26.0[a] (10–74) | NR | 50.8 ± 11.6 (32–79) |
| Sex (m:f) | All male | NR | 12:6 |
| SCI level | Cervical: 4<br>Thoracolumbar: 5 | NR | Quadriplegia: 8<br>Paraplegia: 8<br>Spina bifida: 2 |
| SCI duration | 4.0 wk given as median (3–35) | NR | 23 y ± 11 (5–41) |
| Wound location | Buttocks-ischium: 1<br>Sacrum-coccyx: 8 | Sacrum: 20<br>Trochanter: 11<br>Legs: 10<br>Buttocks: 4<br>Other locations: 3 | Ischial tuberosity: 11<br>Sacrum, coccyx, hip: 4<br>Leg: foot, ankle, knee: 3 |
| Wound duration | 3.0 wk given as median (1–30) | 125 d ± 129 | 3.0 y ± 5.6 (0.3–15, 20) |
| Wound severity | Stage II: 2<br>Stage III: 6<br>Stage IV: 1 | NR | Stage II: 4<br>Stage III: 4<br>Stage IV: 10<br>Stage X: 0 |
| Initial WSA | 271.8 $mm^2$ given as median (41–4,067) | 17.2 $cm^2$ ± 20 | 2.73 $cm^2$ ± 2.89 (1.1 ± 10.9) |

Abbreviations: NR, not reported; SCI, spinal cord injury; WSA, wound surface area.
[a]Age is given as median.

**Table 4: Patients With Spinal Cord Injuries in Treatment and Control Groups Receiving Multiple Types of Electrical Stimulation**

| Patient Characteristics | Stefanovska et al, 1993[36] | | | Karba et al, 1997[35] | | | Ahmad, 2008[27] | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | DC | PC | Control | DC + | DC +/− | Control | 45 min | 60 min | 120 min | Control |
| Age (y) | 35.7 ± 15.2 | 35.5 ± 13.3 | 33.1 ± 17.7 | NR | NR | NR | 38.40 ± 6.82 | 38.47 ± 1.68 | 39.40 ± 1.74 | 39.40 ± 1.69 |
| Sex (m:f) | NR | NR | NR | NR | NR | NR | 6:9 | 7:8 | 8:7 | 9:6 |
| SCI level | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| SCI duration | 6.5 mo ± 13.5 | 26.7 mo ± 45.0 | 19.4 mo ± 61.8 | NR | NR | NR | NR | NR | NR | NR |
| Wound location | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Wound duration | 52.5 d ± 28.5 | 55.8 d ± 35.7 | 56.4 d ± 43.1 | NR | NR | NR | 4.41 mo ± 0.9 | 4.40 mo ± 0.9 | 4.41 mo ± 0.9 | 4.48 mo ± 0.9 |
| Wound severity | NR | NR | NR | NR | NR | NR | All Grade II[a] | All Grade II[a] | All Grade II[a] | All Grade II[a] |
| Initial wound surface area | 15.2 $cm^2$ ± 18.7 | 13.0 $cm^2$ ± 16.9 | 16.6 $cm^2$ ± 21.6 | 1,332 $mm^2$ ± 285 | 1,078 $mm^2$ ± 272 | 1,111 $mm^2$ ± 291 | 7.12 $cm^2$ ± 1.63 | 7.12 $cm^2$ ± 1.62 | 7.14 $cm^2$ ± 1.57 | 7.21 $cm^2$ ± 1.54 |

Abbreviations: DC, direct current; NR, not reported; PC, pulsed current; SCI spinal cord injury.
[a]Measured by Yarkony-Kirk classification.

**Table 5: Treatment Group of Older Adults**

| Patient Characteristics | Gentzkow and Miller, 1991[29] | Wood et al, 1993[34] | Adunsky and Ohry, 2005[26] | Franek et al, 2012[28] | Polak et al, 2016[32] |
|---|---|---|---|---|---|
| Age (y) | 63.3 ± 17.8 (29–91) | 75.6 | 71.8 ± 19.5 | 59.0 ± 18.6 | 79.9 ± 8.5 (60–92) |
| Sex (m:f) | 61.9% male | 26:15 | 13:15 | 8:18 | 6:19 |
| Wound location | Hip-ischium: 9<br>Sacrum-coccyx: 4<br>Leg: 2<br>Foot: 6 | Toe: 3<br>Ankle: 5<br>Foot: 7<br>Leg: 4<br>Hip: 10<br>Buttocks: 5<br>Coccyx: 9 | NR[a] | NR | Sacrum-coccyx: 13<br>Ischial tuberosity: 8<br>Trochanter major: 4 |
| Wound duration | < 1 mo: 20%<br>1–3: 5%<br>3–6: 25%<br>6–12: 35%<br>> 12 mo: 15% | 5.5 mo ± 5.2 | 5.0 d ± 1.2 | 3.17 mo ± 2.0 | 2.54 mo ± 2.05 |
| Wound severity | Stage II: 0<br>Stage III: 16<br>Stage IV: 5 | NR | All Stage III | Stage IIA: 5<br>Stage IIB: 12<br>Stage III: 9 | Stage II: 11<br>Stage III: 14 |
| Initial wound surface area | 19.2 $cm^2$ ± 23.2 | 2.61 $cm^2$ ± 2.46 | 7.6 $cm^2$ ± 1.1 | 4.54 $cm^2$ ± 3.1 | 10.58 $cm^2$ ± 10.57 |

Abbreviation: NR, not reported.

[a]Reported for overall sample—sacrum: 25, trochanters: 13, calves or ankles: 13, heels: 6, buttocks: 4, ischium: 2.

**Table 6: Control Group of Older Adults**

| Patient Characteristics | Gentzkow and Miller, 1991[29] | Wood et al, 1993[34] | Adunsky and Ohry, 2005[26] | Franek et al, 2012[28] | Polak et al, 2016[32] |
|---|---|---|---|---|---|
| Age (y) | 62.2 ± 18.4 (31–90) | 74.9 | 71.4 ± 18.9 | 56.2 ± 19.7 | 76.3 ± 12.7 (60–95) |
| Sex (m:f) | 47.4% male | 15:15 | 26:37 | 14:10 | 6:18 |
| Wound location | Hip-ischium: 6<br>Sacrum-coccyx: 8<br>Leg: 1<br>Foot: 4 | Toe: 2<br>Ankle: 1<br>Foot: 13<br>Leg: 1<br>Hip: 2<br>Buttocks: 5<br>Coccyx: 7 | NR[a] | NR | Sacrum-coccyx: 12<br>Ischial tuberosity: 9<br>Trochanter major: 3 |
| Wound duration | < 1 mo: 11.1%<br>1–3: 16.7%<br>3–6: 22.2%<br>6–12: 16.7%<br>> 12 mo: 33.3% | 4.9 mo ± 5.2 | 4.2 d ± 1.0 | 2.83 mo ± 1.97 | 2.81 mo ± 2.67 |
| Wound severity | Stage II: 1<br>Stage III: 14<br>Stage IV: 4 | NR | All Stage III | Stage IIA: 5<br>Stage IIB: 11<br>Stage III: 8 | Stage II: 11<br>Stage III: 13 |
| Initial wound surface area | 12.5 $cm^2$ ± 11.9 | 1.91 $cm^2$ ± 1.24 | 7.5 $cm^2$ ± 2.1 | 3.97 $cm^2$ ± 4.15 | 9.71 $cm^2$ ± 6.70 |

Abbreviation: NR, not reported.

[a]Reported for overall sample—sacrum: 25, trochanters: 13, calves or ankles: 13, heels: 6, buttocks: 4, ischium: 2.

### *Effect on Complete Pressure Injury Healing*

Six[26,30-34] of eleven studies measured complete pressure injury healing (Table 7, Figure 2), defined as complete formation of granulation tissue in the pressure injury. One of the six studies was not included in the analysis on the basis of study design (crossover trial). Crossover trials can add bias to the estimate originating from the carry-over effect in crossover trials. The crossover trial included in this review did not analyze periods separately, so was not included. A meta-analysis of the five included studies was done and the $I^2$ value was 84%. Therefore, a summary estimate was not determined because of large differences in the study characteristics (heterogeneity); the risk difference for each study without a summary estimate is presented in Figure 2. We present the risk ratio for complete pressure injury healing. The $I^2$ was 68% (moderate heterogeneity) for this estimate, meaning there were moderate differences in the study characteristics (Figure 3). There was no significant difference for complete healing between those who received electrical stimulation plus standard wound care and those who received standard wound care alone. In accordance with our a priori decision on subgroup analysis, we conducted a meta-analysis presenting the risk difference and risk ratio for randomized controlled trials that administered pulsed current (Figures 4 and 5). This subgroup analysis showed uncertainty in the effectiveness of electrical stimulation and standard wound care (+/− sham electrical stimulation) to completely heal the wound (GRADE: low quality of evidence).

### *Post-Hoc Analysis on Complete Pressure Injury Healing*

During the public comment period of our health technology assessment, experts stated the importance of dividing patients with spinal cord injuries into subgroups. On the basis of this feedback, we conducted a meta-analysis of the risk difference for trials that included older adults and trials that included patients with only spinal cord injuries (Figure 6). Given the nonsignificant *P* value (*P* = .72), subgroup analysis might not be appropriate.

| Study or Subgroup | Electrical Stimulation Events | Total | Standard Wound Care Events | Total | Risk Difference M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|
| Griffin et al, 1991 | 2 | 8 | 2 | 9 | 0.03 [-0.38, 0.43] | 1991 |
| Wood et al, 1993 | 25 | 43 | 1 | 31 | 0.55 [0.39, 0.71] | 1993 |
| Jercinovic et al, 1994 | 51 | 81 | 15 | 48 | 0.32 [0.15, 0.49] | 1994 |
| Adunsky and Ohry, 2005 | 9 | 35 | 10 | 28 | -0.10 [-0.33, 0.13] | 2005 |
| Houghton et al, 2010 | 11 | 16 | 7 | 18 | 0.30 [-0.02, 0.62] | 2010 |
| Polak et al, 2016 | 12 | 25 | 7 | 24 | 0.19 [-0.08, 0.46] | 2016 |

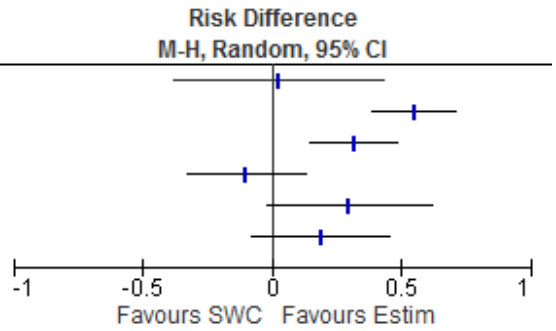


**Figure 2: Risk Difference for Complete Pressure Injury Healing in Six Studies**

Abbreviations: CI, confidence interval; Estim, electrical stimulation; M-H, Mantel-Haenszel statistic; SWC, standard wound care.

| Study or Subgroup | Electrical Stimulation Events | Total | Standard Wound Care Events | Total | Weight | Risk Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Griffin et al, 1991 | 2 | 8 | 2 | 9 | 12.6% | 1.13 [0.20, 6.24] | 1991 |
| Wood et al, 1993 | 25 | 43 | 1 | 31 | 10.7% | 18.02 [2.58, 126.01] | 1993 |
| Adunsky and Ohry, 2005 | 9 | 35 | 10 | 28 | 25.1% | 0.72 [0.34, 1.53] | 2005 |
| Houghton et al, 2010 | 11 | 16 | 7 | 18 | 26.4% | 1.77 [0.91, 3.44] | 2010 |
| Polak et al, 2016 | 12 | 25 | 7 | 24 | 25.2% | 1.65 [0.78, 3.47] | 2016 |
| **Total (95% CI)** | | **127** | | **110** | **100.0%** | **1.68 [0.77, 3.65]** | |
| Total events | 59 | | 27 | | | | |

Heterogeneity: Tau² = 0.48; Chi² = 12.49, df = 4 (P = 0.01); I² = 68%
Test for overall effect: Z = 1.31 (P = 0.19)

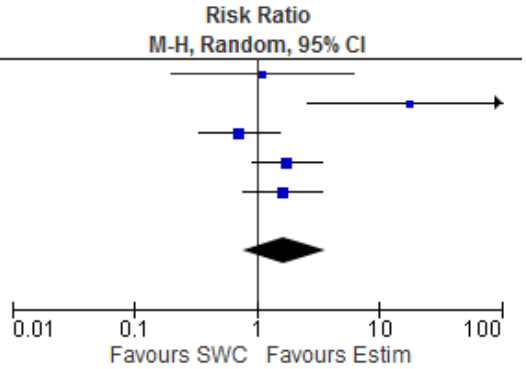


**Figure 3: Risk Ratio for Complete Pressure Injury Healing in Five Studies**

Abbreviations: CI, confidence interval; df, degrees of freedom; Estim, electrical stimulation; M-H, Mantel-Haenszel statistic; SWC, standard wound care.

**Table 7: Complete Pressure Injury Healing in Six Randomized Controlled Trials**

| Author, Year | Population | Follow-Up | Type of Electrical Stimulation | Duration of Electrical Stimulation | Number of Injuries Healed | |
|---|---|---|---|---|---|---|
| | | | | | Treatment Group | Control Group |
| Griffin et al, 1991[30] | Spinal cord injury | 20 d | Pulsed current | 60 min/once daily, 7 times/wk | 2/8 (25%) | 2/9 (22.2%) (*P* = NR) |
| Wood et al, 1993[34] | Older adults | 8 wk | Direct current | No information on duration of ES | 25/43 (58.1%) | 1/31 (3.2%) (*P* > .0001) |
| Jercinovic et al, 1994[33] | Spinal cord injury | 4 wk[a] | Pulsed current | 120 min, once daily, 5 times/wk | 51/81 (62.9%)[b] | 15/28 (31.3%) (*P* = NR) |
| Adunsky and Ohry, 2005[26] | Older adults | 12 wk[c] | Direct current | 20 min, thrice daily, 7 days/wk (42 h) reduced to 2 daily sessions after 14 d | 9/35 (25.7%) | 10/28 (35.7%) (*P* = .39) |
| Houghton et al, 2010[31] | Spinal cord injury | 6 mo | Pulsed current | 8 h daily, 7 d/wk (treatments were done typically at night) | 11/16 (69%) | 7/18 (39%)[d] (*P* = NR) |
| Polak et al, 2016[32] | Older adults | 6 wk | Pulsed current | 50 min, once daily, 5 times/wk | 12/25 (48%) | 7/24 (29.1%) (*P* = NS) |
| **Total** | | | | | 110/208 | 42/138 |

Abbreviations: ES, electrical stimulation; NR, not reported; NS, not significant.

[a]Includes crossover group where complete pressure injury healing was measured at approximately 8 weeks.

[b]Treatment group includes 20 injuries in crossover group that received 4 weeks of standard wound care and then additional 4 weeks of standard wound care plus ES.

[c]Adunsky and Ohry[26] state that follow-up for this outcome was 147 days (21 weeks).

[d]Some patients in control group received ES; however, number was not given.

| Study or Subgroup | Electrical Stimulation Events | Total | Standard Wound Care Events | Total | Weight | Risk Difference M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Griffin et al, 1991 | 2 | 8 | 2 | 9 | 20.4% | 0.03 [-0.38, 0.43] | 1991 |
| Houghton et al, 2010 | 11 | 16 | 7 | 18 | 32.7% | 0.30 [-0.02, 0.62] | 2010 |
| Polak et al, 2016 | 12 | 25 | 7 | 24 | 46.9% | 0.19 [-0.08, 0.46] | 2016 |
| **Total (95% CI)** | | **49** | | **51** | **100.0%** | **0.19 [0.01, 0.37]** | |
| Total events | 25 | | 16 | | | | |

Heterogeneity: Tau² = 0.00; Chi² = 1.07, df = 2 (P = 0.59); I² = 0%
Test for overall effect: Z = 2.05 (P = 0.04)

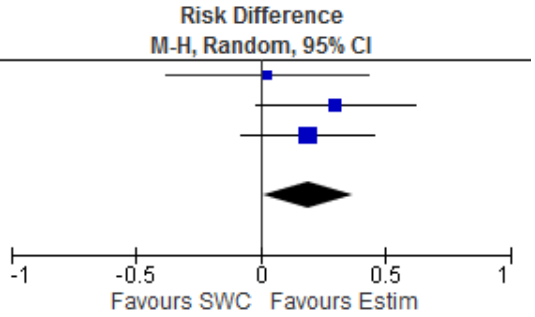


**Figure 4: Risk Difference for Complete Pressure Injury Healing in Three Studies That Administered Pulsed Current**

Abbreviations: CI, confidence interval; df, degrees of freedom; Estim, electrical stimulation; M-H, Mantel-Haenszel statistic; SWC, standard wound care.

| Study or Subgroup | Electrical Stimulation Events | Total | Standard Wound Care Events | Total | Weight | Risk Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Griffin et al, 1991 | 2 | 8 | 2 | 9 | 7.8% | 1.13 [0.20, 6.24] | 1991 |
| Houghton et al, 2010 | 11 | 16 | 7 | 18 | 51.2% | 1.77 [0.91, 3.44] | 2010 |
| Polak et al, 2016 | 12 | 25 | 7 | 24 | 41.0% | 1.65 [0.78, 3.47] | 2016 |
| **Total (95% CI)** | | **49** | | **51** | **100.0%** | **1.66 [1.03, 2.67]** | |
| Total events | 25 | | 16 | | | | |

Heterogeneity: Tau² = 0.00; Chi² = 0.24, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 2.08 (P = 0.04)

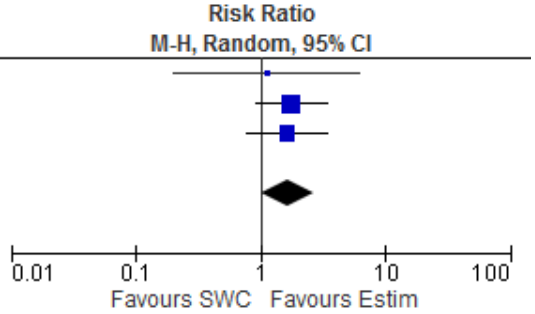


**Figure 5: Risk Ratio for Complete Pressure Injury Healing in Three Studies That Administered Pulsed Current**

Abbreviations: CI, confidence interval; df, degrees of freedom; Estim, electrical stimulation; M-H, Mantel-Haenszel statistic; SWC, standard wound care.

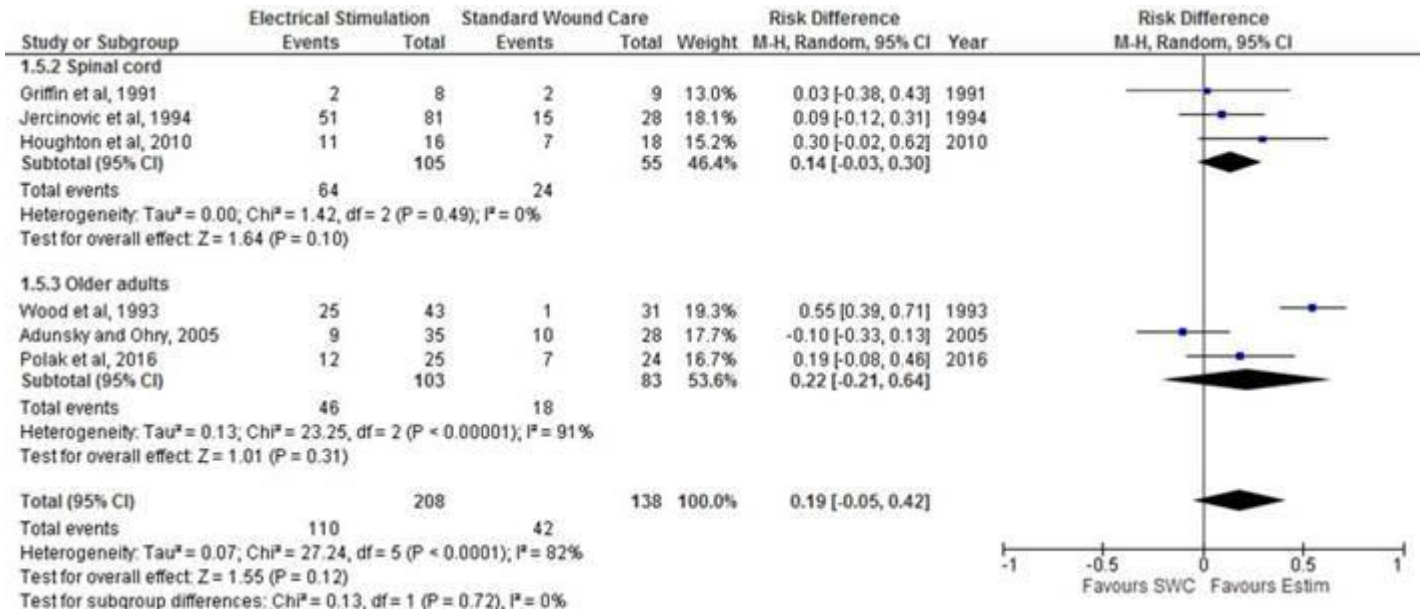


**Figure 6: Risk Difference for Complete Pressure Injury Healing in Studies of Patients with Spinal Cord Injury and Older Adults**

Abbreviations: CI, confidence interval; df, degrees of freedom; Estim, electrical stimulation; M-H, Mantel-Haenszel statistic; SWC, standard wound care

Jercinovic et al[33] reported that, of the wounds that healed in the treatment group, 13 were deeper than 5 mm, while 45 were superficial. The average initial wound surface area of healed pressure injuries was 7.9 ± 8.8 $cm^2$. Of 28 ulcers in the control group, all were superficial pressure injuries with an average initial wound surface area of 6.1 ± 6.7 $cm^2$. It should be noted that patients in the treatment group included 20 crossover patients who had 4 weeks of treatment in the control group (standard wound care) and then received 4 weeks of electrical stimulation. Complete pressure injury healing was not reported separately for the original treatment and crossover group; therefore, the data were not used in the meta-analysis.

