Guidance Document for Spinal Cord Stimulation Clinical Studies: Designing, Reporting and Sharing Clinical Data in Spinal Cord Injury

Purpose of this Document

The purpose of this document is to provide guidance on facilitating data sharing for clinical studies involving spinal cord stimulation in spinal cord injury (SCI) and covers recommended: 1) data variables to promote the standardization and combining of existing data sets; and 2) data sharing repositories for completed SCI clinical studies that include spinal cord stimulation.

Background

Neuromodulation is defined as "the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body."[1] The most common type of neuromodulation treatment is spinal cord stimulation for neuropathic pain that may persist following spinal surgery or following a spinal cord injury.[2] Epidural spinal cord stimulation has been used for forty years with several mature device platforms and an extensively documented safety and device durability record. More recently, implanted or skin surface (transcutaneous) spinal cord stimulation has been used to promote recovery of the motor, sensory, and autonomic nervous systems and body functions. Given the growing interest in spinal cord stimulation, standardizing the variables included and reported in clinical studies and then sharing this data will accelerate the translation of this technology so individuals living with spinal cord injury (SCI) can access it.

The recommended data reporting standards are an adaptation of Malik et al. 2024 minimum reporting standards for clinical spinal cord stimulation research studies (REPORT-SCS),[3] along with input from Bresnahan et al. 2024 SPIRIT-iNeurostim extension,[4] Duarte et al. 2024 CONSORT-iNeurostim extension,[5] and relevant clinical expertise. The SPIRIT-iNeurostim and CONSORT-iNeurostim extensions refer to protocols and reporting guidelines, respectively, for controlled randomized trials for implantable neurostimulation devices.

There are six categories of data reporting standards. *Category 1*, 'Patient Selection', ensures that the participant selection is clearly described. *Category 2*, 'Spinal Cord Stimulation Hardware', refers to the stimulation device. *Category 3*, 'Spinal Cord Stimulation Configuration and Current Parameters', refers to the placement of electrodes and adjustable device parameters used throughout the intervention. *Category 4*, 'Spinal Cord Stimulation Intervention', refers to the session goals and details. *Category 5*, 'Spinal Cord Stimulation Control or Comparator' refers to details for control arm (if applicable). *Category 6,* 'Spinal Cord Stimulation Adverse Events', refers to any adverse events experienced by the participant. Researchers should select only data variables that are relevant for their clinical study. For clinical study data variables related to characteristics of the participants (e.g. age, sex), type of SCI, other treatments, care management and outcomes, please see the NINDS Common Data Elements for SCI website.

Data Reporting Standards [3-5]

Category 1: Patient Selection

- Clear Candidate Criteria that recognize the relatively limited data set for SCI application at this point.
- Eligibility Criteria
- Exclusion Criteria

Category 2: Spinal Cord Stimulation Hardware

- Device name, manufacturer, model, software, and any software changes that differ from the FDA-approved product sheet
- Electrode manufacturer, product number, size

Category 3: Spinal Cord Stimulation Configuration and Current Parameters

Note: Consider these recommendations for the 'Spinal Cord Stimulation Intervention' (Category 4) and if applicable, for the 'Spinal Cord Stimulation Control or Comparator' (Category 5).

- Cathode Placement: Reporting the anatomical location(s) of the cathode(s) (i.e., negative electrode(s)) with respect to spinal roots and vertebral levels
- Anode Placement: Reporting the anatomical location(s) of the anode(s) (i.e., positive electrode(s)) with respect to spinal roots and vertebral levels
- Overall Electrode Montages: Reporting a visual depiction of the arrangement of the cathode and anode placements (e.g., graphical)
- Waveform: Reporting the waveform of the electrical pulse (e.g., square, sine, sweep, monophasic, biphasic, polarity (i.e., cathodic-leading or anodic-leading), etc.
- Pulse Width: Reporting pulse width in units of time (i.e., the duration of the pulse in milliseconds)
- Phase Duration & Interphase Interval: For biphasic waveforms, reporting the anodic and cathodic phase durations and any interphase interval (IPI)
- Intensity: Reporting the intensity of the stimulation as amplitude (constant-current) or voltage (constant-voltage)
- Intensity Threshold: Reporting how the effective amplitude (i.e., intensity) of stimulation was determined (e.g., based on EMG, motor, or sensory threshold)
- Period: Reporting the period of the pulse in units of time (i.e., the time taken for the signal to complete one cycle)
- Frequency: Reporting pulse frequency in Hertz (Hz) (i.e., the number of pulses per second)
- Duty Cycle: Reporting the duty cycle of the pulse (i.e., percentage of ON time)
- Charge-balanced: Reporting details on the pulse design if possible (e.g., charge-balanced, and if so, symmetrically or asymmetrically)
- Temporal Characteristics: Reporting the temporal characteristics of stimulation trains over time (e.g., burst, continuous, etc.)
- Carrier Waveform: Reporting the presence and frequency of a carrier waveform if applicable

- Carrier Intensity: Reporting the strength of carrier intensity reported as amplitude or voltage if applicable

