**SCOPE OF WORK 2020-2**

**SPINAL STIMULATION (COST ANALYSIS)**

*February 18, 2020*

## Introduction/Background

Spinal cord stimulation has shown potential for functional improvement for people living with spinal cord injury (SCI). Spinal cord stimulation is a general term used to describe when a stimulus is applied to any area of the spinal cord. The stimulus can be electrical or magnetic and is delivered either over the skin (transcutaneous) or directly onto the spinal cord through an implant (epidural). Spinal cord stimulation is currently approved for the treatment of chronic pain. It is also being researched as a potential technique for activating the spinal cord at regions below the level of injury which remain intact but cannot properly receive and relay information along the spinal cord to maximize recovery of body systems effected by spinal cord injury.   
  
Currently, the development of spinal cord stimulation as a therapy is being tested in individuals with SCI in a research setting and evidence is being collected through clinical trials to determine efficacy and safety for motor, sensory and autonomic recovery. The evidence so far is from studies conducted in a small number of people and in research settings that often have strict recruitment criteria, intensive physical training, and individually-optimized stimulation protocols.   
  
There are many challenges preventing spinal cord stimulation therapy from being generalizable to the wider SCI population and available in the health care system or home-setting. These challenges include clinical trial design, high costs, inaccessibility, scalability, and lack of concrete knowledge about the efficacy, safety and underlying mechanism (i.e. how it works). Additional research is needed to overcome these challenges. The results of this analysis are intended to help shape the future of spinal cord stimulation research so that, if proven safe and effective, it can be more easily available to individuals living with SCI. 

## 2. Economics Research Questions

* What kinds of costs are incurred when providing spinal cord stimulation as a therapy? How much are they?
* How much would it cost to provide these services – at a single site and across sites?

## 3. Population, Setting, Intervention and Control/Comparison Group

To answer the above research questions, the following data could be used:

* literature review of costs, including in other jurisdictions and related to the use of spinal stimulators for neuropathic pain
* interviews with clinicians, researchers and individuals living with SCI
* other data sources e.g., magazines, newspapers/media

## 4. Outcomes

Praxis is requesting an analysis of the types and levels of costs incurred for spinal cord stimulation therapy.

## 5. Time Frame and Budget

Study activities are planned in 2020 and/or 2021. The table below shows the proposed tasks for this project. All project deliverables will be provided to Praxis in English.

The budget for this analysis is CDN$9,000-$18,000.

|  |  |
| --- | --- |
|  | **Schedule** |
| **TASKS** | **TBD** |
| Request Proposals/Review/Select and Set Up Contract |  |
| Start Up Meeting/Confirm Scope of Work |  |
| Conduct Scoping/Literature Review |  |
| Develop Data Collection and Analysis Plan |  |
| Conduct Data Collection and Analysis |  |
| Summarize Results |  |
| Draft/Final Report |  |

## Attachment - Potential Costs

### Regulatory Assessment/Approval costs

* Canadian Agency for Drugs and Technologies in Health (CADTH) assessment costs
* Health Canada application costs

### Testing, Screening, Eligibility and Monitoring

* Measurement costs – at baseline, mid-point (pre-intervention), mid-point (after implant), mid-point (during intervention), final, follow up (sub-sets) – could include for:
* Physical assessment
* Bone density (pre/post)
* Pre-training criteria
* ISNCSCI (pre, mid, post)
* Motor potential, sensory potential, H reflex (pre, mid, post)
* Urodynamics (pre, mid, post)
* Sexual function (pre, mid, post)
* Bowel (pre, mid, post)
* Cardiovascular
* Respiratory
  + Other clinical measures such as QoL indicators, Berg Balance, GRASSP, Ashworth spasticity, etc.
* Patient out of pocket – compensation for time, travel/transportation (bus fare, parking, mileage)

### Epidural Spinal Stimulator

* Spinal stimulator and batteries (including replacements) per participant/patient
* Surgery – surgical staff and patient time/cost for preparation, day surgery procedure (on an outpatient basis) and follow up
  + If there’s a trial period e.g., of 2 weeks when the stimulator is implanted but not permanently (the battery is still external)
  + If there are adverse events e.g., infections (incidence/cost)
* Device optimizing/mapping – clinician and/or engineer’s time and participant time
  + If there are multiple visits to change settings
* Explantation of the device (if it needs to be removed)

### Transcutaneous Spinal Stimulator

* Spinal stimulator and batteries (including replacements) e.g., two per site rather than for each individual/person
* No surgery costs
* Consumables - Disposable electrodes (fresh each session – 6 per person per session – 1 session a day), gel pads, swabs, gloves, etc.

### Therapy

* Rehab protocols – several scenarios e.g.,
  + For 2 hours/day, 2 to 5 days a week
  + For 16 to 24 weeks (4 to 6 months) e.g., 1 month of baseline testing, 8 weeks of training, 8 weeks of training with intervention, one month (post-follow up) (6 month)
    - Other protocols may also be of interest e.g., Harkema, Darrow, Courtine, Edgerton, Martin, etc.
* Personnel – two physical therapists, consulting physician, data analyst, etc.
* Patient out of pocket – compensation for time, travel/transportation (bus fare, parking, mileage)
  + Including for home protocol e.g., up to an hour per day (night)
* Facility and equipment – gym, treadmill, overhead track, rent space, safety harness, heart rate monitor, blood pressure checks, fall protection, safety precautions around fracture risks (hips, knees, feet), recording/data equipment

### Long-term

* Follow up – check-ups and more specifically for:
  + (Electrical) leads migration
  + Adverse events
  + Additional rehabilitation