Houghton et al[31] measured complete healing at two times. At 3 months, all Stage II ulcers (one pressure injury in the treatment group and four pressure injuries in the control group) healed completely. Of Stage III, IV, and X ulcers, 5/15 (33.3%) healed in the treatment group compared with 1/14 (7.1%) in the control group (*P* = .55). At 6 months, 11 (69%) of 16 subjects had complete wound healing in the treatment group. By comparison, 7 (39%) of 18 ulcers healed completely in the control group. However, some participants in the control group received electrical stimulation (after 3 months). No statistical test was performed to determine whether the difference between groups was significant.

Polak et al[32] found that 12 pressure injuries healed (9 of 11 Stage II and 3 of 14 Stage III) in the treatment group compared with seven pressure injuries in the control group (6 of 11 Stage II and 1 of 13 Stage III). However, this difference was not statistically significant.

### *Effect on Time to Heal*

Of the studies that reported complete pressure injury healing (Table 8), two[26,31] provided information on the time it took those injuries to heal (Table 9). When electrical stimulation was compared with standard wound care (+/− sham electrical stimulation), there were no definitive differences in healing times. The quality of evidence was low according to the GRADE criteria.

Houghton et al[31] reported that the average time for the treatment group to produce complete healing was 4.5 months (136.4 days). In the treatment groups, six participants had complete wound healing after 3 months, three wounds closed within 6 months, and two wounds closed within 1 year. In the control group, wounds that healed completely did so by 6 months (approximately 180 days). No statistical test of the difference between groups reached significance.

Adunsky and Ohry[26] reported that the mean time to heal was 89.7 ± 9.2 days for the control group and 63.4 ± 15.1 days for the treatment group (*P* = .16).

### *Effect on Wound Surface Area Reduction*

Seven[26-32] of eleven studies measured wound healing by wound surface area reduction (Tables 10 and 11). Four studies expressed wound surface area reduction as an average percentage of reduction from the baseline wound surface area, where one study expressed wound surface area reduction as a median percentage of reduction from baseline wound surface area. Two studies described the difference for wound surface areas in $cm^2$. Therefore, we conducted a meta-analysis using the four studies that measured the average percentage of wound surface area reduction at various times. The effect of electrical stimulation on wound surface area reduction was examined by pooling data from four studies with 173 participants using a random-effects model (Figure 7). Comparing electrical stimulation with standard wound care (+/− sham electrical stimulation), six of seven studies found a statistically significant difference in wound

surface area reduction; however, the quality of evidence was low according to the GRADE criteria, meaning we are uncertain about whether electrical stimulation reduces the size of the wound.

Gentzkow and Miller[29] reported that wound surfaces in the treatment groups were reduced at a rate of 12.5% per week compared with 5.8% per week in the control group ($P$ = .04).

At 6-week follow-up, Franek et al[28] observed statistically significant differences between the treatment and control groups in the following variables: decrease in wound area ($P$ = .00003), wound length and width ($P$ = .0003 and $P$ = .00008) and volume ($P$ = .008). The Gillman method, which estimated the wound size on the basis of its surface area and length of its perimeter, was used to ensure precise evaluation and comparison of changes in the size of pressure ulcers having differently shaped contours. Change in Gillman parameter was also significantly greater in the treatment than in the control group ($P$ = .000003).

**Table 8: GRADE Evidence Profile for Complete Pressure Injury Healing, Electrical Stimulation Versus Standard Wound Care**

| No. of Studies (Design) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Publication Bias | Upgrade Considerations | Quality |
|---|---|---|---|---|---|---|---|
| 6 (RCTs) | Serious limitations (–1)[a] | No serious limitations | No serious limitations[b] | Serious limitations (–1)[c] | Undetected | No other considerations | ⊕⊕ Low |
| 3 (RCTs)[d] | No serious limitations[a] | No serious limitations | No serious limitations | Very serious limitations (–2)[e] | Undetected | No other considerations | ⊕⊕ Low |

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial

[a]Unclear methods on randomization, allocation concealment, blinding, and participants and personnel.

[b]Four of six studies used pulsed current. Duration ranged from 40 minutes to 8 hours, 5 to 7 times weekly. Other parameters (frequency, voltage, pulses per second) also differed across studies.

[c]Wide confidence intervals ranged from more complete pressure injury healing in either standard wound care groups or electrical stimulation in five of six studies. Complete pressure injury healing was a primary outcome only in Wood et al[34] and Adunsky and Ohry.[26] Adunsky and Ohry were the only researchers who calculated sample sizes, but didn't achieve optimal information size because of loss to follow-up.

[d]GRADE for subgroup analysis looking at pulsed current electrical stimulation.

[e]None of the three RCTs had complete pressure injury healing as the primary outcome; therefore, no study met the optimal information size. Houghton et al[31] stated that some patients in the control group received electrical stimulation as part of standard wound care in that region. Sample size and event rates for RCTs are small (100 participants and 41 events).

**Table 9: GRADE Evidence Profile for Time to Heal, Electrical Stimulation Versus Standard Wound Care**

| No. of Studies (Design) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Publication Bias | Upgrade Considerations | Quality |
|---|---|---|---|---|---|---|---|
| 2 (RCTs) | No serious limitations | No serious limitations | No serious limitations | Very serious limitations (–2)[a] | Undetected | No other considerations | ⊕⊕ Low |

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.

[a]No standard deviation given by Houghton et al.[31] Also, median time would have been a more appropriate measure for time to heal.

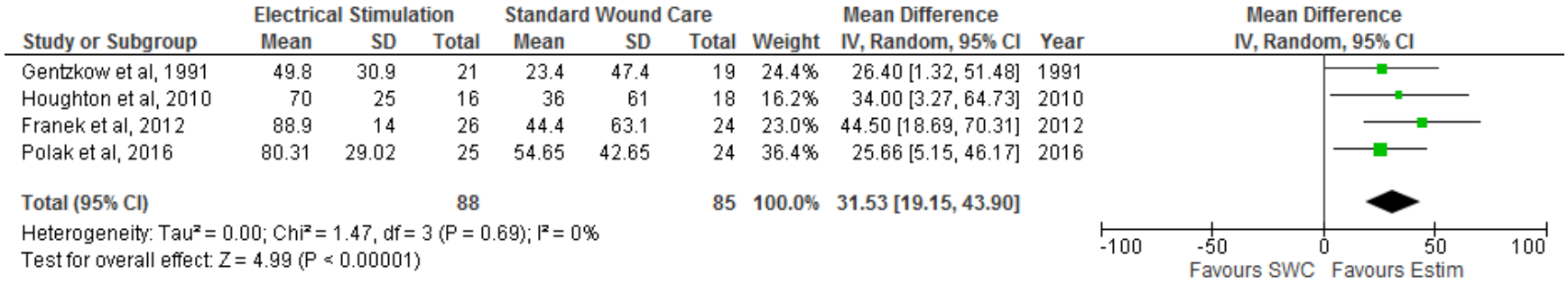


**Figure 7: Mean Difference for Wound Surface Area Reduction in Four Studies**

Abbreviations: CI, confidence interval; df, degrees of freedom; Estim, electrical stimulation; IV, inverse variance; SD, standard deviation; SWC, standard wound care.

**Table 10: Percentage of Wound Surface Area Reduction in Seven Randomized Controlled Trials**

| Author, Year | Population | Follow-Up | Parameters of ES | Duration of ES | WSA Reduction | |
|---|---|---|---|---|---|---|
| | | | | | Treatment Group | Control Group |
| Gentzkow and Miller, 1991[29] | Older adults | 4 wk | Pulsed current | 30 min, twice daily | 49.8 ± 30.9% | 23.4 ± 47.4% (*P* = .04) |
| Griffin et al, 1991[30] | Spinal cord injury | 20 d | Pulsed current | 60 min, once daily, 7 times/wk | Median % change: −80[a] | Median % change: −52 (*P* = .05) |
| Adunsky and Ohry, 2005[26] | Older adults | 12 wk | Direct current | 20 min, thrice daily, 7 d/wk (42 h) reduced to two daily sessions after 14 d | Initial WSA: 7.6 ± 1.1 $cm^2$<br>2.53 ± 2.11 $cm^2$ | Initial WSA: 7.5 ± 2.1 $cm^2$<br>2.88 ± 1.92 $cm^2$ (*P* = .31)[b] |
| Ahmad, 2008[27] | Spinal cord injury | 5 wk | Pulsed current | Three treatment groups receiving treatment for 45, 60, and 120 min, once daily, 7 d/wk | Initial WSA: 7.1 ± 1.6 $cm^2$<br>45 min: 5.10 $cm^2$<br>Initial WSA: 7.1 ± 1.6 $cm^2$<br>60 min: 0.60 $cm^2$<br>Initial WSA: 7.1 ± 1.5 $cm^2$<br>120 min: 0.64 $cm^2$ | Initial WSA: 7.2 ± 1.5 $cm^2$<br>5.39 $cm^2$ (*P* < .001) |
| Houghton et al, 2010[31] | Spinal cord injury | 6 mo[c] | Pulsed current | 8 h daily, 7 d/wk (treatments were typically done at night) | 70 ± 25% | 36 ± 61% (*P* = .04) |
| Franek et al, 2012[28] | Older adults | 6 wk | Pulsed current | 50 min/once daily, 5 times/wk | 88.9 ± 14% | 44.4 ± 63.1% (*P* = .00003) |
| Polak et al, 2016[32] | Older adults | 6 wk | Pulsed current | 50 min, once daily, 5 times/wk | 80.31 ± 29.02% | 54.65 ± 42.65% (*P* = .04) |

Abbreviations: ES, electrical stimulation; WSA, wound surface area;

[a]No confidence intervals were provided.

[b]Result was 6 weeks after ES stopped and more than 50% of participants dropped out. Researchers found a trend toward greater reduction of WSA in treatment group than in control group until Day 45.

[c]This outcome was measured at 3 months.

### *Effect on Relative Rate of Healing*

Three[33,35,36] of eleven studies measured the relative rate of healing expressed as percentage of reduction in wound surface area daily (Table 12). When comparing electrical stimulation with standard wound care (+/− sham electrical stimulation), two of three studies found a statistically significant difference in relative rate of healing (Table 13). The quality of evidence was low according to the GRADE criteria.

Stefanovska et al[36] measured relative rate of healing per day in two treatment groups (direct current vs. pulsed current) compared with standard wound care. The authors found that the relative rate of healing was 5.40% ± 4.10 daily in the pulsed-current treatment group, 4.62% ± 3.29 daily in the direct-current treatment group, and 2.87% ± 3.12 daily in the control group. The authors made no statistical comparison between groups. However, they concluded that pulsed current contributes to faster healing of pressure ulcers.

Jercinovic et al[33] measured relative rate of healing using linear and exponential equations. During the first 4 weeks, mean relative rate of healing in the treatment group was 2.2% for linear and 5.7% per day for the exponential fitting method. Mean relative rate of healing in the control group was 1.5% for linear and 2.7% daily for the exponential fitting method. The difference in daily mean healing rate was statistically significant ($P$ = .006) for just the exponential fitting method, but just the linear fitting method ($P$ = .07) was not statistically significant.

Karba et al[35] compared direct current with different polarity (two treatment groups) to standard wound care. The relative healing rate per day was 7.4 ± 1.6% for the direct current + group, 4.8 ± 1.5% for the direct current +/− group, and 4.2 ± 1.1% for the control group. There was no significant difference between the direct current +/− and the control groups. However, the difference between the direct current + group and control group was statistically significant ($P$ = .02).

**Table 11: GRADE Evidence Profile for Reduction in Wound Surface Area, Electrical Stimulation Versus Standard Wound Care**

| No. of Studies (Design) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Publication Bias | Upgrade Considerations | Quality |
|---|---|---|---|---|---|---|---|
| 7 (RCTs) | Serious limitations (–1)[a] | No serious limitations | Serious limitations (–1)[b] | No serious limitations[c] | Undetected | No other considerations | ⊕⊕ Low |

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.
[a]Unclear methods on randomization, allocation concealment, blinding, or participants and personnel.
[b]Wound surface area reduction is surrogate outcome.
[c]Griffin et al[30] and Gentzkow and Miller[29] did power calculation but did not have enough participants (because of exclusions/drop-outs) to be adequately powered. No power calculation was done by Adunsky and Ohry,[26] Ahmad,[27] Houghton et al,[31] or Franek et al.[28] Polak et al[32] did calculate power and met criteria for adequately powered sample.

**Table 12: Relative Rate of Healing in Four Studies**

| | | | | Relative Rate of Healing | |
|---|---|---|---|---|---|
| Author, Year | Population | Follow-Up | Parameters of ES | Treatment Group | Control Group |
| Stefanovska et al, 1993[36a] | Spinal cord injury | 4 wk | Two groups: PC and DC; received ES for 120 min daily | PC: 5.40% ± 4.10/d<br>DC: 4.62% ± 3.29/d | 2.87% ± 3.12/d (*P* = NR)[b] |
| Jercinovic et al, 1994[33] | Spinal cord injury | 4 wk | PC; received ES for 120 min, once daily, 5 times/wk | 5.7% ± 7.1/d[c] | 2.7% ± 3.6/d (*P* = .006) |
| Karba et al, 1997[35a] | Spinal cord injury | NR | DC (two groups looking at varied polarities); received ES for 120 min daily | DC +: 7.4 ± 1.6%/d<br>DC +/−: 4.8 ± 1.5%/d | 4.2 ± 1.1%/d (*P* = .02)[d] |

Abbreviations: DC, direct current; ES, electrical stimulation; NR, not reported; PC, pulsed current;
[a]Non–randomized controlled trial.
[b]This relative rate of healing was for equalized conditions, meaning groups had significant differences at baseline, and outliers were removed to make groups' characteristics similar at baseline.
[c]Relative healing rate expressed with exponential fitting method.
[d]Statistically significant difference between DC + and control group.

**Table 13: GRADE Evidence Profile for Relative Rate of Healing, Electrical Stimulation Versus Standard Wound Care**

| No. of Studies (Design) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Publication Bias | Upgrade Considerations | Quality |
|---|---|---|---|---|---|---|---|
| 1 (RCT) | Serious limitations (–1)[a] | No serious limitations | Serious limitations (–1)[b] | No serious limitations[c] | Undetected | No other considerations | ⊕⊕ Low |
| 2 (NRCT) | Serious limitations (–1)[d] | No serious limitations | Serious limitations (–1)[b] | No serious limitations | Undetected | No other considerations | ⊕⊕ Low |

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; NRCT, non–randomized controlled trial; RCT, randomized controlled trial.

[a]Unclear methods on randomization, allocation concealment, blinding, or participants and personnel. Jercinovic et al[33] had minimal details on crucial patient characteristics.

[b]Relative rate of wound healing is surrogate outcome. Intervention ranging from 60 to 120 minutes, 5 to 7 times weekly. Direct and pulsed current was administered.

[c]Estimate from Jercinovic et al[33] has large confidence intervals.

[d]Poorly reported studies with few details given on many risk-of-bias domains.

### *Complications of Electrical Stimulation Treatment*

Five[26,28,29,31,32] of eleven studies measured complications (Table 14). The evidence showed that minor complications occurred during electrical stimulation. The quality of evidence was high according to the GRADE criteria, meaning we are very certain that there are minor complications with electrical stimulation therapy.

Gentzkow and Miller[29] reported no significant adverse events during the study with no participants withdrawing. The minor complaints during active treatment were uncomfortable sensations in the ulcer when the current was turned on. This occurred in 13.6% (3/21) of ulcers in the treatment group and 4.2% (1/19) of ulcers in the control group.

Adunsky and Ohry[26] reported complications associated with treatment were minimal. Two patients in the treatment group reacted to electrical stimulation with excessive granulation of the pressure injuries. Two patients who were treated with topical sulfadiazine ointment (for skin irritation around the pressure injuries) reacted with local irritation, probably as a result of the effect of the direct current on the silver ions in this type of ointment.

Adverse events in Houghton et al[31] were minor. The most common adverse event reported was red, raised, itchy skin beneath the electrode. These reactions were attributed to dermatitis because the issue was resolved within 24 hours of discontinuing the use of self-adhesive electrodes. A nonadhesive carbon electrode was substituted in these cases. However, the number of participants who experienced this reaction was not given. Only two patients experienced other adverse events. One patient had a persistent (> 24 hours) red area or burn under the active electrode. This was remedied by turning down the intensity of the electrical stimulation treatment. One patient complained of dizziness and delusions while he was receiving electrical stimulation treatment. After evaluation, however his symptoms were deemed to arise from an unrelated issue.

Franek et al[28] and Polak et al[32] reported no adverse events in their studies.

**Table 14: GRADE Evidence Profile for Minor Complications, Electrical Stimulation Versus Standard Wound Care**

| No. of Studies (Design) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Publication Bias | Upgrade Considerations | Quality |
|---|---|---|---|---|---|---|---|
| 5 (RCTs) | No serious limitations | No serious limitations[a] | No serious limitations[b] | No serious limitations | Undetected | No other considerations | ⊕⊕⊕⊕ High |

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.
[a]Similar minor complications across studies.
[b]Four of five studies administered pulsed current. Three of four studies used high-voltage frequency. Very little variation in treatment and control groups across studies.

### *Patient Adherence With Electrical Stimulation*

Patient adherence to the electrical stimulation protocol was measured in only one study (Table 15). Houghton et al[31] had participants self-administer treatment, and the electrical stimulation device could track patient usage. The quality of evidence was moderate according to the GRADE criteria.

Houghton et al[31] measured patient adherence to electrical stimulation treatment. Patients administered treatments at home. While the electrical stimulation protocol for this study was 8 hours daily, participants used electrical stimulation for a mean ± SD of 3.0 ±1.5 h/d, which was much lower than the recommended treatment time. Four of the 16 patients in the treatment group administered treatment for the recommended time. Patients who healed used the electrical stimulation machine for more time (539 total hours; 3.54 h/d) than those who did not heal with electrical stimulation (331 total hours; 2.24 h/d).

### *Wound Healing in Included Studies With Crossover Design*

Two[29,33] of eleven studies employed a crossover design, allowing participants in the control group to receive active electrical stimulation. When standard wound care (+/− sham electrical stimulation) was compared with active electrical stimulation, there was a statistically significant difference in wound surface area reduction and relative rate of healing.

Gentzkow and Miller[29] allowed patients to cross over to the treatment group from the control group at the end of the 4-week study period. Of the 19 ulcers in the control group, 15 crossed over to complete 4 weeks of electrical stimulation. This crossover group received on average 9.8 weeks of treatment (range 5–16 weeks). The crossover group had an average wound area surface reduction of 13.4% before crossing over to electrical stimulation. After the 4 weeks of active treatment, the crossover group healed an average of 47.9% of their size. When wound surface area reduction during the sham period was compared with active treatment, the difference was statistically significant ($P$ = .012). Six (40%) of 15 ulcers healed completely after an average of 9 weeks.

Jercinovic et al[33] had 20 participants cross over after 4 weeks of sham treatment. Looking at just the sham period by way of the exponential fitting method, ulcers healed between −2.2% and 6.2% daily. After 4 weeks of electrical stimulation, 19 ulcers had improved ranging from −0.3% to 14.7% daily. When the daily rate of healing was compared in the sham and active treatment periods, the difference was statistically significant ($P$ = .001).

**Table 15: GRADE Evidence Profile for Patient Adherence, Electrical Stimulation Versus Standard Wound Care**

| No. of Studies (Design) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Publication Bias | Upgrade Considerations | Quality |
|---|---|---|---|---|---|---|---|
| 1 (RCT) | No serious limitations | No serious limitations | No serious limitations | No serious limitations | Undetected | No other considerations | ⊕⊕⊕ Moderate[a] |

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT; randomized controlled trial.
[a]Rated down because patient adherence is based on one RCT.

## Discussion

We included 11 studies (9 randomized controlled trials and 2 non–randomized controlled trials) in this review examining the clinical effectiveness of electrical stimulation for pressure injuries. Given the low quality of evidence, we are uncertain about the effect of electrical stimulation on complete wound healing and on wound size reduction.

Several systematic reviews have been published on electrical stimulation for pressure injuries. Two systematic reviews combined results, but at least nine systematic reviews did not combine results of primary studies because the intervention and outcomes varied widely.