Category 4: Spinal Cord Stimulation Intervention

- Target Function: Reporting the primary target of the stimulation intervention (e.g., bladder function, upper extremity motor function, etc.) and identifying primary and secondary outcomes
- Delivery Method: Reporting the method of stimulation (e.g., transcutaneous, epidural, intraspinal etc.)
- Session Duration: Reporting the duration of each stimulation session in minutes
- Session Details: Reporting the number of minutes of stimulation on vs. off during treatment. (e.g., continuous, intervals etc.)
- Sessions per Week: Reporting the number of stimulation sessions per week
- Total Number of Sessions: Reporting the total number of sessions conducted
- Adjunct Therapy: Reporting whether stimulation treatment was combined with another modality (e.g., robotic gait training, arm ergometry, etc.)
- Open or Closed Loop: Reporting whether stimulation was under open-loop or closed-loop control, and the control signal (e.g., EEG, EMG, IMU) used for closed-loop
- Environmental Setting: Reporting the environmental setting during the treatment program (e.g., laboratory under supervision, home but supervised (e.g., telehealth or unsupervised home setting))
- Participant Position: Reporting the position of the participant during stimulation (e.g., supine, upright, side-lying)
- Program Adherence: Reporting program adherence (i.e., number of sessions completed or missed possibly with reason)
- Team Qualifications: Reporting the qualifications of the individual (or team) administering stimulation or that provided education training if self-administered
- Modifications to Initial Treatment Plan: Reporting whether the initial treatment program was modified, personalized, or titrated over the course of the intervention, and if so, how

Category 5: Spinal Cord Stimulation Control or Comparator (if applicable)

- Target Function: Reporting the primary target of the control or comparator stimulation intervention (e.g., bladder function, upper extremity motor function, etc.) and identifying primary and secondary outcomes
- Delivery Method: Reporting the method of the control or comparator stimulation (e.g., transcutaneous, epidural, intraspinal etc.) and delivery (e.g., subtherapeutic, subthreshold or sham)
- Session Duration: Reporting the duration of each control or comparator stimulation session in minutes
- Session Details: Reporting the number of minutes of the control or comparator stimulation on vs. off during treatment. (e.g., continuous, intervals etc.)

- Sessions per Week: Reporting the number of the control or comparator stimulation sessions per week
- Total Number of Sessions: Reporting the total number of sessions conducted
- Adjunct Therapy: Reporting whether the control or comparator stimulation treatment was combined with another modality (e.g., robotic gait training, arm ergometry, etc.)
- Open or Closed Loop: Reporting whether the control or comparator stimulation was under open-loop or closed-loop control, and the control signal (e.g., EEG, EMG, IMU) used for closed-loop
- Environmental Setting: Reporting the environmental setting during the treatment program (e.g., laboratory under supervision, home but supervised (e.g., telehealth or unsupervised home setting))
- Participant Position: Reporting the position of the participant during control or comparator stimulation (e.g., supine, upright, side-lying)
- Program Adherence: Reporting program adherence (i.e., number of sessions completed or missed possibly with reason)
- Team Qualifications: Reporting the qualifications of the individual (or team) administering control or comparator stimulation or that provided education training if self-administered
- Modifications to Initial Treatment Plan: Reporting whether the initial treatment program including the control or comparator spinal cord stimulation was modified, personalized, or titrated over the course of the intervention, and if so, how

Category 6: Spinal Cord Stimulation Adverse Events

Note: Recommended data variables for reporting adverse events that occur during SCI clinical trials is available on the NINDS Common Data Elements for SCI website, under the Domain Name 'Assessments and Examinations'. Key considerations are described below.

- Reporting Plan: Reporting the plan for collecting and assessing occurrences of adverse events (investigator responsibility or participant self-reporting, solicitated or spontaneously reported…)
- Transient Events: Reporting the presence or absence of any transient adverse event(s) from the stimulation program, whether it is expected or unexpected and severity (i.e., mild, moderate, or severe)
- Persisting Events: Reporting the presence or absence of any persisting adverse event(s) from the stimulation program whether it is expected or unexpected and severity (i.e., mild, moderate, or severe)
- Required Treatment: Reporting the presence or absence of any adverse event(s) requiring treatment from the stimulation program whether it is expected or unexpected and severity (i.e., mild, moderate, or severe)
- Frequency: Reporting the frequency of any adverse event(s) (single occurrence, repeated…)

Data Sharing for Spinal Cord Injury Clinical Data

In the National Institutes of Health Strategic Plan for Data Science,[6] it is recommended that data follows the FAIR principles for data management and stewardship,[7] that is, data must be **F**indable, **A**ccessible, **I**nteroperable and **R**eusable.

Federal agencies that fund research now require as a condition of funding that data be publicly available in an open data repository.[8] For SCI, the Open Data Commons for SCI (ODC-SCI) (https://odc-sci.org/) is a platform for FAIR data sharing and is a resource of available legacy and prospective SCI data.[9,10] It is recommended that clinical data including spinal cord stimulation and other human spinal cord injury studies are shared on the ODC-SCI.

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Please send comments/feedback to NINDSCDE@emmes.com.