However, all systematic reviews reached similar conclusions. Regardless of the parameters of electrical stimulation, electrical stimulation is effective for treatment of pressure injuries.[37-40] However, the variation in parameters across electrical stimulation makes it difficult to advocate for any one standard approach. Our assessment concluded that the evidence did not support the use of electrical stimulation for pressure injuries. This conclusion was based largely on the variation across the population, intervention, comparator, outcomes, and settings.

Study populations included either patients with spinal cord injuries or older adults. Although all experts suggested that these populations would not differ in their pressure injury healing, the populations themselves differ. Patients with spinal cord injury tend to be younger (about 30 vs. 60–70 years of age). Also, patients with spinal cord injuries (depending on the level of injury) will not be able to redistribute their weight on their own. They generally require a caregiver, a constant personal support worker, or a nurse. However, older adults might also be less mobile than younger people in general.

Electrical stimulation involves many parameters (waveform, polarity, frequency, intensity, and duration of treatment). Studies included in this review administered electrical stimulation in various ways. Most studies administered pulsed current, while a few administered direct current. Experts suggested that waveform did not affect healing rate. However, Kawasaki et al[37] found that pulsed current yields better wound healing results than direct current. Experts also stated that the other parameters should be chosen by the clinician programming the device. However, duration of treatment should be specified, as there might be no benefit to administering electrical stimulation for longer than 60 minutes. Ahmad[27] used high-voltage pulsed current in three treatment groups (duration of treatment varied: 120 minutes vs. 60 minutes vs. 45 minutes) and used standard wound care in a control group. There was a significant reduction in wound surface area among patients treated for 60 minutes versus 45 minutes (60 minutes: 0.60 $cm^2$ vs 45 minutes: 5.10 $cm^2$; $P < .001$) and in the wound surface area among patients treated for 120 minutes versus 45 minutes (120 minutes: 0.64 $cm^2$ vs. 45 minutes: 5.10 $cm^2$; $P < .001$), but no significant reduction in wound surface area in patients treated for 120 minutes versus 60 minutes (120 minutes: 0.64 $cm^2$ vs. 60 minutes: 0.60 $cm^2$; $P > .05$).

Standard wound care also differed across studies. Some studies included no information on what standard wound care entailed and others gave a detailed description. The variation makes it difficult to draw conclusions about the benefit of electrical stimulation on wound healing; wound care might not be optimal.

Wound healing outcomes in the studies varied. While six studies did measure complete wound healing, these studies did not have statistical strength to determine a significant difference between groups. Also some studies examined reduction of wound size by calculating a percentage of reduction on the basis of baseline wound surface area, while others did not

calculate a percentage of reduction and reported only the wound surface area (in $cm^2$ or $mm^2$) at various times. Relative rate of healing was also used to measure wound healing. This rate was calculated as a percentage of reduction in wound surface area daily. Reduction of wound size and relative rate of healing are surrogate outcomes.

Follow-up also varied across studies: one study was as short as 20 days and one was as long as 6 months. Settings also varied from acute care to home care. The setting could have also affected the follow-up time. If a patient was being treated in acute care, the treatment period might not be long enough to show wound healing outcomes. Electrical stimulation administered through home care could allow for longer treatment time.

There were some limitations to the studies and to our systematic review. Many studies are from the 1990s, and some do not report methods or results well. The samples were small and follow-up times varied. Therefore, most follow-up was not long enough to capture complete healing. Clinicians, however, are advised to use the percentage of area reduction at 4 weeks as a relevant predictor for wound closure.[41]

We were also unable to subgroup research according to pressure injury stage, wound duration, or surface area, which could be associated with complete healing. We included pressure injuries only and excluded studies that combined types of wounds.

## Conclusions

Our conclusions on the effectiveness of electrical stimulation plus standard wound care compared with standard wound care (+/− sham electrical stimulation) alone for treatment of pressure injuries are as follows:

- We are uncertain whether electrical stimulation improved healing rates (GRADE quality of evidence: low)
- We are uncertain whether electrical stimulation improved average time to heal (GRADE quality of evidence: low)
- We are uncertain whether electrical stimulation reduced size of wounds (GRADE quality of evidence: low)
- We are uncertain whether electrical stimulation improved daily rate of healing (GRADE quality of evidence: low)
- We are certain that electrical stimulation is safe (GRADE quality of evidence: high)
- In terms of patient adherence, patients who healed used the electrical stimulation machine for longer stretches than those who did not heal (GRADE quality of evidence: moderate)

# ECONOMIC EVIDENCE

## Research Question

What is the cost-effectiveness of electrical stimulation for treatment of pressure injuries reported in the published literature?

## Methods

### *Literature Search*

We performed an economic literature search on December 8, 2016, for studies published from inception to the search date. The search was developed using the clinical search strategy with an economic filter applied. Database auto-alerts were created in MEDLINE, Embase, and CINAHL and monitored for the duration of the health technology assessment review. We performed targeted grey literature searching of health technology assessment agency sites and clinical trial registries.

See Clinical Evidence, Literature Search, page 13, above, for methods used, and Appendix 1 for literature search strategies, including all search terms.

### *Literature Screening*

A single reviewer reviewed titles and abstracts, and, for those studies meeting the eligibility criteria, we obtained full-text articles.

### *Types of Studies*

We looked at cost-effectiveness studies that compared electrical stimulation with standard care for patients with pressure injuries (i.e., ulcers).

We did not include editorials, case reports, or commentaries.

### *Types of Participants*

Adults (18 years of age and older) with pressure injuries Stage II and above.

### *Types of Interventions*

Electrical stimulation and standard care.

### *Types of Outcome Measures*

- Incremental cost per quality-adjusted life-year (QALY)
- Incremental cost per unit clinical outcome

### *Data Extraction*

We extracted relevant data on the following:

- Source (i.e., name, location, year)

- Population and comparator
- Interventions
- Outcomes (i.e., health outcomes, costs, and incremental cost-effectiveness ratio [ICER])

We contacted authors of the studies to provide clarification as needed.

### *Study Applicability and Methodologic Quality*

We determined the usefulness of each identified study for decision-making by applying a modified applicability checklist for economic evaluations that was originally developed by the National Institute for Health and Care Excellence (NICE) in the United Kingdom.[42] The original checklist is used to inform development of clinical guidelines by NICE. We modified the wording of questions to remove references to guidelines and to make the checklist Ontario specific. We separated the checklist into two sections. In the first section, applicability of the study to the research questions was assessed. If the study was deemed directly applicable or partially applicable to the research questions, quality of the study was assessed using the second section of the checklist. Each study was assessed as having minor limitations, potentially serious limitations, or very serious limitations in its methodologic quality.

## Results

### *Literature Search*

The database search yielded 132 citations published from inception to December 8, 2016. An additional 15 citations were identified from grey literature search. After removing duplicates, there were 117 citations to review. We excluded 116 articles on the basis of information in the title and abstract. We then obtained the full text of one potentially relevant article for further assessment. Figure 8 presents the flow diagram for the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).

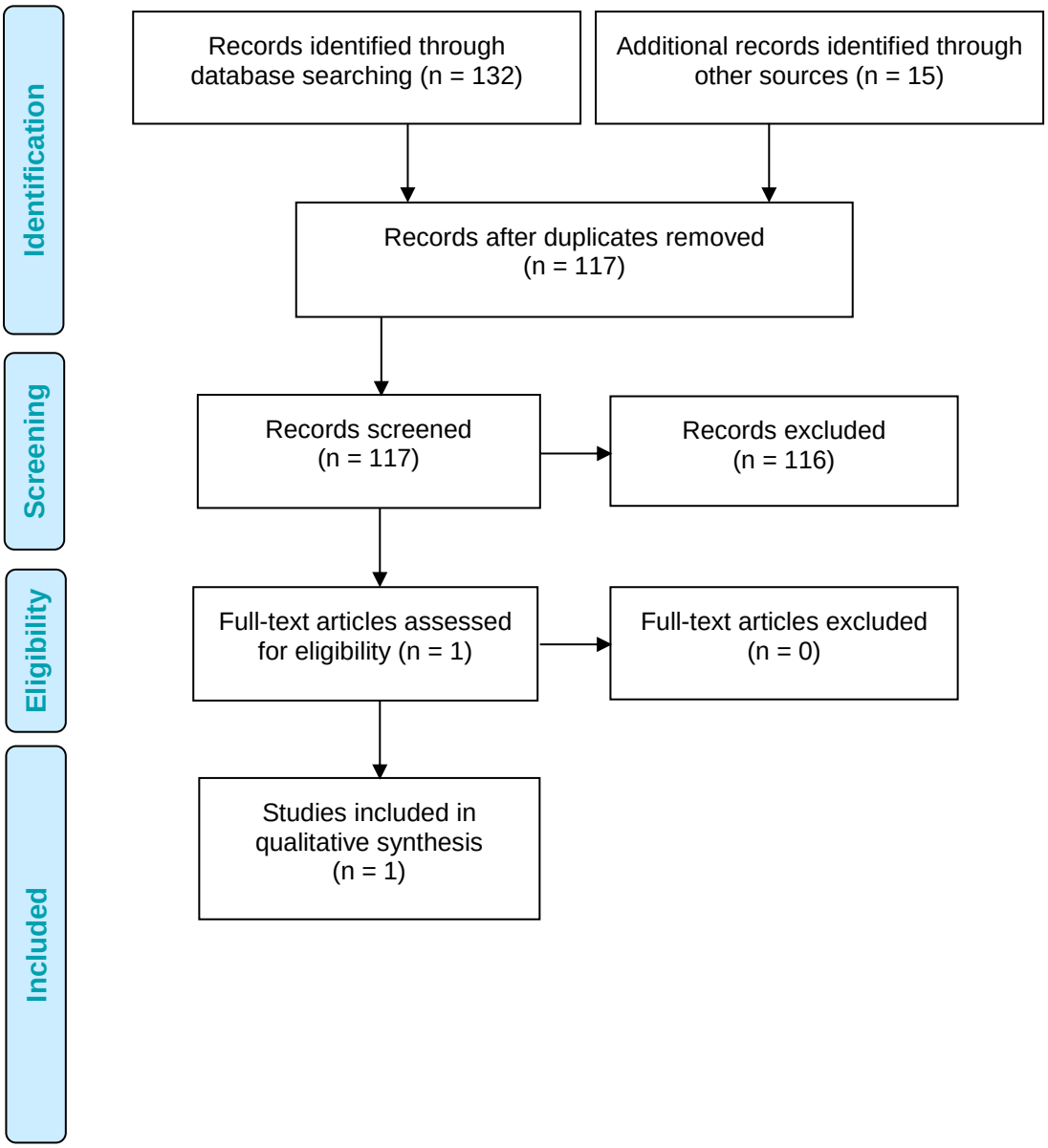


**Figure 8: PRISMA Flow Diagram for Economic Review**

Abbreviation: PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.
*Source: Adapted from Moher et al.*[25]

One study met the inclusion criteria. We hand-searched the reference lists of included studies and health technology assessment websites to identify other relevant studies, and no additional citations were included.

### *Review of Included Economic Study*

The included study was a cost-effectiveness analysis that evaluated the incremental cost per pressure injury (each ulcer) healed in community-dwelling patients with spinal cord injuries.[43] The study compared those receiving electrical stimulation and standard care with those receiving standard care alone. Data were analyzed from the perspective of Canadian public health system payer and had a 1-year time horizon. Clinical effectiveness and costing of electrical stimulation were based on an Ontario clinical trial.[31] Other clinical and costing parameters were based on published literature. Researchers reported a 16.4% decrease in pressure injuries for electrical stimulation with standard care compared with standard care alone at 1 year. At 1 year, electrical stimulation also resulted in a cost savings of $224. Thus, electrical stimulation with standard care dominated standard care alone (the combination cost less and had better health outcomes). In the probabilistic sensitivity analysis, electrical stimulation with standard care was dominant in 62% of the total simulations.

### *Applicability and Methodologic Quality of Included Economic Studies*

The results of the applicability and methodologic quality checklists for economic evaluations applied to the included article[43] are presented in Appendix 4. The included study was deemed partially applicable to the research question and had potentially serious limitations.

## Discussion

One study evaluated the cost-effectiveness of electrical stimulation for pressure injuries.[43] This study was partially applicable to our research question. All model parameters were obtained from Ontario sources. However, the study was limited to community-dwelling patients (self-administering electrical stimulation) with spinal cord injuries. How these results apply to other patients with pressure injuries is unknown. The clinical effectiveness of electrical stimulation in this model was based on a single clinical trial, with a small sample size, and did not consider other published studies.

There is little information on the cost-effectiveness of electrical stimulation for pressure injuries. However, owing to uncertainty and heterogeneity in clinical evidence, and limited research on resource use, we decided not to conduct a primary economic evaluation.

## Conclusions

The single economic study we identified[43] suggested that electrical stimulation for pressure injuries saves on costs and offers better clinical outcomes in community-dwelling patients with spinal cord injuries. Currently the cost-effectiveness of electrical stimulation in the general population with pressure injuries cannot be determined.

## BUDGET IMPACT ANALYSIS

We conducted a budget impact analysis from the perspective of the Ontario Ministry of Health and Long-Term Care to determine the estimated cost of funding electrical stimulation for the treatment of pressure injuries over the next 5 years. All costs are reported in 2017 Canadian dollars.

### Research Question

What is the 5-year budget impact of funding electrical stimulation for treatment of pressure injuries from the perspective of the Ontario Ministry of Health and Long-Term Care?

### Methods

#### *Main Assumptions*

Several assumptions were made in development of the budget impact analysis. The main assumptions are presented below.

- Electrical stimulation treatment is given only to incident pressure injuries.
- All patients are treated for only one pressure wound at a time.
- All pressure injuries are considered "healable" or "treatable."
- Patients with pressure injuries in acute care are treated with electrical stimulation in another health care setting.
- Care in all health care settings is mutually exclusive.
- Only patients in the home can "self-administer" electrical stimulation.
- All patients receive standard wound care; electrical stimulation is an adjunct therapy.
- Introducing electrical stimulation does not affect use of alternate adjunct therapies.

Potential limitations of these assumptions are presented in the Discussion below.

#### *Target Population*

We examined the budget impact of electrical stimulation for pressure injuries in five Ontario-specific health care settings: 1) acute care, 2) complex continuing care, 3) home care, 4) inpatient rehabilitation, and 5) long-term care. Given the limited evidence, we were unable to directly incorporate patients with pressure injuries who receive outpatient rehabilitation.

To determine the number of patients with pressure injuries who would likely be treated with electrical stimulation, we estimated the incidence of pressure injuries in each health care setting and the number of pressure injuries that would be eligible for treatment with electrical stimulation.

#### Incident Pressure Injuries

A study published in 2015 by Woo and colleagues evaluated the incidence of pressure injuries in various health care settings in Ontario.[10] The average annual incidence of pressure injuries in Ontario (2010–2013) is between 1.4% and 7.0%, depending on the health care setting (Table 16).[10] The incidence of pressure injuries in inpatient rehabilitation was not reported. In our base case analysis, we assumed the incidence of pressure injuries in inpatient rehabilitation was the same as the incidence in complex continuing care. The total number of patients in Ontario requiring health care in these settings ranges between 27,389 and 1,167,032 (Table 16).[10,44-46]

Therefore, the total number of patients in each health care setting expected to experience a new pressure injury each year ranges from 1,917 in complex continuing care to 52,516 in acute care (Table 16).

We assumed patients in complex continuing care, home care, inpatient rehabilitation, and long-term care with new (incident) pressure injuries would be treated in the same setting for the entirety of their therapy. However, given the short average stay (i.e., 6.6 days in 2014/15 Ontario[47]), we assumed acute care patients would be discharged to alternate health care facilities. This assumption was supported by clinical experts. In our base case analysis, we assumed that acute care patients with pressure injuries discharged to one of the four other health care settings captured would receive electrical stimulation. The proportion of acute care patients treated in each setting (complex continuing care, home care, inpatient rehabilitation, or long-term care) was based on 2015 discharges of patients with a pressure injury from the Discharge Abstract Database obtained from IntelliHEALTH ONTARIO (Table A6, Appendix 5).[48] We assumed patients discharged to different settings or with unknown discharge status would not receive electrical stimulation. This assumption was explored in the sensitivity analysis.

In the base case analysis, the total number of pressure injury cases per year in any health care setting is estimated to be 47,463 (Table 16).

## Patients Eligible for Electrical Stimulation

Guidelines and clinical expertise on the recommended use of electrical stimulation varies. Conservatively, we assumed all pressure injuries would be considered healable. We tested this assumption in the sensitivity analysis. In our base case analysis, consistent with the Canadian Best Practice Guidelines for the Prevention and Management of Pressure Injuries in People with Spinal Cord Injury[49] and expert consultations within Ontario, we assumed only Stages III and IV pressure injuries would be considered eligible for electrical stimulation. In addition, we assumed recalcitrant pressure injuries were those that did not heal within 30 days. These assumptions are consistent with current clinical practice and with Medicare coverage of electrical stimulation in the United States.[50]

In the absence of stage-specific incidence rates, we assumed the proportion of pressure injuries that would eventually progress to Types III and IV was equivalent to the prevalence of Stages III and IV pressure injuries (Table A7, Appendix 5). Prevalence was obtained from nine international prevalence surveys.[51]

We assumed that all Stages III and IV pressure injuries would be unhealed for at least 30 days. This assumption aligns with evidence on average time to healing (i.e., Stage III = 127 days, Stage IV = 155 days[52]) and percent of pressure injuries healed over time (i.e., 8% of Stages III and IV pressure injuries healed within 56 days[53]).

Scenarios depicting various eligibility criteria were explored in the sensitivity analysis.

In the base case analysis, the annual total number of pressure injury cases eligible for electrical stimulation is estimated to be 7,817 (Table 16).

**Table 16: Incident and Eligible Pressure Injuries in Various Ontario Health Care Settings**

| Strategy | Acute Care | Complex Continuing Care | Home Care | Inpatient Rehabilitation | Long-Term Care | Total |
|---|---|---|---|---|---|---|
| Incidence[10,54] | 4.5% | 7.0% | 1.4% | 7.0%[a] | 4.1% | 4.2%[b] |
| Total patients requiring health care services in Ontario yearly | 1,167,032[45] | 27,389[44] | 192,402[46] | 32,741[55] | 114,929[44] | 1,534,493 |
| Total estimated pressure injury cases yearly | 52,516 | 1,917 | 2,694 | 13,352 | 4,712 | 64,131 |
| Total estimated pressure injury cases yearly, acute care moved[c] | 0 | 7,737 | 19,207 | 7,167 | 13,352 | 47,463 |
| Pressure injury cases eligible for electrical stimulation[d] | 16.47% | 16.47% | 16.47% | 16.47% | 16.47% | 16.47% |
| Total estimated patients eligible for electrical stimulation | 0 | 1,274 | 3,164 | 1,180 | 2,199 | 7,817 |

[a]Assumed incidence in inpatient rehabilitation was equivalent to complex continuing care.
[b]Total incidence reweighted to include inpatient rehabilitation.
[c]We assumed patients with pressure ulcers in acute care would be discharged to and treated with electrical stimulation in other health care settings.
[d]Based on prevalence of Stages III and IV pressure injuries,[51] assumed unhealed for 30 days.

## *Uptake Rate*

We assumed, in our base case analysis, the annual uptake rate of electrical stimulation would be 10%. This assumption was based on input from clinical experts. Our estimates for number of pressure injuries treated in 5 years are presented in Table 17. We explored various rates of uptake in the sensitivity analysis.

**Table 17: Pressure Injuries Treated With Electrical Stimulation in Various Ontario Health Care Settings (2017–2021)**

| | No. of Pressure Injuries/Y (Uptake Rate) | | | | |
|---|---|---|---|---|---|
| **Health Care Setting** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| Complex continuing care | 127 | 255 | 382 | 510 | 637 |
| Home care | 316 | 633 | 949 | 1,265 | 1,582 |
| Inpatient rehabilitation | 118 | 236 | 354 | 472 | 590 |
| Long-term care | 220 | 440 | 660 | 880 | 1,100 |
| **Total** | **782** | **1,563** | **2,345** | **3,127** | **3,909** |

## *Resource and Costs*

Electrical stimulation practices in various health care settings are summarized in Table 18. The cost of electrical stimulation therapy consisted of the costs of the device, treatment supplies, training time, and treatment administration time. Clinical experts suggested that the type of

device used for electrical stimulation therapy and who administers therapy would differ depending on whether patients are treated at a health care facility or at home.

We assumed patients receiving care in all settings other than home care (complex community care, inpatient rehabilitation, and long-term care) would receive therapy in a health care facility, where we assumed therapy would be administered by a health care professional (i.e., nurse or physiotherapist). We estimated that 50% of patients receiving therapy at home would self-administer or have a caregiver administer electrical stimulation, and 50% would have a health care professional administer electrical stimulation. This assumption was confirmed by clinical experts.

In terms of the type of device used, clinical experts explained that health care professionals administering electrical stimulation would use a more expensive clinical device designed for professional administration. A less expensive, user-friendly, portable model has been developed for patients and caregivers.

On the basis of consultation with clinical experts, we assumed that health care professionals who administer treatment in long-term care would be registered nurses, and in complex continuing care, inpatient rehabilitation, or home care would be registered nurses or physiotherapists. We explored using only registered nurses and registered practical nurses in the sensitivity analysis.

**Table 18: Electrical Stimulation Therapy in Various Ontario Health Care Settings**

| Strategy | Complex Continuing Care | Home Care | Inpatient Rehabilitation | Long-Term Care |
|---|---|---|---|---|
| Location | Health care facility | Home | Health care facility | Health care facility |
| Device | Clinical device | 50% clinical device, 50% patient or caregiver device | Clinical device | Clinical device |
| Device administration | Health care professional | 50% health care professional, 50% patient or caregiver | Health care professional | Health care professional |
| Health care professional | 50% nurse, 50% physiotherapist | 50% nurse, 50% physiotherapist | 50% nurse, 50% physiotherapist | Nurse |

## Electrical Stimulation Device

Capital costs, maintenance costs, and amortized per-person costs for electrical stimulation devices are shown in Table 19. Clinical experts indicated that a more expensive device would be purchased for health care professionals administering electrical stimulation. These devices are expected to be used by multiple patients over many years for various indications beyond pressure injuries. The cost per device is $1,665. According to experts, a typical device is expected to last 10 years. Replacement wires that attach the electrodes to this device cost $52.70.[56] We assume these wires will be replaced every year. We also assumed that these devices will be used to treat 10 patients yearly. The total number of patients to receive electrical stimulation during the device's life cycle is therefore 100. The total cost of the device and replacement wires throughout the expected lifecycle of the device is estimated to be $2,192.00 ($1,665 + [10 · $52.70]). The total per-person costs of devices administered by health care professionals are estimated to be $21.92 ($2,192/100).

A patient-administered portable electrical stimulation device is expected to cost approximately $360. According to the manufacturer, the typical life cycle of the device is 5 years (J. P. Johnson, oral communication, January 2017). Replacement wires cost $14.95.[57] Wires are replaced at a frequency of every year. We also assumed that these devices would be used to treat two patients yearly. The total number of patients receiving electrical stimulation during the device's life cycle is 10. The total cost of the device and replacement wires throughout the expected life cycle of the device is estimated to be $434.75 ($360 + [5 · $14.95]). The total per-person cost of patient-administered devices for home care is estimated to be $43.48 ($434.75/10).

**Table 19: Clinical and Patient- or Caregiver-Administered Device Costs of Electrical Stimulation**

| Variable | Clinical Administered Device | Source | Patient-Administered Device | Source |
|---|---|---|---|---|
| Base cost ($) | 1,665 | Clinical consultation | 360 | Clinical consultation |
| Life cycle (y) | 10 | Clinical consultation | 5 | Manufacturer |
| Replacement wires ($) | 52.70 | Patterson Medical | 14.95 | Maugee's Market[57] |
| Frequency of wire replacement (y) | 1 | Assumption | 1 | Assumption |
| Annual number of patients treated per device | 10 | Assumption | 2 | Assumption |
| **Total per-person cost ($)** | **21.92** | **Calculation** | **43.48** | **Calculation** |

## Treatment Supplies

Administration of electrical stimulation requires the use of a pair of electrodes through which electrical impulses are transmitted to the skin. We assumed a pair of 4- by 2.25-inch self-adhering electrodes would be used for each session. Conservatively, we assumed the electrodes would be used for only one session. The total cost of a pair of electrodes suitable for high-voltage electrical stimulation is $1.54.[57]

## Electrical Stimulation Training

Training for administration of electrical stimulation was based on the cost of nurses' and physiotherapists' time. Wages for registered nurses in Ontario are calculated to be approximately $41.98/h, assuming mid-range wages plus benefits of registered nurses in hospitals and long-term care facilities.[58,59] Wages for physiotherapists in Ontario are calculated to be approximately $44.28/h, assuming mid-range wage of $38.84 + 14% benefits).[60]

Implementation of electrical stimulation therapy in Ontario would require training both health care professionals and patients or caregivers. Clinical experts report devices are quite easy to use and basic training can be completed in 1 hour or less. To gain more in-depth knowledge of electrical stimulation and its mechanisms, a 1-day training course is available for health professionals.

In the base case analysis, we assumed health care professionals would receive 1 hour of training before administering therapy. We assumed one health care professional would need to be trained for every 10 patients who are treated. Therefore, the cost of training per patient was approximately $4.20 and $4.43 for registered nurses and physiotherapists, respectively.

In addition, we assumed patient-administered electrical stimulation in the home would require each patient or caregiver to be trained to administer electrical stimulation by a registered nurse ($41.98) or physiotherapist ($44.28) for 1 hour.

In the sensitivity analysis we explored the use of registered nurses or registered practical nurses exclusively in addition to varying lengths of training.

## Administration and Length of Electrical Stimulation Treatment

The cost of administering electrical stimulation was based on the treatment protocol and the cost of health professionals' time. In the base case analysis, we assumed each patient in each setting would receive 60-minute sessions of electrical stimulation daily for 57 days, for a total of 57 hours. Several electrical stimulation protocols in clinical trials apply treatment for at least 60 minutes of treatment daily.[26,27,29] Although protocols for much longer treatment sessions (i.e., 8 hours) exist,[31] longer sessions are primarily used in patient administration. Further, Ahmad[27] showed that 60-minute sessions were superior to longer treatments. As in Adunsky and Ohry,[26] we assumed patients received electrical stimulation therapy for 57 days. This study, identified from the clinical evidence review, included some patients whose pressure injuries healed completely.

In most health care settings (complex continuing care, inpatient rehabilitation, long-term care), we assumed for each electrical stimulation session health care professionals would be required only to set up and remove the device (about 15 minutes). While the device was running, we assumed health care professionals could attend to other patients or tasks. Thus, only 15 minutes of health care professionals' time was required per session. In home care, we assumed health care professionals administering electrical stimulation would remain with patients for the full session. Thus, we costed health care professionals' time for the full 60-minute session.

Wages were multiplied by the number of sessions and health care professionals' time required for each session to determine the total administration cost per patient. It is assumed that, in the long-term care setting, electrical stimulation would be exclusively administered by a nurse ($41.98/h). In complex continuing care, inpatient rehabilitation, and home care, health care was administered by either a physiotherapist ($44.28/h) or a nurse ($41.98/h). In these settings, we assumed physiotherapists and nurses would each administer treatment 50% of the time. In home care, when electrical stimulation would be administered by patients or family members, there were no additional costs from the perspective of Ontario's Ministry of Health and Long-term Care.

Scenarios capturing various treatment protocols, and health professionals' time required per session, are explored in the sensitivity analysis.

### *Base Case Analysis*

The base case budget impact analysis was calculated by multiplying the total number of patients with pressure injuries eligible for electrical stimulation with the total cost of electrical stimulation per patient. Electrical stimulation is an adjunct to standard wound care; therefore, the budget impact was based only on the additional cost of electrical stimulation over the next 5 years. All costs are reported in 2017 Canadian dollars.

### *Sensitivity Analysis*

In the sensitivity analysis, we explored several scenarios and their effect on results of the budget impact analysis. These included scenarios varying eligibility criteria, uptake, acute care discharges, several parameters, and the potential cost offsets of electrical stimulation.

#### Uptake Scenarios

We explored two additional uptake scenarios: 1) uptake of 5% of patients and 2) uptake of 25% of patients annually. The respective number of patients treated in these scenarios is presented in Appendix 5 (Table A8).

#### Acute Care Discharge Scenarios

Two additional scenarios examining acute care discharges were explored. The first scenario assumes all patients (including those with unknown or other discharge locations) would be discharged to one of the captured health care settings and receive electrical stimulation according to the proportions in Table A6 (Appendix 5). The second scenario assumed no patients from acute care would receive electrical stimulation. The respective number of patients treated in these scenarios is presented in Appendix 5 (Table A8).

#### Eligibility Scenarios

We examined four scenarios of patient eligibility for electrical stimulation: 1) 50% of Stage IV injuries would not heal; 2) Stages III and IV pressure injuries would not heal for 3 months; 3) Stages II, III, and IV pressure injuries would not heal for 30 days (according to guidelines from the Registered Nurses' Association of Ontario[11]); 4) 20% of all incident pressure injuries would be eligible for electrical stimulation; or 5) 80% of all incident pressure injuries would be eligible for electrical stimulation. The latter two scenarios were included to capture the range of pressure injuries that are eligible for electrical stimulation (according to several health professionals) in Ontario. The respective number of patients treated in these scenarios is presented in Appendix 5 (Table A8).

#### Additional Scenarios

Several additional parameters in the budget impact analysis were varied to examine effects on the results. These parameters include:

- Incidence of pressure injuries in inpatient rehabilitation = 1.4%
- Proportion of patients self-administering at home (minimum) = 0
- Proportion of patients self-administering at home (maximum) = 1
- Proportion of patients self-administering in all health care settings = 1
- Proportion of electrical stimulation done using Micro-Z (lower-cost) device = 1
- Per-patient cost of clinical device (according to clinical experts) and wire replacement[61] based on GV 350 model = $7.21
- Frequency of wire replacement = each patient
- Annual number of patients using patient-administered device (minimum) = 1
- Annual number of patients using patient-administered device (maximum) = 4
- Number of hours required for patients' or caregivers' training (minimum) = 0.5
- Number of hours required for patients' or caregivers' training (maximum) = 1
- Number of hours required for health care professionals' training (minimum) = 0

- Number of hours required for health care professionals' training (maximum) = 8
- Health care professionals' hourly wage (registered nurse only) = $41.98[58,59]
- Health care professionals' hourly wage (registered practical nurse only) = $34.35[62]
- Total number of treatment hours (minimum) = 20[30]
- Total number of treatment hours, for 120-minute sessions (maximum) = 114
- Total health care professional time (minutes) required per session in all settings = 60

### Potential Cost Offsets of Electrical Stimulation

We explored the potential cost offsets of electrical stimulation compared with standard wound care. We calculated the shorter time to healing and determined the savings from shorter periods of standard wound care treatment. We based our wound-healing time estimates on findings from Adunsky and Ohry.[26] In this study, the average time to wound healing, among those who healed during the study period, was 89.7 days for those receiving standard wound care alone. For those using standard wound care plus electrical stimulation, average time was 63.4 days. An Ontario cost-effectiveness analysis of electrical stimulation in spinal cord patients found the average daily cost of standard wound care to be $8.53.[43] This means that, for each patient, using electrical stimulation could save $224 ([89.7 days−63.4 days] · $8.53) in standard wound care costs. These cost offsets were applied to all patients expected to receive electrical stimulation from 2017 to 2021.

#### *Expert Consultation*

From November 2016 to April 2017, experts on electrical stimulation were consulted. These experts included health care professionals in the specialty area of wound care. The role of expert advisors was to provide advice on the costs, resource use, and assumptions surrounding the budget impact of electrical stimulation in Ontario.

## Results

### *Base Case*

Total cost of electrical stimulation per patient is presented in Table 20. When electrical stimulation was administered by a health care professional, cost per patient ranged from $712 in long-term care to $2,572 in home care. When administered by a patient or caregiver, cost per patient was $179.

**Table 20: Annual per-Patient Costs of Electrical Stimulation for Various Ontario Health Care Settings**

| Cost Variables | Complex Continuing Care[a] | Home Care[b] | Home Care[a] | Inpatient Rehabilitation[a] | Long-Term Care[a] |
|---|---|---|---|---|---|
| Device ($) | 109.79 | 131.35 | 109.79 | 109.79 | 109.79 |
| Admin device ($) | 614.55 | 0 | 2,458.21 | 614.55 | 598.15 |
| Patient training ($) | NA | 43.13 | NA | NA | NA |
| Health personnel training ($) | 4.31 | 4.31 | 4.31 | 4.31 | 4.20 |
| **Total Cost Per Person ($)** | **728.66** | **178.79** | **2,572.32** | **728.66** | **712.14** |

Abbreviation: NA, not applicable.
[a]Administered by a health care professional.
[b]Administered by patient or caregiver.

Estimated annual budget impact of funding electrical stimulation for treatment of pressure injuries ranges from $0.77 million in 2017 to $3.85 million in 2021 (Table 21). The budget impact ranges from $0.09 million to $0.46 million in complex continuing care, $0.43 million to $2.18 million in home care, $0.09 million to $0.43 million in inpatient rehabilitation, and $0.16 million to $0.78 million in long-term care.

**Table 21: Budget Impact of Electrical Stimulation in Ontario (2017–2021)**

| | Year (Uptake Rate), $ Millions | | | | |
|---|---|---|---|---|---|
| **Health Care Setting** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| Complex continuing care | 0.09 | 0.19 | 0.28 | 0.37 | 0.46 |
| Home care | 0.43 | 0.87 | 1.31 | 1.74 | 2.18 |
| Inpatient rehabilitation | 0.09 | 0.17 | 0.26 | 0.34 | 0.43 |
| Long-term care | 0.16 | 0.31 | 0.47 | 0.63 | 0.78 |
| **Total** | **0.77** | **1.54** | **2.31** | **3.08** | **3.85** |

## *Sensitivity Analysis*

### Uptake Rate Scenarios

The annual budget impact ranged from $0.39 to $1.93 million under 5% annual uptake and from $1.93 to $7.71 million under 25% annual uptake (Table 22).

**Table 22: Budget Impact of Electrical Stimulation Under Various Levels of Uptake in Ontario (2017–2021)**

| | Year | | | | |
|---|---|---|---|---|---|
| **Scenario** | **2017** | **2018** | **2019** | **2020** | **2021** |
| 100% uptake | | | | | |
| Uptake (%) | 5 | 10 | 15 | 20 | 25 |
| **Total budget impact ($, million)** | **0.39** | **0.77** | **1.16** | **1.54** | **1.93** |
| 25% annual uptake | | | | | |
| Uptake (%) | 25 | 50 | 75 | 100 | 100 |
| **Total budget impact ($, million)** | 1.93 | 3.85 | 5.78 | 7.71 | 7.71 |

## Acute Care Discharge Scenarios

The annual budget impact of electrical stimulation was between $1.05 and $5.26 million when all acute care discharges were included, and was between $0.17 and $0.83 million when no acute care discharges were included (Table 23).

**Table 23: Budget Impact of Electrical Stimulation Under Various Acute Care Discharge Scenarios in Ontario (2017–2021)**

| | Year (Uptake Rate), $ Million | | | | |
|---|---|---|---|---|---|
| **Scenario** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| 100% of acute care discharges included | 1.05 | 2.10 | 3.15 | 4.21 | 5.26 |
| 0% of acute care discharges included | 0.17 | 0.33 | 0.50 | 0.67 | 0.83 |

## Eligibility Scenarios

The annual budget impact ranged from $0.56 million to $18.72 million under various eligibility scenarios (Table 24). The smallest budget impact resulted when only Stages III and IV pressure injuries that had not healed for 3 months were considered eligible for electrical stimulation. The largest budget impact resulted when 80% of all pressure injuries were considered eligible for electrical stimulation.

**Table 24: Budget Impact of Electrical Stimulation Under Various Eligibility Scenarios in Ontario (2017–2021)**

| Scenario | Year (Uptake Rate), $ Million | | | | |
|---|---|---|---|---|---|
| | 2017 (10%) | 2018 (20%) | 2019 (30%) | 2020 (40%) | 2021 (50%) |
| Base case,[a] 50% of Stage IV pressure injuries are "unhealable" | 0.58 | 1.16 | 1.73 | 2.31 | 2.89 |
| Stages III and IV pressure injuries that are unhealed for 3 months | 0.56 | 1.12 | 1.67 | 2.23 | 2.79 |
| Stages II, III, and IV pressure injuries that are unhealed for 30 days | 2.05 | 4.11 | 6.16 | 8.22 | 10.27 |
| 20% of all pressure injuries | 0.94 | 1.87 | 2.81 | 3.74 | 4.68 |
| 80% of all pressure injuries | 3.74 | 7.49 | 11.23 | 14.97 | 18.72 |

[a]Stages III and IV pressure injuries that are unhealed for 30 days.

## Additional Scenarios

The entire results from the parameter scenario analyses can be found in Table A9 (Appendix 5). Overall, most parameters had a small effect on the budget for electrical stimulation in Ontario. Treatment hours, the proportion of administration by patients or caregivers, and health professionals' time per session had the largest influence on the budget.

When we assumed patients would receive 20 hours of treatment, the total budget impact ranges from $0.29 to $1.45 million over the next 5 years. When we assumed patients would receive 114 hours of treatment, the budget impact ranges from $1.16 to $5.80 million over the next 5 years. Details specific to each health care setting can be found in Table A10 (Appendix 5).

The budget impact ranged from $1.15 to $5.75 million when we assumed no electrical stimulation would be administered by patients or caregivers and from $0.14 to $0.70 million when we assumed electrical stimulation would be exclusively administered by patients or caregivers. The budget impact for these scenarios stratified by health care setting can be found in Table A11 (Appendix 5).

Finally, the budget impact ranged from $1.62 to $8.09 million over the next 5 years when we incorporated the cost of health care professionals' time for the full session length (60 minutes) in all health care settings. The budget impact for this scenario stratified by health care setting can be found in Table A12 (Appendix 5).

## Potential Cost Offsets of Electrical Stimulation

With potential cost offsets included, the budget impact of electrical stimulation ranged from $0.59 to $2.97 million over the next 5 years (Table A13, Appendix 5).

## Budget Impact Analysis in Patients with Spinal Cord Injury

During the public comment period of our health technology assessment process, experts stated the importance of subgrouping patients with spinal cord injuries. Based on this feedback we estimated the budget impact of funding electrical stimulation in patients with spinal cord injury. According to experts we consulted, approximately 100 patients with pressure injuries in this subpopulation would be eligible for treatment with electrical stimulation per year. The estimated budget impact would be $88,188 per year over the next five years in patients with spinal cord injury.

## Discussion

The base case budget impact of electrical stimulation for treatment of pressure injuries ranged from $0.77 million in the first year (2017) to $3.85 million in the fifth year (2020). The budget impact was the highest in the home care setting, followed by long-term care, complex continuing care, and finally, inpatient rehabilitation. The budget impact was related to the number of patients requiring treatment in each setting and to administration details.

In long-term care, complex continuing care, and inpatient rehabilitation, electrical stimulation was administered exclusively by health care professionals. Treatment cost between $712 and $729 per patient, of which approximately 15% were device-related costs and 84% were administration costs. Consistently, in these settings it was assumed 15 minutes of health professionals' time would be required for each electrical stimulation session. This time included set up and removal of the device. During the rest of the session, clinical experts confirmed patients could be left alone with the device running, and staff could attend to other patients or duties. Relative costs in these settings were directly proportional to the number of patients treated; long-term care had the most patients followed by complex continuing care and inpatient rehabilitation.

Home care offered a different scenario, where electrical stimulation treatment is administered in the patient's home. When electrical stimulation was administered by health care professionals, we assumed their time would be required for the full 60-minute electrical stimulation session. In the home, health care professionals would not be able to attend to other patients while the device ran. This increases the cost of electrical stimulation to $2,572 per person, of which 95% were administration costs. When we assumed health care professionals would be paid for 60-minute sessions in all settings, budget impact increased to between $1.6 and $8.09 million/y.

In home care, the high cost of administration by health care professionals was offset because we assume that 50% of patients could self-administer electrical stimulation. The annual cost of electrical stimulation per person was much lower ($176) when the treatment was self-administered by a patient or caregiver. When we assume no patients or caregivers would administer electrical stimulation in any health care setting, the total budget impact increased to between $1.15 and $5.75 million annually. Correspondingly, when we assumed electrical stimulation would be administered exclusively by patients or caregivers, the budget impact was $0.14 to $0.70 million annually. Given caregivers and patients will sometimes be unable to prepare the wound and apply electrical stimulation, the latter scenario is unrealistic in many settings. However, these results highlight that using patients or caregivers for administration, when appropriate, will lower the budget impact. Results also highlight the potential high costs of administration by health care professionals.

The cost of treatment administered by health care professionals is a result of wages paid to health care professionals over the total treatment time. This is evident because the budget impact decreased under low estimates of total treatment time and increased under high estimates of total treatment time. Clinical trial protocols for electrical stimulation vary widely, but usually therapy is applied for several weeks with at least 60 minutes daily.[26,27,29] On average, Stages III and IV pressure injuries take 127 days and 155 days to heal, respectively.[52] Even if electrical stimulation reduces healing time, therapy could still require several weeks of administration.

When considering the funding of electrical stimulation, eligibility of patients should be considered, as it will likely affect the budget impact in Ontario. In our base case analysis, we

considered Stages III and IV recalcitrant (30 days without healing) pressure injuries to be eligible for electrical stimulation. However, several additional eligibility scenarios were examined. Previous wound-management protocols in Ontario considered electrical stimulation only when a patient is unhealed after 3 months of receiving standard wound care.[63] When we increased the recalcitrant criteria from 3 weeks to 3 months, the budget impact was reduced to between $0.56 and $2.79 million/y. Guidelines from the Registered Nurses' Association of Ontario[64] that were based on a recent meta-analysis[41] suggest electrical stimulation be used on Stages II to IV pressure injuries. When we included Stage II recalcitrant pressure injuries, budget impact increased to $2.05 to $10.27 million/y.