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Appendix: Guidance Document for SCI Spinal Stim Clinical Studies Data Form[1]

Items	Guideline	Variable Label	Notes
Category 1: Patient Selection			
Clear candidate criteria Eligibility criteria Exclusion criteria	Clear candidate criteria that recognize the relatively limited data set for SCI application at this point.		
Category 2: SCS Hardware			
Device name, manufacturer, model, software, and any software changes that differ from the FDA-approved product sheet Electrode manufacturer, product number, size			
Category 3: SCS Configuration and Current Parameters			
Cathode placement	Reporting the anatomical location(s) of the cathode(s) (i.e., negative electrode(s)) with respect to spinal roots and vertebral levels		
Anode placement	Reporting the anatomical location(s) of the anode(s) (i.e., positive electrode(s)) with respect to spinal roots and vertebral levels		
Overall electrode montages	Reporting a visual depiction of the arrangement of the cathode and anode placements (e.g., graphical)		
Waveform	Reporting the waveform of the electrical pulse (e.g., square, sine, sweep, monophasic, biphasic, polarity (i.e., cathodic-leading or anodic-leading), etc.		
Pulse width	Reporting pulse width in units of time (i.e., the duration of the pulse in milliseconds)		
Phase duration & interphase interval	For biphasic waveforms, reporting the anodic and cathodic phase durations and any interphase interval (IPI)		

[1] Other relevant SCI clinical study CDEs may be found on the NINDS SCI CDE website.

Intensity	Reporting the intensity of the stimulation as amplitude (constant-current) or voltage (constant-voltage)		
Intensity threshold	Reporting how the effective amplitude (i.e., intensity) of stimulation was determined (e.g., based on EMG, motor, or sensory threshold)		
Period	Reporting the period of the pulse in units of time (i.e., the time taken for the signal to complete one cycle)		
Frequency	Reporting pulse frequency in Hertz (Hz) (i.e., the number of pulses per second)		
Duty cycle	Reporting the duty cycle of the pulse (i.e., percentage of ON time)		
Charge-balanced	Reporting details on the pulse design if possible (e.g., charge-balanced, and if so, symmetrically or asymmetrically)		
Temporal characteristics	Reporting the temporal characteristics of stimulation trains over time (e.g., burst, continuous, etc.)		
Carrier waveform	Reporting the presence and frequency of a carrier waveform if applicable		
Carrier intensity	Reporting the strength of carrier intensity reported as amplitude or voltage if applicable		
Category 4: SCS Intervention			
Target function	Reporting the primary target of the stimulation intervention (e.g., bladder function, upper extremity motor function, etc.) and identifying primary and secondary outcomes		
Delivery method	Reporting the method of stimulation (e.g., transcutaneous, epidural, intraspinal…)		
Session duration	Reporting the duration of each stimulation session in minutes		
Session details	Reporting the number of minutes of stimulation on vs. off during treatment. (e.g., continuous, intervals, etc.)		
Sessions per week	Reporting the number of stimulation sessions per week		
Total number of sessions	Reporting the total number of sessions conducted		
Adjunct therapy	Reporting whether stimulation treatment was combined with another modality (e.g., robotic gait training, arm ergometry, etc.)		
Open or closed loop	Reporting whether stimulation was under open-loop or closed-loop control, and the control signal (e.g., EEG, EMG, IMU) used for closed-loop		

Environmental setting	Reporting the environmental setting during the treatment program (e.g., laboratory under supervision, home but supervised (e.g., telehealth or unsupervised home setting))		
Participant position	Reporting the position of the participant during stimulation (e.g., supine, upright, side-lying)		
Program adherence	Reporting program adherence (i.e., number of sessions completed or missed possibly with reason)		
Team qualifications	Reporting the qualifications of the individual (or team) administering stimulation or that provided education training if self-administered		
Modifications to initial treatment plan	Reporting whether the initial treatment program was modified, personalized, or titrated over the course of the intervention, and if so, how		
Category 5: SCS Control or Comparator (if applicable)			
Target function	Reporting the primary target of the stimulation intervention (e.g., bladder function, upper extremity motor function, etc.) and identifying primary and secondary outcomes		
Delivery method	Reporting the method of the control or comparator stimulation (e.g., transcutaneous, epidural, intraspinal…) and delivery (e.g., subtherapeutic, subthreshold or sham)		
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Modifications to initial treatment plan	Reporting whether the initial treatment program was modified, personalized, or titrated over the course of the intervention, and if so, how		
Category 6: SCS Adverse Events			
Reporting plan	Reporting the plan for collecting and assessing occurrences of adverse events (investigator responsibility or patient self-reporting, solicitated or spontaneously reported)		
Transient events	Reporting the presence or absence of any transient adverse event(s) from the stimulation program, whether it is expected or unexpected and severity (mild, moderate, or severe)		
Persisting events	Reporting the presence or absence of any persisting adverse event(s) from the stimulation program whether it is expected or unexpected and severity (mild, moderate, or severe)		
Required treatment	Reporting the presence or absence of any adverse event(s) requiring treatment from the stimulation program whether it is expected or unexpected and severity (mild, moderate, or severe)		
Frequency	Reporting the frequency of any adverse event(s) (single occurrence, repeated)		