Our analysis had several strengths. We were able to explore the budget impact for several Ontario health care settings. We did this by using setting-specific pressure injury incidence from a recent Ontario study.[10,54] Patients develop pressure injuries in a variety of settings; thus, it was important to capture funding requirements in each situation. Each setting could have different funding mechanisms; presenting setting-specific budget impacts could enhance planning and implementation of the technology. In addition, we captured various administration methods (by health care professionals or by patients or caregivers) and highlighted the budget variation between methods. Finally, we captured training requirements for health care professionals. Clinical consultations suggest that a lack of training and lack of knowledge of the intervention limit uptake of the technology. Addressing this factor in the budget impact helps to demonstrate the potential costs associated with increasing training for health care professionals.

Our analysis also had several limitations. Only incident pressure injuries were included in the analysis. While some patients with current pressure injuries are eligible for electrical stimulation, many injuries could heal by the time electrical simulation therapy is implemented. Longer-lasting injuries tend to be considered unhealable and ineligible for electrical stimulation. Conservatively, we assumed different patients would have each pressure injury. It is possible for patients to have multiple pressure injuries, however; providing electrical stimulation for one patient would likely be less expensive than for multiple patients. Due to the scarcity of data, we were unable to include patients with pressure injuries who received outpatient rehabilitation in our analysis. However, we assume several outpatient wound clinics would take transfers from inpatient rehabilitation and referrals from home care; thus a portion of these patients would be captured in the analysis. In addition, we had to make assumptions about the incidence of pressure injuries in inpatient rehabilitation. We assumed the incidence was equivalent to that of complex continuing care, the Ontario setting with the highest incidence of pressure injuries. Prevalence of pressure injuries in rehabilitation from a study in the United States[65] was most similar to, albeit slightly lower than, prevalence of pressure injuries in complex continuing care in Ontario.[10,54] A lower incidence in sensitivity analyses caused little variation in the budget impact.

Finally, our ability to estimate the potential cost offsets of electrical stimulation was limited. We calculated cost offsets by multiplying reduction in healing time by the daily cost of standard wound care. Several limitations to this approach coincide with our decision not to perform a primary economic evaluation. The effectiveness data (reduction in time to healing) was based only on patients who healed within the study's 147-day follow-up.[26] Mean time to healing for Stages III and IV pressure injury ranged from 127 to 155 days.[52] Thus, a substantial proportion of patients would not be captured, resulting in a potentially biased estimate. Further, costing data were based on a clinical trial of community-dwelling patients in Ontario with spinal cord injuries. Findings might not be generalizable to the broader pressure-injury population. However, we wanted to present a potential scenario where some cost offsets could be realized. As high-quality data on long-term clinical effectiveness and Ontario resource use become available, a full cost-effectiveness analysis should be performed.

## Conclusions

Our budget impact analysis indicates that publicly funding electrical stimulation for pressure injuries could result in spending $0.77 million to $3.85 million extra annually for the next 5 years.

# PATIENT, CAREGIVER, AND PUBLIC ENGAGEMENT

## Background

Public and patient engagement explores the lived experience of a person with a health condition, including the impact that the condition and its treatment has on the patient as well as the patient's family or other caregivers, and on the patient's personal environment. Public and patient engagement increases awareness and builds appreciation for the needs, priorities, and preferences of the person at the centre of a treatment program.

Lived experience is a unique source of evidence about the personal impact of a health condition and how that condition is managed, including what it is like to navigate the health care system with that condition and how technologies may or may not make a difference in people's lives. Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcome measures that do not reflect what is important to those with lived experience).[66-68] Additionally, lived experience can provide information or perspectives on the implications of technologies and treatments for ethical and social values. Because the needs, priorities, preferences, and values of those with lived experience in Ontario are not often adequately explored by published literature, Health Quality Ontario reaches out to and directly speaks with people who live with the health condition, including those who might have experience with the intervention in question.

For this study, six patients were engaged to discuss their lived experience with pressure injuries. We spoke to people who had experience of electrical stimulation in addition to standard wound care (two patients and two caregivers) and people who had experience of standard wound care only (two patients). Understanding and appreciating their day-to-day function and experience with any treatments, including electrical stimulation, helped to assess the potential value of the interventions from a lived experience perspective.

## Methods

### *Engagement Plan*

Engagement as a concept captures a range of efforts used to involve the public and patients in various domains and stages of health technology assessment decision-making.[69] Rowe and Frewer outline three types of engagement: communication, consultation, and participation.[70] Communication constitutes a one-way transfer of information from the sponsor to the patient, while participation involves the sponsor and patient collaborating through real-time dialogue. Consultation, on the other hand, refers to the sponsor's seeking out and soliciting information (e.g., experiential input) from the public, patients, and caregivers affected by the health technology or intervention in question.

The engagement approach for this health technology assessment was consultation. The Engagement design focused on interviews to examine the lived experience of patients with pressure injuries, including those with experience of electrical stimulation in addition to standard wound care and patients with experience of standard wound care only.[71]

The qualitative interview was selected as an appropriate method because it allowed Health Quality Ontario staff to explore the meaning of central themes in the lived experience of the participants. The main task in interviewing is to understand the meaning of what participants say.[72] Interviews are particularly useful for getting the story and context behind a participant's

experiences, which was the objective in this portion of the report. The sensitive nature of exploring quality-of-life issues is another reason for using confidential one-on-one interviews for this project.

### *Participant Recruitment*

Our recruitment strategy for this project consisted of an approach called purposive sampling to actively recruit individuals with direct lived experience. Patient, Caregiver, and Public Engagement staff contacted patients through a variety of partner organizations, University Health Network, advocacy groups (such as Ontario Wound Care Interest Group), patient support groups (such as Spinal Cord Injury Ontario), and long-term homes.

## Inclusion Criteria

Participants who had experienced pressure injuries who might or might not have been treated with electrical stimulation were sought. Patients of various ages, sexes, socio-economic backgrounds, and geographic locations were sought to capture equity issues and differing decision-making priorities across the province.

## Exclusion Criteria

We set no exclusion criteria.

## Participants

Patient, Caregiver, and Public Engagement staff spoke with six people with lived experience of pressure injuries across Ontario. Four patients and two caregivers were interviewed. All patients and caregivers were familiar with a variety of standard treatments for pressure injuries. Four of the six participants had experience with standard treatments and electrical stimulation.

### *Interview Approach*

As part of the call for participation, participants received a letter of information outlining the risks of participation and protection of personal health information (See Appendix 6). At the outset of the interview, Patient, Caregiver, and Public Engagement staff explained the mandate of Health Quality Ontario, the role of the Ontario Health Technology Advisory Committee, and the purpose of health technology assessment, and consent was obtained verbally before the start of the interview. Interviews were audio-recorded and transcribed.

The interview was semistructured, consisting of a series of open-ended questions, and lasted for about 30 to 45 minutes. Interview questions were based on a list of questions developed by Health Technology Assessment International's Patient and Citizen Involvement Group to elicit lived experience specific to how a health technology or intervention affects lived experience and quality of life.[73]

Interview questions focussed on how pressure injuries affected the patients' and families' quality of life, experiences with other treatments, and perceived benefits and limitations of electrical stimulation treatment. The interview guide is attached as Appendix 7.

### *Data Extraction and Analysis*

We selected a modified version of a grounded-theory method to analyze transcripts of participant interviews. This method was used because it captures themes and allows elements of lived experience to be compared among participants. The inductive nature of grounded theory follows an iterative process of eliciting, documenting, and analyzing responses while simultaneously collecting and analyzing data using a constant comparative approach.[74,75] Through this approach, staff coded transcripts and compared themes using NVivo, a qualitative software program that enables the identification and interpretation of patterns in the interview data about the meaning and implications of the lived condition (QSR International, Doncaster, Victoria, Australia).

## Results

### *Physical and Emotional Experience of Living with Pressure Injuries*

Patients and caregivers who were consulted described several health challenges that co-existed with the pressure injuries, such as spine injury, stroke, bone growth, and loss of sensation around their wounds. Patients and caregivers identified a spectrum of challenges depending on the location of pressure injuries and the length of time injuries took to heal.

Some of these challenges were psychological and related to social isolation. Patients consistently discussed the lack of independence to care for themselves, difficulty of social interactions, and fear of developing infections and other pressure injuries.

> "*Wounds to [a] paraplegic [are] almost a death sentence."*
>
> *"And obviously it affects my mood, my character, and even my interaction with other people. You become obviously depressed, you feel sort of alone because you're not up and about and doing things that you normally would do.*
>
> *"Because of wounds, I am unable to get my own groceries; … getting a haircut is a big deal."*
>
> *"I fear potential for infection at any moment. ... I feel trapped almost."*

Caregivers as well as patients were considerably affected by pressure injuries. Caregivers described greater strain on their time from caring for people with pressure injuries. They reported increased anxiety, financial burden, and social isolation while caring for patients living with pressure injuries.

> *"It's a panic almost every night when I take the bandage off. … I am scared of what I am going to see. … I am constantly telling him it's time to take pressure off."*
>
> *"Our life has been on hold for a long, long time because of these pressure sores."*
>
> *"I don't mind taking care of him, but the truth is it takes my time away from my business. … I need to run my business to provide for the family."*

Patients with informal caregivers appreciated their support, care, and social interactions. As one patient explained, [I'm] *"lucky to have [my] brother to help me get into bed. He picks up my prescriptions for me. He is my liaison to [the pharmacy] or home health care."* The lack of caregiver supports led to greater challenges for some patients. For example, inability to see the injury and properly care for themselves led to disappointment at their results:

> *"[Its improving],…and then I go to see a health care professional and they say 'Well, no, the measurements show us that it's just as bad [as] or worse than it was.' So, yeah, it's very frustrating."*

### *Treatment for Pressure Injuries*

Patients and caregivers reported familiarity with a variety of standard treatments for pressure injuries, including reducing pressure through repositioning and support surfaces (such as mattresses and cushions), cleaning and dressing wounds with various creams, removal of damaged tissues, and surgery. Patients reported encountering these treatments at hospitals, at wound care clinics, and at home through nursing visits with Community Care Access Centres (CCACs).

> "*He was on [standard] wound care for 3 years: Silversel. Acticote slack, nissol cream, Intrasite gel."*

> *"Getting [a] proper mattress [is important]; … [a] board is required to transfer in and out of bed."*

Patients and caregivers who were interviewed reported frustration with standard treatment for the pressure injuries. They noticed inconsistencies between settings and providers.

> *"I get into hospital, and they have their own wound care regimen. The products in the hospital [are] of less value."*

> *"I have changed dressings. Different nurses do it differently; … it can set him back."*

> *"It's a constant battle: … lots of dressings, products, and nurses' time, doctor appointments."*

Treatments varied and required several products and medical appointments, and yet were ineffective in healing injuries. Participants noted the home care appointment times were not firm and patients waited for assistance for several hours. Patients and caregivers reported that they had a few nurse visits scheduled per week, leading to many hours spent waiting.

> *"I need to wait for nurses and [my] home care schedule to live my life. They come anytime. … I need to keep my door unlocked for nurses to come in and out."*

Patients and caregivers also commented on setbacks in wound healing that came with hospital stays and travel for medical appointments.

> *"Getting a proper mattress in the hospital is an issue—now you have done harm on wounds. Many hours go by, and I ring and tell [nurses] to turn me."*

> *"We are home bound; we can't go anywhere. Every visit to Toronto from Courtice, there was a setback, whatever improvement there was, … we are back to square one again."*

Patients and caregivers found time as a major theme in determining the success of treatment. This includes time needed for healing, time for monitoring pressure on injuries, time to change dressings, time to travel for medical appointments, time of health care providers, and time to experiment with different ointments, creams, and dressings.

With this mindset, patients and caregivers considered a reduced time of healing to be the main benefit of any treatment. This finding is consistent with "time of healing" as a treatment outcome identified in the clinical literature. This engagement activity found that patients and caregivers perceived faster healing to minimize setbacks, reduce product use, minimize development of new pressure injuries, and improve their daily life.

> *"If you count the time it takes for a visiting to nurse to change the dressing, appointments, the wound care, x-rays, all kinds of things, it really is a drain on the limited amount of time that I get to do my activities of daily living."*

Standard treatments were viewed as resource intensive and economically ineffective for both patients and the health care system.

> *"[T]he cost factor of all the supplies and creams and nurse visits and … doctor visits. We are not government, but OHIP [health insurance system] has to pay for all these appointments."*

### *Perceived Effect of Electrical Stimulation*

For the purpose of this patient engagement report, the effect of electrical stimulation was assessed by posing questions related to electrical stimulation and to its effectiveness, efficiency, cost, and ease of access. It should be noted that evidence of perceived effectiveness obtained from a few qualitative interviews with patients who have been treated with this technology should be interpreted alongside the systematic review of published clinical studies.

## Treatment Process

Patients and caregivers received training from health care professionals—nurses or physiotherapists—on applying electrical stimulation. Patients and caregivers reported that health care professionals were willing to explain the benefits, risks, and alternatives to their satisfaction. They found the machine unintimidating and easy to use. Most interviewees, especially those with spinal cord injuries, did not report any adverse effects from the electrical current.

> *"It's a 9-V battery in a little component; there is a pad that's covering the sore and attaches to either the red wire or the black wire… this larger pad that goes on her hip, and hooks in for an hour. She doesn't feel the pulsing; she doesn't feel anything."*

> **"***My nurse in Lyndhurst was the one that taught me originally how to do it, and then I taught the CCAC nurses."*

> *"I have—well, I have near-zero sensation. So, I'm sure that [electrical current] wouldn't be an issue."*

Patients who did not have the support of an informal caregiver found placement of the electrodes challenging, especially when they were unable to see the wound.

> "*Yeah, because the wounds are not as bad now as what they were originally, so it was harder for me to place [electrodes] accurately, if you know what I mean, without putting them in an area that we were worried about."*

Patients and caregivers reported the health care professionals personalized and titrated the length and frequency of treatment according to their wound's reaction to the current.

> *"We started on electrical stimulation for 4 months for 8 hours/night and dressings were soaked. For 2 months we went down to 1 hour at night and in the morning and then further down after that; … then the wound closed up."*

## Effectiveness

Patients and caregivers reported high satisfaction with the healing progress through electrical stimulation. Because these patients had experience with standard treatment for pressure injuries, they were able to reflect upon how quickly they felt the wounds healed with either treatment. A common theme was that patients felt pressure injuries healed faster than had been anticipated when they used the electrical stimulation.

> *"Gives us … our life back again. He can get up early in the morning. Time in chair is bigger; … I don't have to worry about it every half hour."*

Patients reported that they had suffered from chronic pressure injuries for several months or years before adding on electrical stimulation and were surprised at what they perceived as quick healing. Some patients continued electrical stimulation to protect their new skin and to ensure that the injury was healing on the inside. Some people continued to apply electrical stimulation to prevent recurrence.

> *"I was very surprised about all the time that had passed and all the things that we had tried and we weren't getting anywhere: very, very slow progress compared to the couple of months that we did the electrical stim; the change was very dramatic, very dramatic."*

> *"I think this is the greatest thing they came up with, this e-stimulation. … I know they use it on other wounds there, open sore wounds with other patients. ... So I do know that it's fast healing."*

## Cost and Access

The total financial burden of electrical stimulation includes one-time purchase of an electrical stimulation machine and ongoing purchase of supplies that are dependent on the rate of healing. For individual patients, the cost and access to this treatment depended on their financial capacity, their insurance coverage, their geographical location, and the length of the treatment period. Some patients were able to purchase the machine through partial insurance coverage and ongoing supplies were provided by their local CCAC. Some patients were able to obtain the machine through a research trial and had to pay for their supplies.

> *"We did the electro stim for a few months, and then after that, after we stopped it, we ran out of pads and stuff like that."*

> *"The insurance paid 80%. We paid another 20%. Supplies and dressing [came] from CCAC."*

Patients who were on disability found this treatment unattainable.

> *"That definitely wasn't an option. I'm on [the Ontario Disability Support Program], and the pads are pretty expensive."*

### Awareness and Access

Access to electrical stimulation also depended on whether the patient or health care professional was aware of the treatment. Some patients heard about this option for the first time when they were approached by their nurse for this health technology assessment interview. Patients expressed surprise that this technology was not widely available for treatment of pressure injuries.

> *"I remember her saying it was several hundred dollars; … it certainly would put a dent in my income, … but I'm 100% sure I would like to try it."*

## Discussion

Patients and caregivers with lived experience of pressure injuries recognized many challenges in coping with the overall disease burden. All patients described the physical, psychological, and social burden of having pressure injuries. Caregivers spoke about social isolation, emotional burden, and anxiety that came with hyper-vigilance about pressure reduction methods and medical appointments. Perceptions of patients and caregivers depended on their health knowledge, experience, social and caregiver support, and co-existing medical problems. Both patients and caregivers noted standard treatments were time consuming, inconsistent, and ineffective. Patients saw pursuit of additional treatments as necessary to reduce and avoid the possibility of infections and recurrence.

All patients and caregivers with experience of electrical stimulation had experience with several standard treatment methods. They were able to comment on the effectiveness of standard treatments alone and in combination with electrical stimulation.

A common theme for both patients and caregivers was a perceived faster rate of healing with the addition of electrical stimulation. Patients who were unaware of the treatment option and found it cost prohibitive were willing to take a chance with it. Patients and caregivers who tried electrical stimulation were surprised at the perceived dramatic results, some noting a perceived healing on a daily basis.

## Conclusions

Pressure injuries reduce the quality of life of patients and caregivers. Standard treatments are time consuming, inconsistent, and sometimes ineffective at meeting patients' expectations. Faster rate of healing was associated with reduction of treatment burden and improvement of their daily living. Patients and caregivers interviewed reported great interest in the addition of electrical stimulation to standard treatment for their pressure injuries.

## ABBREVIATIONS

| | |
|---|---|
| **CCAC** | Community Care Access Centre |
| **CINAHL** | Cumulative Index to Nursing & Allied Health Literature |
| **DARE** | Database of Abstracts of Reviews of Effects |
| **GRADE** | Grading of Recommendations Assessment, Development, and Evaluation |
| **MINORS** | Methodological Index for Non-Randomized Studies |
| **NICE** | National Institute for Health and Care Excellence |
| **PRISMA** | Preferred Reporting Items for Systematic Reviews and Meta-analyses |

## GLOSSARY

| | |
|---|---|
| **Eschar** | Dead tissue in a wound that extends completely through the skin and into the tissue beneath. |
| **Grounded theory** | A type of research that examines a concept by analyzing patterns in data. |
| **Purposive sampling** | A technique in which researchers rely on their own judgment to choose the members of a study population. |
| **Slough** | A layer of dead tissue that is separating from the surrounding healthy tissue. |

# APPENDICES

## Appendix 1: Literature Search Strategies

### *Clinical Evidence Search*

**Search date:** Dec 7, 2016
**Librarians:** Corinne Holubowich and Melissa Walter
**Databases searched:** Ovid MEDLINE, Embase, CINAHL, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, CRD Health Technology Assessment Database, and NHS Economic Evaluation Database

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <November 2016>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 01, 2016>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2015>, EBM Reviews - Health Technology Assessment <4th Quarter 2016>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2015>, Embase <1980 to 2016 Week 49>, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---
1 exp Skin Ulcer/ (104455)
2 (((skin or decubitus or pressure or bed or chronic or isch?emic or foot or feet) adj2 (ulcer* or sore*)) or bedsore*).ti,ab,kf. (61784)
3 exp Wound Healing/ (259183)
4 exp Skin/in [Injuries] (7889)
5 wound heal*.ti,ab,kf. (115409)
6 or/1-5 (409123)
7 Electric Stimulation Therapy/ (21457)
8 Electric Stimulation/is, mt, pp [Instrumentation, Methods, Physiopathology] (15593)
9 transcutaneous electric nerve stimulation/ (5228)
10 (((electric* or nerve) adj stimulation adj2 (therap* or tran?cutaneous or percutaneous or transdermal or cutaneous or sensory or neuromuscular or neuro muscular or neuromotor or neuro motor)) or TENS or TNS or electro?stimulation or electro?therap* or electroanalgesia or electric* stimulator* or bio?electrical stimulation).ti,ab,kf. (49463)
11 electric* stimulation.ti. (27151)
12 ((high voltage adj2 (galvanic or pulsed or electrical or monophasic or stimulation)) or (pulsed adj (current or electric* stimulation)) or direct current or (low voltage adj2 pulsed) or micro?current or dermapulse or frequency rhythmic electrical modulation system* or electrophysical therap* or electrophysical modalit*).ti,ab,kf. (19052)
13 or/7-12 (118862)
14 6 and 13 (1735)
15 Case Reports/ or Comment.pt. or Editorial.pt. or Letter.pt. or Congresses.pt. (4856663)
16 14 not 15 (1634)
17 exp Animals/ not (exp Animals/ and Humans/) (15820290)
18 16 not 17 (1091)
19 limit 18 to english language [Limit not valid in CDSR,DARE; records were retained] (895)
20 19 use ppez,coch,cctr,dare,clhta,cleed (629)
21 exp skin ulcer/ (104455)
22 (((skin or decubitus or pressure or bed or chronic or isch?emic or foot or feet) adj2 (ulcer* or sore*)) or bedsore*).tw,kw. (62485)

23 exp wound healing/ (259183)
24 skin injury/ (11667)
25 wound heal*.tw,kw. (119748)
26 or/21-25 (412402)
27 electrotherapy/ (21456)
28 exp high frequency electrotherapy/ (5070)
29 low frequency electrotherapy/ (10)
30 nerve stimulation/ (31455)
31 functional electrical stimulation/ (2468)
32 nerve cell stimulation/ (7482)
33 neuromuscular electrical stimulation/ (1307)
34 transcutaneous electrical nerve stimulation/ (5228)
35 electrostimulation/ (78210)
36 (((electric* or nerve) adj stimulation adj2 (therap* or tran?cutaneous or percutaneous or transdermal or cutaneous or sensory or neuromuscular or neuro muscular or neuromotor or neuro motor)) or TENS or TNS or electro?stimulation or electro?therap* or electroanalgesia or electric* stimulator* or bio?electrical stimulation).tw,kw,dv. (51561)
37 electric* stimulation.ti. (27151)
38 ((high voltage adj2 (galvanic or pulsed or electrical or monophasic or stimulation)) or (pulsed adj (current or electric* stimulation)) or direct current or (low voltage adj2 pulsed) or micro?current or dermapulse or frequency rhythmic electrical modulation system* or electrophysical therap* or electrophysical modalit*).tw,kw,dv. (19234)
39 or/27-38 (209982)
40 26 and 39 (2439)
41 Case Report/ or Comment/ or Editorial/ or Letter/ or conference abstract.pt. (9069668)
42 40 not 41 (2077)
43 (exp animal/ or nonhuman/) not exp human/ (10360703)
44 42 not 43 (1586)
45 limit 44 to english language [Limit not valid in CDSR,DARE; records were retained] (1357)
46 45 use emez (715)
47 20 or 46 (1344)
48 47 use ppez (557)
49 47 use emez (715)
50 47 use coch (1)
51 47 use cctr (60)
52 47 use clhta (2)
53 47 use cleed (4)
54 47 use dare (5)
55 remove duplicates from 47 (992)

**CINAHL**

| # | Query | Results |
|---|---|---|
| S1 | (MH "Skin Ulcer+") | 22,613 |
| S2 | (((skin or decubitus or pressure or bed or chronic or isch?emic or foot or feet) N2 (ulcer* or sore*)) or bedsore*) | 17,318 |
| S3 | (MH "Wound Healing+") | 20,986 |
| S4 | (MH "Skin/IN") | 745 |
| S5 | wound heal* | 19,621 |
| S6 | S1 OR S2 OR S3 OR S4 OR S5 | 45,717 |
| S7 | (MH "Electric Stimulation+") | 12,837 |
| S8 | (MH "Electrical Stimulation, Functional") | 600 |
| S9 | (MH "Electrical Stimulation, Neuromuscular") | 586 |
| S10 | (MH "Transcutaneous Electric Nerve Stimulation") | 1,570 |
| S11 | (MH "Electrotherapy+") | 15,664 |
| S12 | (((electric* or nerve) N1 stimulation N2 (therap* or tran?cutaneous or percutaneous or transdermal or cutaneous or sensory or neuromuscular or neuro muscular or neuromotor or neuro motor)) or "TENS" or TNS or electro?stimulation or electro?therap* or electroanalgesia or electric* stimulator* or bio?electrical stimulation) | 3,731 |
| S13 | TI electric* stimulation | 2,947 |
| S14 | ((high voltage N2 (galvanic or pulsed or electrical or monophasic or stimulation)) or (pulsed N1 (current or electric* stimulation)) or direct current or (low voltage N2 pulsed) or micro?current or dermapulse or frequency rhythmic electrical modulation system* or electrophysical therap* or electrophysical modalit*) | 1,293 |
| S15 | S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 | 17,440 |
| S16 | S6 AND S15 | 458 |
| S17 | PT Case Study or Commentary or Editorial or Letter or Proceedings | 387,015 |
| S18 | S16 NOT S17 | 392 |
| S19 | (MH "Animals+") or (MH "Rodents+") | 122,436 |
| S20 | S18 NOT S19 | 361 |
| S21 | S18 NOT S19<br>Limiters - English Language | 352 |

**Grey Literature**

Performed on:
Nov 28 – Dec 7, 2016

Websites searched:
HTA Database Canadian Repository, Alberta Health Technologies Decision Process reviews, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), McGill University Health Centre Health Technology Assessment Unit, National Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Australian Government Medical Services Advisory Committee, Centers for Medicare & Medicaid Services Technology Assessments, Institute for Clinical and Economic Review, Ireland Health Information and Quality Authority Health Technology Assessments, Washington State Health Care Authority Health Technology Reviews, ClinicalTrials.gov

Keywords used: Stimulation, electrical, electric, bioelectrical, electrostimulation, electrotherapy, electrophysical, current, electrotherapie, électrophysique, stimulation électrique, bioélectrique, TNS, TENS

Results: 15

## *Economic Evidence Search*

**Search requested by:** Brian Chan
**Search date:** Dec 8, 2016
**Librarians:** Corinne Holubowich and Melissa Walter
**Databases searched:** Ovid MEDLINE, Embase, CINAHL, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, CRD Health Technology Assessment Database, and NHS Economic Evaluation Database

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <November 2016>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 07, 2016>, EBM Reviews - Database of Abstracts of Reviews of Effects <1st Quarter 2015>, EBM Reviews - Health Technology Assessment <4th Quarter 2016>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2015>, Embase <1980 to 2016 Week 49>, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---
1 exp Skin Injury/ (104455)
2 (((skin or decubitus or pressure or bed or chronic or isch?emic or foot or feet) adj2 (injury* or sore*)) or bedsore*).ti,ab,kf. (61788)
3 exp Wound Healing/ (259183)
4 exp Skin/in [Injuries] (7889)
5 wound heal*.ti,ab,kf. (115412)
6 or/1-5 (409129)
7 Electric Stimulation Therapy/ (21457)

8 Electric Stimulation/is, mt, pp [Instrumentation, Methods, Physiopathology] (15593)
9 transcutaneous electric nerve stimulation/ (5228)
10 (((electric* or nerve) adj stimulation adj2 (therap* or tran?cutaneous or percutaneous or transdermal or cutaneous or sensory or neuromuscular or neuro muscular or neuromotor or neuro motor)) or TENS or TNS or electro?stimulation or electro?therap* or electroanalgesia or electric* stimulator* or bio?electrical stimulation).ti,ab,kf. (49459)
11 electric* stimulation.ti. (27148)
12 ((high voltage adj2 (galvanic or pulsed or electrical or monophasic or stimulation)) or (pulsed adj (current or electric* stimulation)) or direct current or (low voltage adj2 pulsed) or micro?current or dermapulse or frequency rhythmic electrical modulation system* or electrophysical therap* or electrophysical modalit*).ti,ab,kf. (19048)
13 or/7-12 (118851)
14 6 and 13 (1735)
15 economics/ (253679)
16 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (778258)
17 economics.fs. (412260)
18 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw. (744854)
19 exp "costs and cost analysis"/ (543845)
20 cost*.ti. (250366)
21 cost effective*.tw. (270109)
22 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab. (170224)
23 models, economic/ (162684)
24 markov chains/ or monte carlo method/ (70578)
25 (decision adj1 (tree* or analy* or model*)).tw. (36751)
26 (markov or markow or monte carlo).tw. (110585)
27 quality-adjusted life years/ (33223)
28 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw. (56808)
29 ((adjusted adj (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw. (108039)
30 or/15-29 (2410812)
31 14 and 30 (82)
32 31 use ppez,coch,cctr,dare,clhta (33)
33 14 use cleed (4)
34 exp skin injury/ (104455)
35 (((skin or decubitus or pressure or bed or chronic or isch?emic or foot or feet) adj2 (injury* or sore*)) or bedsore*).tw,kw. (62488)
36 exp wound healing/ (259183)
37 skin injury/ (11667)
38 wound heal*.tw,kw. (119754)
39 or/34-38 (412409)
40 electrotherapy/ (21456)
41 exp high frequency electrotherapy/ (5070)
42 low frequency electrotherapy/ (10)
43 nerve stimulation/ (31455)
44 functional electrical stimulation/ (2468)
45 nerve cell stimulation/ (7482)
46 neuromuscular electrical stimulation/ (1307)
47 transcutaneous electrical nerve stimulation/ (5228)

48 electrostimulation/ (78210)
49 (((electric* or nerve) adj stimulation adj2 (therap* or tran?cutaneous or percutaneous or transdermal or cutaneous or sensory or neuromuscular or neuro muscular or neuromotor or neuro motor)) or TENS or TNS or electro?stimulation or electro?therap* or electroanalgesia or electric* stimulator* or bio?electrical stimulation).tw,kw,dv. (51556)
50 electric* stimulation.ti. (27148)
51 ((high voltage adj2 (galvanic or pulsed or electrical or monophasic or stimulation)) or (pulsed adj (current or electric* stimulation)) or direct current or (low voltage adj2 pulsed) or micro?current or dermapulse or frequency rhythmic electrical modulation system* or electrophysical therap* or electrophysical modalit*).tw,kw,dv. (19230)
52 or/40-51 (209970)
53 39 and 52 (2439)
54 Economics/ (253679)
55 Health Economics/ or exp Pharmacoeconomics/ (221730)
56 Economic Aspect/ or exp Economic Evaluation/ (429466)
57 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw. (744854)
58 exp "Cost"/ (543845)
59 cost*.ti. (250366)
60 cost effective*.tw. (270109)
61 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab. (170224)
62 Monte Carlo Method/ (57160)
63 (decision adj1 (tree* or analy* or model*)).tw. (36751)
64 (markov or markow or monte carlo).tw. (110585)
65 Quality-Adjusted Life Years/ (33223)
66 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw. (56808)
67 ((adjusted adj (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw. (108039)
68 or/54-67 (1999316)
69 53 and 68 (130)
70 69 use emez (77)
71 32 or 33 or 70 (114)
72 limit 71 to english language [Limit not valid in CDSR,DARE; records were retained] (107)
73 72 use ppez (27)
74 72 use coch (1)
75 72 use cctr (2)
76 72 use dare (0)
77 72 use clhta (0)
78 72 use cleed (4)
79 72 use emez (73)
80 remove duplicates from 72 (86)

**CINAHL**

| # | Query | Results |
|---|---|---|
| S1 | (MH "Skin Injury+") | 22,616 |
| S2 | (((skin or decubitus or pressure or bed or chronic or isch?emic or foot or feet) N2 (injury* or sore*)) or bedsore*) | 17,327 |

| | | |
|---|---|---|
| S3 | (MH "Wound Healing+") | 20,989 |
| S4 | (MH "Skin/IN") | 745 |
| S5 | wound heal* | 19,632 |
| S6 | S1 OR S2 OR S3 OR S4 OR S5 | 45,735 |
| S7 | (MH "Electric Stimulation+") | 12,842 |
| S8 | (MH "Electrical Stimulation, Functional") | 600 |
| S9 | (MH "Electrical Stimulation, Neuromuscular") | 586 |
| S10 | (MH "Transcutaneous Electric Nerve Stimulation") | 1,570 |
| S11 | (MH "Electrotherapy+") | 15,671 |
| S12 | (((electric* or nerve) N1 stimulation N2 (therap* or tran?cutaneous or percutaneous or transdermal or cutaneous or sensory or neuromuscular or neuro muscular or neuromotor or neuro motor)) or "TENS" or TNS or electro?stimulation or electro?therap* or electroanalgesia or electric* stimulator* or bio?electrical stimulation) | 3,732 |
| S13 | TI electric* stimulation | 2,947 |
| S14 | ((high voltage N2 (galvanic or pulsed or electrical or monophasic or stimulation)) or (pulsed N1 (current or electric* stimulation)) or direct current or (low voltage N2 pulsed) or micro?current or dermapulse or frequency rhythmic electrical modulation system* or electrophysical therap* or electrophysical modalit*) | 1,294 |
| S15 | S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 | 17,444 |
| S16 | S6 AND S15 | 458 |
| S17 | (MH "Economics") | 10,912 |
| S18 | (MH "Economic Aspects of Illness") | 6,529 |
| S19 | (MH "Economic Value of Life") | 514 |
| S20 | MH "Economics, Dental" | 104 |
| S21 | MH "Economics, Pharmaceutical" | 1,752 |
| S22 | MW "ec" | 139,618 |
| S23 | (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*) | 208,660 |
| S24 | (MH "Costs and Cost Analysis+") | 83,318 |
| S25 | TI cost* | 38,884 |
| S26 | (cost effective*) | 26,353 |

| | | |
|---|---|---|
| S27 | AB (cost* N2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)) | 17,316 |
| S28 | (decision N1 (tree* or analy* or model*)) | 4,792 |
| S29 | (markov or markow or monte carlo) | 2,942 |
| S30 | (MH "Quality-Adjusted Life Years") | 2,524 |
| S31 | (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs) | 5,516 |
| S32 | ((adjusted N1 (quality or life)) or (willing* N2 pay) or sensitivity analys?s) | 10,594 |
| S33 | S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 | 277,196 |
| S34 | S16 AND S33 | 25 |
| S35 | S34<br>Limiters - English Language | 25 |

## Appendix 2: Additional Tables and Analysis

**Table A1: Characteristics of Included Studies**

| Author, Year, Country, Study Design | Setting and Eligibility Criteria | N (Participants and Ulcers) | | Therapies | | Outcome, Follow-Up Period |
|---|---|---|---|---|---|---|
| | | Intervention | Control | Intervention | Control | |
| **Spinal Cord Injuries** | | | | | | |
| Griffin et al, 1991,[30] USA, RCT | *Setting*<br>Rehabilitation hospital<br>*Inclusion*<br>Male patients<br>Diagnosed with complete or incomplete SCI<br>Pelvic pressure ulcer (over either sacral/coccygeal or gluteal/ischial regions)<br>Grades II and IV<br>*Exclusion*<br>Severe cardiac disease, cardiac arrythmia, uncontrolled autonomic dysreflexia, or pacemaker use<br>Stratified by ulcer grade and smoking status (factors known to affect rate of healing). If more than one ulcer, largest WSA was selected | N = 8<br>No. of ulcers = 8 | N = 9<br>No. of ulcers = 9 | Device: Intelect 500 HVPC stimulator<br>Waveform: pulsed current produces a twin peaked pulse with around 75-µs spacing between pulses<br>Frequency: was set at 100 pps, with a continuous mode. Intensity was slowly increased to 200 V<br>Duration: ES 60 min daily for 20 consecutive d (20 h total) | Sham ES. Ulcers were cleansed twice daily, followed by application of gel and dry dressing. Wounds were mechanically debrided as necessary. All ulcers were cultured before treatment began. All possible efforts were made to keep pressure off ulcers. Routine 2-h turning schedule was followed when patients were in bed. Nutritional status of patients was evaluated and regular diet planned | WSA on Days 5, 10, 15, and 20 calculated as percentage of change (%) from baseline WSA<br>20 d |

| Author, Year, Country, Study Design | Setting and Eligibility Criteria | N (Participants and Ulcers) | | Therapies | | Outcome, Follow-Up Period |
|---|---|---|---|---|---|---|
| | | Intervention | Control | Intervention | Control | |
| Stefanovska et al, 1993,[36] Slovenia, NRCT | *Setting*<br>Rehabilitation hospital<br>*Eligibility*<br>NR | AC group (N = 42)<br>No. of ulcers = 42<br>DC group (N = 12)<br>No. of ulcers = 12 | N = 34<br>No. of ulcers = 34 | *Group 1*<br>Waveform: DC<br>Amplitude: 600 µA<br>Duration: 120 min daily<br>*Group 2*<br>Waveform: Pulsed current<br>Frequency: Pulse duration of 0.25 ms and repetition rate of 40 Hz. 4-s stimulation trains were rhythmically alternated with pauses of same duration (low frequency)<br>Amplitude: 15–25 mA<br>Duration: 120 min, once daily (56 h total) | No details on standard treatment<br>Authors stated participants received standard treatment for 1 mo | Relative healing rate using exponential trajectory<br>4 wk |
| Jercinovic et al, 1994,[33] Slovenia, RCT (crossover) | *Setting*<br>Inpatient<br>*Inclusion*<br>Spinal cord injury<br>*Exclusion*<br>Diagnosis of diabetes<br>Vascular disease<br>Cancer<br>(No time frame stated for eligibility) | N = 42<br>No. of ulcers = 61 | N = 31<br>No. of ulcers = 48 | Waveform: Pulsed current<br>Biphasic, asymmetric, charge-balanced pulses<br>Frequency: 40 pps and pulse duration of 250 µs<br>Amplitude: up to 35 mA<br>Duration: ES 120 min, once daily, 5 times/wk (40 h total) | Standard treatment included initial selective debridement, application of new standard dressing to ulcer two or more times daily, as needed, and broad-spectrum antibiotic in cases of infection. SCI patients were lying on dry-flotation mattresses and were turned to new position every 4 h during night | Rate of healing using linear and exponential trajectory<br>4 wk |

| Author, Year, Country, Study Design | Setting and Eligibility Criteria | N (Participants and Ulcers) | | Therapies | | Outcome, Follow-Up Period |
|---|---|---|---|---|---|---|
| | | Intervention | Control | Intervention | Control | |
| Karba et al, 1997,[35] Slovenia, NRCT | *Setting*<br>Inpatient<br>*Inclusion*<br>Initial ulcer area of ≥ 500 $mm^2$<br>Stages III or IV<br>*Exclusion*<br>Previous plastic surgery at same location<br>Additional illnesses, such as diabetes or cancer | DC + (N = 16)<br>No. of ulcers = 16<br>DC +/− (N = 18)<br>No. of ulcers = 18 | N = 16<br>No. of ulcers = 16 | Device: Encore TM Plus<br>Waveform: DC<br>Amplitude: 0.6 mA<br>Duration: ES for 120 min daily<br>*Group 1*<br>Electrode placement: DC + positive stimulation electrode overlaid ulcer, other 4 were on periulcer (representing ring-shaped negative electrode)<br>*Group 2*<br>Electrode placement: DC +/− 2 electrodes were positioned on periulcer (one positive and one negative) | Sham ES. Standard treatment (daily cleaning and dry gauze dressing exchanges) | Relative healing rate using exponential trajectory<br>Follow-up NR |
| Ahmad, 2008,[27] Egypt, RCT | *Setting*<br>Inpatient (from 4 investigation sites)<br>*Inclusion*<br>Grade II pressure injuries | N = 15 in all groups (45 min, 60 min, 120 min)<br>No. of ulcers = 15 in each group | N = 15<br>No. of ulcers = 15 | Waveform: Pulsed current Twin monophasic pulses at interphase interval of 50 µs<br>Frequency: 120 Hz<br>Voltage: 100–175 V<br>Duration: 3 treatment groups receiving treatment for 45, 60, and 120 min daily, 7 d/wk | Sham ES. Standard treatment (wet dressing and whirlpool therapy 4–5 times/wk). All wounds were debrided before admission | WSA at Weeks 3 and 5<br>5 wk |
| Houghton et al, 2010,[31] Canada, RCT | *Setting*<br>Community care<br>*Inclusion*<br>Adults with SCI<br>Stages II–IV<br>Living in community<br>Older than 18 years of age<br>Ulcers 1–20 $cm^2$<br>Ulcer present for at least 3 mo | N = 16<br>No. of ulcers = 16 | N = 18<br>No. of ulcers = 18 | Device: Micro-Z<br>Waveform: Pulsed current Monophasic pulse duration of 50 µs<br>Voltage: 50–150 V<br>Frequency: 20 min at pulse frequency of 100 Hz followed by 20 min at 10 Hz and then 20 min off cycle each h<br>Duration: 8 h daily, 7 d/wk (treatments were done typically at night) (672 h total) | Standard treatment consisted of evaluation by multi-disciplinary team, assessment of nutritional issues, appropriateness of wound dressing protocol assessed for moisture control, bacterial burden, and debridement. Also comprehensive pressure management program | WSA reduction measured as percentage change at end of 3 mo<br>3 mo (full follow-up at 6 mo) |

| Author, Year, Country, Study Design | Setting and Eligibility Criteria | N (Participants and Ulcers) | | Therapies | | Outcome, Follow-Up Period |
|---|---|---|---|---|---|---|
| | | Intervention | Control | Intervention | Control | |
| **Older Adults** | | | | | | |
| Gentzkow and Miller, 1991,[29] USA, RCT (Crossover) | *Setting*<br>Inpatient (at 9 sites)<br>*Inclusion*<br>PUs that were open and Stages II–IV<br>*Exclusion*<br>PUs totally occluded by eschar<br>Bleeding major blood vessel involvement<br>Located in presternal, periorbital, or laryngeal/pharyngeal regions<br>Pregnancy<br>Cardiac pacemaker<br>Osteomyelitis or peripheral vascular problems predisposing patients to thrombosis<br>Cancer<br>Long-term steroid therapy, chemotherapy, radiation therapy<br>Obese | N = NR<br>No. of ulcers = 21 | N = NR<br>No. of ulcers = 19 | Device: Dermapulse<br>Waveform: pulsed current<br>Amplitude: 35 mA<br>Frequency: 128 pps<br>Duration: ES 30 min, twice daily (28 h total). | Sham ES. Standard treatment was prescribed by physicians according to needs of individual patients and was recorded. In all patients, wounds were kept hydrated with saline-moistened gauze between treatments | WSA reduction expressed as percentage change over study period<br>4 wk |
| Wood et al, 1993,[34] Germany, RCT | *Setting*<br>Inpatient (at 4 sites)<br>*Inclusion*<br>Stages II–III<br>Despite nursing care, ulcer had not healed in 5 wk | N = 41<br>No. of ulcers = 43 | N = 30<br>No. of ulcers = 31 | Device: MEMS CS 600<br>Waveform: DC<br>Frequency: 0.8 Hz<br>Amplitude: 300–600 µA<br>Duration: ES 3 d/wk with no information on how long treatment was | Sham ES. Wound cleansing, simple moist dressings, and whirlpool baths | Complete wound closure<br>8 wk |

| Author, Year, Country, Study Design | Setting and Eligibility Criteria | N (Participants and Ulcers) | | Therapies | | Outcome, Follow-Up Period |
|---|---|---|---|---|---|---|
| | | Intervention | Control | Intervention | Control | |
| Adunsky and Ohry, 2005,[26] Israel, RCT [a] | *Setting*<br>Post-acute (rehabilitation hospital)<br>*Inclusion*<br>Age > 18 y<br>Stage III<br>Informed consent<br>Ulcer duration less than 24 mo<br>Size > 1 $cm^2$ but < 50 $cm^2$<br>*Exclusion*<br>No recent history (minimum 30 d) of growth factors or vacuum-assisted treatment<br>Stages other than III<br>Liver function enzymes higher than twice upper limit of normal values<br>Renal failure with creatinine > 2 mg%, anemia (hemoglobin < 10 g%), albumin < 2.6 g%<br>Pacemaker<br>Serious medical disorder that might affect treatment results<br>Recent (within 2 mo) use of steroids, chemotherapy, or other immuno-compromising drugs | N = 35<br>No. of ulcers = 35 | N = 28<br>No. of ulcers = 28 | Waveform: DC (Microcurrent)<br>No other ES parameters provided<br>Duration: ES for 20 min, thrice daily, 7 d/wk reduced to 2 daily sessions after 14 d (42 h total) | Sham ES. Standard treatment of wounds included surgical debridement, if deemed necessary, followed by application of hydrocolloid or collagen dressings | • Complete healing (closure of ulcer)<br>• Speed of wound closure<br>• WSA reduction<br>• Speed of healing (rate of wound area reduction reflected by change from baseline of ulcer area, percentage<br>8 wk (full follow-up 12 wk) |

| Author, Year, Country, Study Design | Setting and Eligibility Criteria | N (Participants and Ulcers) | | Therapies | | Outcome, Follow-Up Period |
|---|---|---|---|---|---|---|
| | | Intervention | Control | Intervention | Control | |
| Franek et al, 2012,[28] Poland, RCT | *Setting*<br>Inpatient<br>*Inclusion*<br>Patients with lower-extremity PU<br>*Exclusion*<br>ABPI < 0.9<br>Diabetes mellitus<br>Sclerosis<br>Cancer<br>Pareses and paralysis caused by injuries to central or peripheral nervous system<br>PU required surgical intervention | N = 26<br>No. of ulcers = 26 | N = 24<br>No. of ulcers = 24 | Device: Ionoson<br>Voltage: 100 V<br>Waveform: pulsed current. Twin monophasic pulses lasting 100 µs in total<br>Frequency: 100 Hz<br>Duration: ES 50 min once daily, 5 times/wk (25.2 h total) | Standard treatment, including cleansing with potassium permanganate followed by covering ulcer base with dressing. Dressings were tailored to meet needs of each subject and to promote moist interactive healing. If wound infection was suspected, it was appropriately treated. Sharp debridement was performed for relatively few participants | Relative and percent change (%) in WSA, volume, longest length and width, and granulation tissue area were calculated<br>Gilman method was used to calculate wound size based on its surface area and length of perimeter<br>6 wk |

| Author, Year, Country, Study Design | Setting and Eligibility Criteria | N (Participants and Ulcers) | | Therapies | | Outcome, Follow-Up Period |
|---|---|---|---|---|---|---|
| | | Intervention | Control | Intervention | Control | |
| Polak et al, 2016,[32] Poland, RCT | *Setting*<br>Nursing and care centre<br>*Inclusion*<br>PUs that did not respond to previous treatment for ≥ 4 wk<br>Older than 60 y<br>PU 1.0–50 $cm^2$<br>Duration 1–12 months<br>Stages II and III located on pelvic girdle<br>*Exclusion*<br>Cancer<br>Electronic implants<br>Malignant, tunneling, and necrotic wounds<br>Osteomyelitis<br>PU requiring surgical intervention<br>Metal implants in PU area<br>Diabetes<br>Venous insufficiency<br>Critical infection<br>Alcoholism<br>Allergy to standard wound care | N = 25<br>No. of ulcers = 25 | N = 24<br>No. of ulcers = 24 | Device: Intelect Advanced Combo unit<br>Waveform: pulsed current. Twin monophasic pulse (154 µs) consisting of two 77-µs exponential pulses<br>Frequency: 100 pps<br>Amplitude: usually 0.24 A<br>Voltage: 100 V; charge was 250 µC/s<br>Duration: ES 50 min, once daily, 5 times/wk (25.2 h total) | Sham ES. Standard treatment consisted of evaluation by a multi-disciplinary team, all patients received pressure redistribution surface, devices and pillows as needed, nutritional assessment, debridement, infection and inflammation control, maintaining moisture balance, and monitoring of wound edges and of epithelization | Percentage reduction in WSA in relation to baseline, Week 4, and Week 6<br>4 wk (full follow-up 6 wk) |

Abbreviations: ABPI, ankle-brachial pressure index; AC, alternate current; DC, direct current; ES, electrical stimulation; HVPC, high-voltage pulsed current; µC, microcoulombs; NR, not reported; NRCT, non–randomized controlled trial; pps, pulses per second; PU, pressure ulcer; RCT, randomized controlled trial; SCI, spinal cord injury; WSA, wound surface area,

[a]Included 54 older adults and 9 SCI patients.

## Appendix 3: Clinical Evidence Quality Assessment

**Table A2: Risk of Bias[a] Among Randomized Controlled Trials (Cochrane Risk of Bias Tool)**

| Author, Year | Random Sequence Generation | Allocation Concealment | Blinding of Participants and Personnel | Incomplete Outcome Data | Selective Reporting | Other Bias |
|---|---|---|---|---|---|---|
| Gentzkow and Miller, 1991[29] | Unclear[b] | Unclear[c] | Low | Low | Unclear[d] | Low |
| Griffin et al, 1991[30] | Unclear[b] | Unclear[c] | Low | Low | Unclear[d] | Low |
| Wood et al, 1993[34] | Unclear[b] | Unclear[c] | Unclear[e] | Low | Unclear[d] | High[f] |
| Jercinovic et al, 1994[33] | Unclear[b] | Unclear[c] | Low | Low | Unclear[d] | High[g] |
| Adunsky and Ohry, 2005[26] | Low | Unclear[c] | Low | High[h] | Low | Low |
| Ahmad, 2008[27] | Unclear[b] | Unclear[c] | Unclear[e] | Low | Unclear[d] | Low |
| Houghton et al, 2010[31] | Low | Low | Low | Low | Low | Low |
| Franek et al, 2012[28] | Unclear[b] | Low | Low | Low | Unclear[d] | Low |
| Polak et al, 2016[32] | Low | Low | Low | Low | Low | Low |

[a]Possible risk of bias levels: low, high, and unclear.
[b]Authors state only that patients who met selection criteria were randomly assigned to treatment or control group (no information on how randomization was done).
[c]Authors do not give details on allocation concealment.
[d]No protocol described, but authors clearly state outcomes of interest and how they will be analyzed.
[e]Authors do not give any information on blinding participants, investigators, or outcome assessors to outcome.
[f]Lack of details on intervention, control treatment, outcomes, and important patient characteristics.
[g]Lack of details on patient characteristics.
[h]Loss of treatment group patients to the “per protocol” group was almost 50% and of the control group was 37%.

**Table A3: Risk of Bias[a] Among Non–Randomized Controlled Trials**

| Study Design | Stefanovska et al[36] | Karba et al[35] |
|---|---|---|
| Clearly stated aim | 2 | 2 |
| Inclusion of consecutive patients | 0 | 2 |
| Prospective collection of data | 0 | 0 |
| End points appropriate to aim of study | 1 [b] | 1 [b] |
| Unbiased assessment of study end point | 0 | 2 |
| Follow-up period appropriate | 0 | 0 |
| Loss to follow-up | 0 | 0 |
| Prospective calculation of study size | 0 | 0 |
| Adequate control group | 1[c] | 1[d] |
| Contemporary groups | 2 | 2 |
| Baseline equivalence of groups | 1[e] | 2 |
| Adequate statistical analyses | 2 | 2 |

[a]Risk of bias assessed using Methodological Index for Non-Randomized Studies (MINORS) [24] Scored as 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate).
[b]No intention to treat.
[c]No details on standard wound care; authors state only that participants had conventional treatment.
[d]Some details provided on standard wound care, but involved only daily cleaning and dressing changes.
[e]Baseline characteristics unequal across groups.

## Appendix 4: Results of Applicability and Quality Checklist for Studies Included in Economic Literature Review

**Table A4: Results of Applicability Checklist for Literature Examining Cost-Effectiveness of Electrical Stimulation for Pressure Injuries**

| Objective: To assess cost-effectiveness of electrical stimulation for pressure injuries | |
|---|---|
| **Checklist Questions** | **Mittmann et al, 2011[76]** |
| Is the study population similar to that specified in the question? | Partially (patients with spinal cord injuries in home care only) |
| Are the interventions similar to those specified in the question? | Yes |
| Is the health care system in which the study was conducted sufficiently similar to the current Ontario context? | Yes |
| Was/were the perspective(s) clearly stated (and what were they)? | Yes (Canadian public health payer) |
| Are estimates of relative treatment effect from the best available source? | Yes |
| Are all future costs and outcomes discounted? (If yes, at what rate?) | Not applicable |
| Is the value of health effects expressed in terms of quality-adjusted life-years? | No |
| Are costs and outcomes from other sectors fully and appropriately measured and valued? | No |
| Overall judgment (directly applicable/partially applicable/ not applicable) | Partially applicable |

**Table A5: Results of Quality Checklist for Literature Examining Cost-Effectiveness of Electrical Stimulation for Pressure Injuries**

| Objective: To assess cost-effectiveness of electrical stimulation for pressure injuries | |
|---|---|
| **Checklist Questions** | **Mittmann et al, 2011**[76] |
| Does the model structure adequately reflect the nature of the health condition's underevaluation? | Yes |
| Is the time horizon sufficiently long to reflect all important differences in costs and outcomes? (e.g., if the rate of mortality differs between interventions, does the model take a lifetime horizon?) | No (1 y). However, not enough clinical data to support longer time line |
| Are all important and relevant health outcomes included? | Yes |
| Are the estimates of relative treatment effects obtained from the best available sources? | No (based on a single study) |
| Do the estimates of relative treatment effect match the estimates contained in the clinical report? | Yes |
| Are all important and relevant (direct) costs included in the analysis? | Yes |
| Are the estimates of resource use obtained from the best available sources? | Yes |
| Are the unit costs of resources obtained from the best available resources? | Yes |
| Is an appropriate incremental analysis presented, or can it be calculated from the reported data? | Yes (no ICER) |
| Are all important and uncertain parameters subjected to appropriate sensitivity analysis? | Unclear |
| Is there a potential conflict of interest? | No |
| Overall assessment (minor limitations/ potentially serious limitations/ very serious limitations) | Potentially serious limitations |

Abbreviation: ICER, incremental cost-effectiveness ratio.

## Appendix 5: Budget Impact Analysis

**Table A6: Acute Care Discharge Locations for Patients Diagnosed with Pressure Injuries in Ontario**

| Discharge Location | Proportion of Patients |
|---|---|
| **Base Case** | |
| Complex continuing care | 0.11 |
| Home care | 0.31 |
| Inpatient rehabilitation | 0.9 |
| Long-term care | 0.16 |
| Other | 0.32 |
| **"Other" Redistributed** | |
| Complex continuing care | 0.16 |
| Home care | 0.46 |
| Inpatient rehabilitation | 0.14 |
| Long-term care | 0.24 |

*Source: Data provided by IntelliHEALTH ONTARIO.*[48]

**Table A7: Proportion of Pressure Injuries in Each Stage**

| Stage | Prevalence[a] (%) |
|---|---|
| I | 40.00 |
| II | 43.53 |
| III | 8.24 |
| IV | 8.24 |

[a]Prevalence adjusted to exclude eschar injuries and wounds that could not be staged.
*Source: Data from VanGilder et al.*[51]

**Table A8: Pressure Injuries Treated with Electrical Stimulation in Various Uptake, Acute Care Discharge, and Eligibility Scenarios (2017–2021)**

| | No. of Pressure Injuries/Y | | | | |
|---|---|---|---|---|---|
| **Scenario** | **2017** | **2018** | **2019** | **2020** | **2021** |
| **Uptake Scenarios** | | | | | |
| 5% uptake/y | 391 | 782 | 1,173 | 1,563 | 1,954 |
| 25% uptake/y | 1,954 | 3,909 | 5,863 | 7,817 | 7,817 |
| **Acute Care Discharge Scenarios[a]** | | | | | |
| All acute care patients receive electrical stimulation | 1,506 | 2,113 | 3,169 | 4,225 | 5,281 |
| No acute care patients receive electrical stimulation | 191 | 383 | 574 | 765 | 957 |
| **Eligibility Scenarios[a]** | | | | | |
| Base case,[b] 50% of Stage IV are unhealable | 586 | 1,173 | 1,759 | 2,345 | 2,932 |
| Stages III and IV pressure injuries that are unhealed for 3 months[c] | 566 | 1,131 | 1,697 | 2,263 | 2,828 |
| Stages II–IV pressure injuries that are unhealed for 30 days[d] | 2,083 | 4,167 | 6,250 | 8,333 | 10,417 |
| 20% of all pressure injuries | 949 | 1,899 | 2,848 | 3,797 | 4,746 |
| 80% of all pressure injuries | 3,797 | 7,594 | 11,391 | 15,188 | 18,985 |

[a]With 10% annual uptake of electrical stimulation.
[b]Stages III and IV pressure injuries, unhealed for 30 days.
[c]16.48% of pressure injuries are Stages III or IV (Table A7, Appendix 5); 68% of Stage III pressure injuries do not heal after 3 months[52]; 77% of Stage IV pressure injuries do not heal after 3 months.[52]
[d]60.01% of pressure injuries are Stages II to IV (Table A7, Appendix 5); 63% of Stage II pressure injuries do not heal after 30 days.[52]

**Table A9: Sensitivity Analysis Results, Total Budget Impact of Electrical Stimulation in Ontario (2017–2021)**

| | Year (Uptake Rate), $ Million | | | | |
|---|---|---|---|---|---|
| **Scenario** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| Inpatient rehabilitation incidence (1.4%) | 0.75 | 1.50 | 2.25 | 3.00 | 3.74 |
| Use Micro-Z (patient device) exclusively | 0.76 | 1.52 | 2.29 | 3.05 | 3.81 |
| Use GV 350 as clinical device | 0.76 | 1.52 | 2.28 | 3.05 | 3.81 |
| Wires replaced for each patient | 0.80 | 1.60 | 2.40 | 3.21 | 4.01 |
| 1 patient treated annually with patient device | 0.78 | 1.56 | 2.33 | 3.11 | 3.89 |
| 4 patients treated annually with patient device | 0.77 | 1.53 | 2.30 | 3.07 | 3.84 |
| Patient training (0.5 h) | 0.77 | 1.53 | 2.30 | 3.07 | 3.84 |
| Patient training (2 h) | 0.78 | 1.55 | 2.33 | 3.12 | 3.89 |
| Treatment hours (20 h) | 0.29 | 0.58 | 0.87 | 1.16 | 1.45 |
| Treatment hours (114 h) | 1.16 | 2.32 | 3.48 | 4.64 | 5.80 |
| Professional training (0 h) | 0.77 | 1.53 | 2.30 | 3.07 | 3.84 |
| Professional training (8 h) | 0.79 | 1.59 | 2.38 | 3.18 | 3.97 |
| Health care professional: all registered nurses | 7.56 | 1.51 | 2.27 | 3.02 | 3.78 |
| Health care professional: all registered practical nurses | 0.63 | 1.27 | 1.90 | 2.54 | 3.17 |
| No patient or caregiver administration in home care | 1.15 | 2.30 | 3.45 | 4.60 | 5.75 |
| All patient or caregiver administration in home care | 0.39 | 0.78 | 1.18 | 1.57 | 1.96 |
| All patient or caregiver administration | 0.14 | 0.28 | 0.42 | 0.56 | 0.70 |
| Health care professionals' time per session maximum (60 min): all settings | 1.62 | 3.24 | 4.85 | 6.47 | 8.09 |

**Table A10: Total Budget Impact of Electrical Stimulation in Ontario for Total Treatment Time Scenarios (2017–2021)**

| | Year (Uptake Rate), $ Million | | | | |
|---|---|---|---|---|---|
| **Health Care Setting** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| **Total Treatment Time = 20 h** | | | | | |
| Complex continuing care | 0.03 | 0.07 | 0.10 | 0.14 | 0.17 |
| Home care | 0.16 | 0.33 | 0.49 | 0.66 | 0.82 |
| Inpatient rehabilitation | 0.03 | 0.06 | 0.10 | 0.13 | 0.16 |
| Long-term care | 0.06 | 0.12 | 0.18 | 0.23 | 0.29 |
| **Total** | **0.29** | **0.58** | **0.87** | **1.16** | **1.45** |
| **Total Treatment Time = 116 h** | | | | | |
| Complex continuing care | 0.09 | 0.19 | 0.28 | 0.37 | 0.46 |
| Home care | 0.82 | 1.65 | 2.47 | 3.30 | 4.12 |
| Inpatient rehabilitation | 0.09 | 0.17 | 0.26 | 0.34 | 0.43 |
| Long-term care | 0.16 | 0.31 | 0.47 | 0.63 | 0.78 |
| **Total** | **1.16** | **2.32** | **3.48** | **4.64** | **5.80** |

**Table A11: Total Budget Impact of Electrical Stimulation in Ontario for Patient or Caregiver Administration Scenarios (2017–2021)**

| | Year (Uptake Rate), $ Million | | | | |
|---|---|---|---|---|---|
| **Health Care Setting** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| **All Patient or Caregiver Administration** | | | | | |
| Complex continuing care | 0.02 | 0.05 | 0.07 | 0.09 | 0.11 |
| Home care | 0.06 | 0.11 | 0.17 | 0.23 | 0.28 |
| Inpatient rehabilitation | 0.02 | 0.42 | 0.06 | 0.08 | 0.11 |
| Long-term care | 0.04 | 0.78 | 0.12 | 0.16 | 0.20 |
| **Total** | **0.14** | **0.28** | **0.42** | **0.56** | **0.70** |
| **No Patient or Caregiver Administration** | | | | | |
| Complex continuing care | 0.09 | 0.19 | 0.28 | 0.37 | 0.46 |
| Home care | 0.81 | 1.63 | 2.44 | 3.26 | 4.07 |
| Inpatient rehabilitation | 0.09 | 0.17 | 0.26 | 0.34 | 0.43 |
| Long-term care | 0.16 | 0.31 | 0.47 | 0.63 | 0.78 |
| **Total** | **1.15** | **2.30** | **3.45** | **4.60** | **5.75** |

**Table A12: Budget Impact of Electrical Stimulation in Ontario for Health Care Professionals' Time Required per Session (2017–2021)**

| | Year (Uptake Rate), $ Million | | | | |
|---|---|---|---|---|---|
| **Health Care Setting** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| **Health Care Professionals' Time per Session = Maximum (60 minutes)** | | | | | |
| Complex continuing care | 0.33 | 0.66 | 0.98 | 1.31 | 1.64 |
| Home care | 0.44 | 0.87 | 1.31 | 1.74 | 2.18 |
| Inpatient rehabilitation | 0.30 | 0.61 | 0.91 | 1.21 | 1.52 |
| Long-term care | 0.55 | 1.10 | 1.65 | 2.20 | 2.76 |
| **Total** | **1.62** | **3.24** | **4.85** | **6.47** | **8.09** |

**Table A13: Budget Impact of Electrical Stimulation in Ontario Given Potential Cost Savings (2017–2021)**

| | Year (Uptake Rate), $ Million | | | | |
|---|---|---|---|---|---|
| **Cost of Electrical Stimulation** | **2017 (10%)** | **2018 (20%)** | **2019 (30%)** | **2020 (40%)** | **2021 (50%)** |
| Total cost | 0.77 | 1.54 | 2.31 | 3.08 | 3.85 |
| Potential cost savings | 0.18 | 0.35 | 0.53 | 0.70 | 0.88 |
| **Budget impact** | **0.59** | **1.19** | **1.78** | **2.38** | **2.97** |

## Appendix 6: Letter of Information

LETTER OF INFORMATION

### SUMMARY:

Health Quality Ontario (HQO) is conducting a formal assessment of **Electrical Stimulation for Pressure Ulcers** to better understand how this treatment option should be funded by the healthcare system. An important part of this assessment involves speaking to patients and families of those who suffer (or may have suffered) from pressure ulcers and may have used electrical stimulation for treatment. Our goal is to ensure that recommendations about funding are informed by the lived-experience of patients and families who have been or are currently being treated with Electrical Stimulation for Pressure Ulcers.

### WHAT DO YOU NEED FROM ME?

- ✓ Willingness to share your story
- ✓ 20-40 minutes of your time for a phone or in-person interview
- ✓ Permission to audio- (not video-) record the interview

### WHY DO YOU NEED THIS INFORMATION?

Health Quality Ontario (HQO) is conducting a Health Technology Assessment of the effectiveness and safety of electrical stimulation for treatment of pressure ulcers in addition to standard wound care. As part of HQO's core function to promote health care supported by the best evidence available, established scientific methods are used to analyze the evidence for a wide range of health interventions, including diagnostic tests, medical devices, interventional and surgical procedures, health care programs and models of care. These analyses may be informed and complemented by input from a range of individuals, including patients and clinical experts, and serve as the basis recommendations about whether health care interventions should be publicly funded or not.

The perspective that you share will be useful to help provide context to the day-to-day realities of patients with healable wounds and the decisions they face in terms of therapies. The ultimate goal of the project is to provide recommendations to the Ontario Health Technology Assessment Committee who advises the Ontario Ministry of Health and Long-term Care on the appropriateness of funding.

### WHAT YOUR PARTICIPATION INVOLVES

If you agree to participate, you will be asked to participate in an interview conducted by HQO staff. The interview will likely last 20-40 minutes. The session will be conducted in a private location and will be audio-taped. The interviewer will ask you questions about your lived experience with pressure ulcers and your perspectives on electrical stimulation treatment in Ontario.

Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before your interview. Withdrawal will in no way affect care you receive.

## CONFIDENTIALITY

All information collected for the review will be kept confidential and privacy will be protected except as required by law. The results of this review will be published, however no identifying information will be released or published. Any records containing information from your interview will be stored securely.

## RISKS TO PARTICIPATION:

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their lived experience.

## HEALTH QUALITY ONTARIO STAFF:

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## Appendix 7: Interview Guide

**Introduction**

History of pressure injuries and other co-existing conditions.

**Lived Experience**

What is the day-to-day routine, quality of life?

What is the impact on families and caregivers?

**Therapies**

What therapies have been used to treat the injury?

Which therapies worked and which did not work?

Was accessibility to therapy(ies) an issue for you? Was cost or caregiver support an issue?

If applicable, what is the impact of the current standard wound care versus standard wound care plus electrical stimulation?

What are the expectations for standard care versus combined care?

Are there any side effects or risks with the therapies that you have experienced?

## REFERENCES


(1) National Pressure Ulcer Advisory Panel [Internet]. Washington, DC: The Panel; 2016. Press release, National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury. Available from: http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/

(2) National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. Pressure ulcer prevention and treatment: clinical practice guideline [Internet]. Washington, DC: The Panel; 2009. Available from: www.npuap.org

(3) Gorecki C, Brown JM, Nelson EA, Briggs M, Schoonhoven L, Dealey C, et al. Impact of pressure ulcers on quality of life in older patients: a systematic review. J Am Geriatr Soc. 2009;57(7):1175-83.

(4) Brem H, Maggi J, Nierman D, Rolnitzky L, Bell D, Rennert R, et al. High cost of stage IV pressure ulcers. Am J Surg. 2010;200(4):473-7.

(5) Perneger TV, Rae AC, Gaspoz JM, Borst F, Vitek O, Heliot C. Screening for pressure ulcer risk in an acute care hospital: development of a brief bedside scale. J Clin Epidemiol. 2002;55(5):498-504.

(6) Rintala DH, Garber SL, Friedman JD, Holmes SA. Preventing recurrent pressure ulcers in veterans with spinal cord injury: impact of a structured education and follow-up intervention. Arch Phys Med Rehabil. 2008;89(8):1429-41.

(7) Schoonhoven L, Grobbee DE, Donders AR, Algra A, Grypdonck MH, Bousema MT, et al. Prediction of pressure ulcer development in hospitalized patients: a tool for risk assessment. Qual Saf Health Care. 2006;15(1):65-70.

(8) Kaltenthaler E, Whitfield MD, Walters SJ, Akehurst RL, Paisley S. UK, USA and Canada: how do their pressure ulcer prevalence and incidence data compare? J Wound Care. 2001;10(1):530-5.

(9) Zakrasek EC, Creasey G, Crew JD. Pressure ulcers in people with spinal cord injury in developing nations. Spinal Cord. 2015;53(1):7-13.

(10) Woo KY, Sears K, Almost J, Wilson R, Whitehead M, VanDenKerkhof EG. Exploration of pressure ulcer and related skin problems across the spectrum of health care settings in Ontario using administrative data. Int Wound J. 2017;14(1):24-30.

(11) Registered Nurses' Association of Ontario. Assessment and management of Stage I to IV pressure ulcers (revised) [Internet]. Toronto (ON): The Association; 2007.

(12) Allen J, Houghton PE. A case study for electrical stimulation on a Stage III pressure ulcer. Wound Care Canada. 2000;2(1):34-6.

(13) Kloth LC. Electrical Stimulation Technologies for Wound Healing. Adv Wound Care (New Rochelle). 2014;3(2):81-90.

(14) Registered Nurses' Association of Ontario. Assessment and management of pressure injuries for the interprofessional team [Internet]. Toronto (ON): The Association; 2016 [cited 2017 Feb]. Available from: http://rnao.ca/sites/rnao-ca/files/Pressure_Injuries_BPG.pdf

(15) Australian Wound Management Association. Pan Pacific Clinical Practice guideline for the prevention and management of pressure injury [Internet]. Osborne Park (WA): Cambridge Media; 2012 [cited 2017 Jun 12]. Available from: http://www.woundsaustralia.com.au/publications/2012_AWMA_Pan_Pacific_Guidelines.pdf

(16) National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and treatment of pressure ulcers [Internet]. Osborne Park (WA): Cambridge Media; 2014. Available from: www.npuap.org

(17) Perry D, Borchert K, Burke S, Chick K, Johnson K, Kraft W, et al. Pressure ulcer prevention and treatment protocol. Bloomington (MN): Institute for Clinical Systems Improvement; 2012.
(18) National Institute for Health and Care Excellence. Pressure ulcers: prevention and management. London, UK: The Institute; 2014.
(19) Health Quality Ontario. Quality standards. Pressure injuries: care for patients in all settings [Internet]. Toronto (ON): Queen's Printer for Ontario. In Press.
(20) McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS peer review of electronic search strategies: 2015 guideline statement. J Clin Epidemiol. 2016;75:40-6.
(21) The Cochrane Collaboration. Cochrane Nordic [Internet]. Copenhagen (Denmark): The Nordic Cochrane Centre; 2014 [cited 2017 October 30]. Available from: http://nordic.cochrane.org/
(22) Guyatt GH, Oxman AD, Schunemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the Journal of Clinical Epidemiology. J Clin Epidemiol. 2011;64(4):380-2.
(23) Higgins JP, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011;343:d5928.
(24) Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological Index for Non-Randomized Studies (MINORS): development and validation of a new instrument. ANZ J Surg. 2003;73(9):712-6.
(25) Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred Reporting Items for Systematic reviews and Meta-Analyses: the PRISMA statement. PLoS Med. 2009;6(7):e1000097.
(26) Adunsky A, Ohry A. Decubitus direct current treatment (DDCT) of pressure ulcers: results of a randomized double-blinded placebo controlled study. Arch Gerontol Geriatr. 2005;41(3):261-9.
(27) Ahmad ET. High-voltage pulsed galvanic stimulation: effect of treatment duration on healing of chronic pressure ulcers. Ann Burns Fire Disasters. 2008;21(3):124-8.
(28) Franek A, Kostur R, Polak A, Taradaj J, Szlachta Z, Blaszczak E, et al. Using high-voltage electrical stimulation in the treatment of recalcitrant pressure ulcers: Results of a randomized, controlled clinical study. Ostomy Wound Manage. 2012;58(3):30-44.
(29) Gentzkow GD, Miller KH. Electrical stimulation for dermal wound healing. Clin Podiatr Med Surg. 1991;8(4):827-41.
(30) Griffin JW, Tooms RE, Mendius RA, Clifft JK, Vander Zwaag R, El-Zeky F, et al. Efficacy of high voltage pulsed current for healing of pressure ulcers in patients with spinal cord injury. Phys Ther. 1991;71(6):433-44.
(31) Houghton PE, Campbell KE, Fraser CH, Harris C, Keast DH, Potter PJ, et al. Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury. Arch Phys Med Rehabil. 2010;91(5):669-78.
(32) Polak A, Kloth LC, Blaszczak E, Taradaj J, Nawrat-Szoltysik A, Walczak A, et al. Evaluation of the healing progress of pressure ulcers treated with cathodal high-voltage monophasic pulsed current: results of a prospective, double-blind, randomized clinical trial. Adv Skin Wound Care. 2016;29(10):447-59.
(33) Jercinovic A, Karba R, Vodovnik L, Stefanovska A, Kroselj P, Turk R, et al. Low frequency pulsed current and pressure ulcer healing. IEEE Trans Rehabil Eng. 1994;4(2):225-33.
(34) Wood JM, Evans IPE, Schallreuter KU, Jacobson WE, Sufit R, Newman J, et al. A multicenter study on the use of pulsed low-intensity direct current for healing chronic stage II and stage III decubitus ulcers. Arch Dermatol. 1993;129(8):999-1009.

(35) Karba R, Semrov D, Vodovnik L, Benko H, Savrin R. DC electrical stimulation for chronic wound healing enhancement. Part 1. Clinical study and determination of electrical field distribution in the numerical wound model. Bioelectrochem Bioenerg. 1997;43 (2):265-70.
(36) Stefanovska A, Vodovnik L, Benku H, Turk R. Treatment of chronic wounds by means of electric and electromagnetic fields. Part 2. Value of FES parameters for pressure sore treatment. Med Biol Eng Comput. 1993;31(3):213-20.
(37) Kawasaki L, Mushahwar VK, Ho C, Dukelow SP, Chan LLH, Chan KM. The mechanisms and evidence of efficacy of electrical stimulation for healing of pressure ulcer: a systematic review. Wound Repair Regen. 2014;22(2):161-73.
(38) Lala D, Spaulding SJ, Burke SM, Houghton PE. Electrical stimulation therapy for the treatment of pressure ulcers in individuals with spinal cord injury: a systematic review and meta-analysis. Int Wound J. 2016;13(6):1214-26.
(39) Liu LQ, Moody J, Traynor M, Dyson S, Gall A. A systematic review of electrical stimulation for pressure ulcer prevention and treatment in people with spinal cord injuries. J Spinal Cord Med. 2014;37(6):703-18.
(40) Smith ME, Totten A, Hickam DH, Fu R, Wasson N, Rahman B, et al. Pressure ulcer treatment strategies: a systematic comparative effectiveness review. Ann Intern Med. 2013;159(1):39-50.
(41) Koel G, Houghton PE. Electrostimulation: current status, strength of evidence guidelines, and meta-analysis. Adv Wound Care. 2014;3(2):118-26.
(42) National Institute for Health and Care Excellence. Process and methods guides. The guidelines manual: appendix G: methodology checklist: economic evaluations. 2012 [cited 2016 Oct 30]. Available from: http://publications.nice.org.uk/the-guidelines-manual-appendices-bi-pmg6b/appendix-g-methodology-checklist-economic-evaluations
(43) Mittmann N, Chan BC, Craven BC, Isogai PK, Houghton P. Evaluation of the cost-effectiveness of electrical stimulation therapy for pressure ulcers in spinal cord injury. Arch Phys Med Rehabil. 2011;92(6):866-72.
(44) Canadian Institute for Health Information. Data quality documentation, Continuing Care Reporting System, 2014-2015 [Internet]. Ottawa (ON): Canadian Institute for Health Information; 2015 [cited 2016 Dec 9]. Available from: https://secure.cihi.ca/free_products/CCRS-Data-Quality-Report-2014-2015_EN.pdf
(45) Canadian Institute for Health Information. Data quality documentation, Discharge Abstract Database--current-year information, 2015-2016 [Internet]. Ottawa (ON): Canadian Institute for Health Information; 2016 [cited 2016 Dec 15]. Available from: https://www.cihi.ca/sites/default/files/document/dad-data-quality_15-16_en.pdf
(46) Canadian Institute for Health Information. Data quality documentation, Home Care Reporting System, 2012-2013 [Internet]. Ottawa (ON): Canadian Institute for Health Information; 2013 [cited 2016 Dec 9]. Available from: https://secure.cihi.ca/free_products/HCRS-External-Data-Quality-Report_2012_EN_web.pdf
(47) Canadian Institute for Health Information. Quick stats: DAD/HMDB inpatient hospitalizations: volumes, length of stay, and standardized rates [Internet]. Ottawa (ON): Canadian Institute for Health Information. 2016. Available from: https://www.cihi.ca/en/quick-stats
(48) Discharge Abstract Database [Internet]. Ontario Ministry of Health and Long-Term Care, IntelliHEALTH ONTARIO. 2015.
(49) Houghton P, Campbell K, CPG Panel. Canadian best practice guidelines for the prevention and management of pressure ulcers in people with spinal cord injury. A resource handbook for clinicians. [Internet]. Mississauga (ON): Katika Integrated Communications Inc; 2013. Available from:

http://onf.org/system/attachments/168/original/Pressure_Ulcers_Best_Practice_Guideline_Final_web4.pdf
(50) Centers for Medicare & Medicaid Services. Decision Memo for Electrostimulation for Wounds (CAG-00068R) [Internet]. 2003 [cited 2017 Feb]. Available from: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=28&fromdb=true
(51) VanGilder C, Macfarlane GD, Meyer S. Results of nine international pressure ulcer prevalence surveys: 1989 to 2005. Ostomy Wound Manage. 2008;54(2):40-54.
(52) Bennett G, Dealey C, Posnett J. The cost of pressure ulcers in the UK. Age Ageing. 2004;33(3):230-5.
(53) Bergstrom N, Horn SD, Smout RJ, Bender SA, Ferguson ML, Taler G, et al. The National Pressure Ulcer Long-Term Care Study: outcomes of pressure ulcer treatments in long-term care. J Am Geriatr Soc. 2005;53(10):1721-9.
(54) Woo KY, Sears K, Almost J, Wilson R, Whitehead M, VanDenKerkhof EG. Exploration of pressure ulcer and related skin problems across the spectrum of health care settings in Ontario using administrative data. Int Wound J. 2015.
(55) Canadian Institute for Health Information. Data quality documentation, National Rehabilitation Reporting System, 2015-2016 [Internet]. Ottawa (ON): Canadian Institute for Health Information; 2016 [cited 2016 Feb 10]. Available from: https://www.cihi.ca/sites/default/files/document/dad-data-quality_15-16_en.pdf
(56) Patterson Medical. Modalities [Internet]. 2016 [cited 2016 Dec 9]. Available from: http://www.pattersonmedical.ca/app.aspx?cmd=getProduct&key=IF_112515
(57) Maugee's Market [Internet]. London (ON): Maugee's Market; 2017 [cited 2017 Mar]. Available from: https://www.maugee.com/
(58) Ontario Nurses' Association. Nursing Homes Template Agreement--July 1, 2016, to June 30, 2019 [Internet]. Toronto (ON): Ontario Nurses' Association; 2016 [cited 2017 April 10]. Available from: https://www.ona.org/wp-content/uploads/ona_nursinghomestemplatefinal_20190630.pdf?x72008&x72008
(59) Ontario Nurses' Association. Collective agreement. Hospital central agreement--March 31, 2018 [Internet]. Toronto (ON): Ontario Nurses' Association; 2016 [cited 2017 Feb 24]. Available from: https://www.ona.org/wp-content/uploads/ona_hospitalcentralagreement_20180331.pdf?x72008
(60) Ontario Public Service Employees Union. Combined full-time and part-time collective agreement [Internet]. Toronto (ON): The Union; 2016 [cited 2016 Dec 12]. Available from: https://www.oha.com/Collective%20Bargaining%20Documents/OPSEU%20Combined%20HPD%20Final%20Collective%20Agreement%20-%20March%2031,%202019.pdf
(61) Clinic Supplies Canada. Wires & probes [Internet]. New Westminster (BC): clinicsuppliescanada.com; 2017 [Available from: https://clinicsuppliescanada.com/other-departments/electrotherapy-machines/wires-and-probes
(62) Ontario Nurses' Association. Collective Agreement. Central East Community Care Access Centre--March 31, 2016 [Internet]. Toronto (ON): Ontario Nurses' Association; 2016 [cited 2017 April 10]. Available from: http://www.sdc.gov.on.ca/sites/mol/drs/ca/Ambulatory%20Health%20Care%20Services/621-3379-16%20(827-0104).pdf
(63) South West Cinical Care Access Centre. South West CCAC Wound Management Program (WMP)--July 2012 [Internet]. 2012 [Available from: http://www.southwesthealthline.ca/healthlibrary_docs/SWCCACClinicianJuly_9_%202012.pdf
(64) Ontario RNAo. Assesment and management of pressure injuries for the interprofessional team, third edition. Toronto, ON: Registered Nurses' Association of Ontario; 2016.

(65) VanGilder C, Lachenbruch C, Algrim-Boyle C, Meyer S. The international pressure ulcer prevalence™ survey: 2006-2015: A 10-year pressure injury prevalence and demographic trend analysis by care setting. J Wound Ostomy Continence Nurs. 2017;44(1):20-8.
(66) Barham L. Public and patient involvement at the UK National Institute for Health and Clinical Excellence. Patient. 2011;4(1):1-10.
(67) Messina J, Grainger DL. A pilot study to identify areas for further improvements in patient and public involvement in health technology assessments for medicines. Patient. 2012;5(3):199-211.
(68) OHTAC Public Engagement Subcommittee. Public engagement for health technology assessment at Health Quality Ontario—final report from the Ontario Health Technology Advisory Committee Public Engagement Subcommittee [Internet]. Toronto (ON): Queen's Printer for Ontario; 2015 April [cited 2016. Available from: http://www.hqontario.ca/Portals/0/documents/evidence/special-reports/report-subcommittee-20150407-en.pdf
(69) Tjornhoj-Thomsen T, Hansen HP. Knowledge in health technology assessment: who, what, how? Int J Technol Assess Health Care. 2011;27(4):324-9.
(70) Rowe G, Frewer LJ. A typology of public engagement mechanisms. Sci Technol Hum Val. 2005;30(2):251-90.
(71) Brundisini F, Giacomini M, DeJean D, Vanstone M, Winsor S, Smith A. Chronic disease patients' experiences with accessing health care in rural and remote areas: a systematic review and qualitative meta-synthesis. Ont Health Technol Assess Ser. 2013;13(15):1-33.
(72) Kvale S. Interviews: an introduction to qualitative research interviewing. Thousand Oaks (CA): Sage; 1996.
(73) Health Technology Assessment International Interest Group on Patient and Citizen Involvement in HTA. Introduction to health technology assessment (HTA) [Internet]. Edmonton (AB): Health Technology Assessment International; 2015 [cited 2016. Available from: http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/v2_files/Resource/PCISG-Resource-Intro_to_HTA__KFacey__Jun13.pdf
(74) Strauss AL, Corbin JM. Grounded theory research: Procedures, canons, and evaluative criteria. Qual Sociol. 1990;13(1):3-21.
(75) Strauss AL, Corbin JM. Grounded theory methodology: an overview. In: Denzin NK, Lincoln YS, editors. Handbook of qualitative research. Thousand Oaks (CA): Sage Publications; 1994. p. 273-85.
(76) Mittmann N, Chan BC, Craven BC, Isogai PK, Houghton P. Evaluation of the cost-effectiveness of electrical stimulation therapy for pressure ulcers in spinal cord injury. Arch Phys Med Rehabil. 2011;92(6):866-72.

# About Health Quality Ontario

Health Quality Ontario is the provincial advisor on the quality of health care. We are motivated by a single-minded purpose: **Better health for all Ontarians.**

## Who We Are.

We are a scientifically rigorous group with diverse areas of expertise. We strive for complete objectivity, and look at things from a vantage point that allows us to see the forest and the trees. We work in partnership with health care providers and organizations across the system, and engage with patients themselves, to help initiate substantial and sustainable change to the province's complex health system.

## What We Do.

We define the meaning of quality as it pertains to health care, and provide strategic advice so all the parts of the system can improve. We also analyze virtually all aspects of Ontario's health care. This includes looking at the overall health of Ontarians, how well different areas of the system are working together, and most importantly, patient experience. We then produce comprehensive, objective reports based on data, facts and the voice of patients, caregivers and those who work each day in the health system. As well, we make recommendations on how to improve care using the best evidence. Finally, we support large scale quality improvements by working with our partners to facilitate ways for health care providers to learn from each other and share innovative approaches.

## Why It Matters.

We recognize that, as a system, we have much to be proud of, but also that it often falls short of being the best it can be. Plus certain vulnerable segments of the population are not receiving acceptable levels of attention. Our intent at Health Quality Ontario is to continuously improve the quality of health care in this province regardless of who you are or where you live. We are driven by the desire to make the system better, and by the inarguable fact that better has no limit.

**About the Ontario Health Technology Advisory Committee (OHTAC)**

**About OHTAS**

**How to Obtain OHTAS Reports**

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