Continuing Medical Education Needs Assessment

Newer Waveform and Closed-Loop Spinal Cord Stimulation for Chronic Pain: Closing the Adoption and Optimization Gap

Heather Smith — Medical Writer & Neuromodulation Clinical Education Consultant
heathercsmith75@gmail.com | linkedin.com/in/heather-colleen-smith

Demonstration writing sample. This needs assessment was self-authored from publicly available, peer-reviewed literature to illustrate CME writing capability. It does not contain proprietary or confidential information, is not commissioned or funded by any commercial interest, and presents a balanced, non-promotional view of all therapy classes.

Proposed activity format: Case-based enduring material with outcomes assessment | **Estimated credit:** 1.0 AMA PRA Category 1 Credit™ | **Therapeutic area:** Interventional pain medicine / neuromodulation

1. Executive Summary

Spinal cord stimulation (SCS) is an established, evidence-based therapy for chronic intractable pain, yet a widening gap separates the rapidly expanding evidence base from routine clinical practice. Over the past decade, multiple pivotal randomized controlled trials (RCTs) have established newer stimulation paradigms—high-frequency 10 kHz, burst, differential target multiplexed (DTM), and fast-acting sub-perception therapy (FAST)—and, most recently, physiologic closed-loop stimulation that uses the evoked compound action potential (ECAP) to measure and maintain neural activation in real time. Despite this evidence, conventional fixed-output (*open-loop*) tonic stimulation remains widely used, loss of efficacy continues to drive device explantation, and surveys of interventional pain physicians document persistent gaps in knowledge of waveform selection, closed-loop physiology, patient selection, and device programming. This needs assessment synthesizes the published evidence for these gaps and proposes an educational intervention to help interventional pain clinicians select, apply, and optimize contemporary SCS technologies.

2. Statement of Need and Practice Gap

Overarching practice gap. Interventional pain physicians have access to a growing array of SCS waveforms and to physiologic closed-loop systems supported by high-quality RCT evidence, but adoption, patient selection, and programming optimization in practice lag behind the evidence—contributing to suboptimal pain relief, loss of efficacy over time, and avoidable device explantation.

This gap can be expressed across three linked dimensions that structure the educational need:

Knowledge gap

Many clinicians are not fully current on the comparative mechanisms and trial evidence distinguishing tonic, 10 kHz, burst, DTM, and FAST stimulation, or on the physiologic rationale for ECAP-controlled closed-loop systems. The concept of the neural *therapeutic window*—and the fact that fixed-output systems cannot measure the dose of stimulation actually reaching the spinal cord as the cord moves relative to the electrode—is incompletely understood.

Competence gap

Clinicians may know newer options exist but lack a structured approach to translate that knowledge into decisions: which patient is best suited to which paradigm, how to counsel on paresthesia-free

options, how to interpret ECAP feedback, and how to respond when a previously effective system loses efficacy.

Performance gap

In practice, these gaps manifest as continued default to conventional programming, under-recognition of loss of efficacy as a modifiable problem, variation in trial-to-implant conversion across providers, and explantation for inadequate relief that earlier optimization or salvage might have prevented.

3. Evidence Supporting the Need

3.1 Burden of disease and rationale for effective neuromodulation

- **Prevalence.** In 2023, an estimated 24.3% of U.S. adults reported chronic pain and 8.5% reported high-impact chronic pain in the prior 3 months, up from 20.4% in 2019 (Lucas & Sohi, NCHS Data Brief No. 518, 2024).
- **Economic cost.** The annual U.S. cost of chronic pain was estimated at $560–635 billion (2010 dollars), exceeding the annual costs of heart disease, cancer, and diabetes (Gaskin & Richard, J Pain. 2012).
- **Opioid-sparing potential.** SCS is associated with reductions in opioid utilization; in a post hoc analysis of the SUNBURST burst-stimulation trial, mean opioid consumption fell from 79.2 to 53.9 MME at 12 months and 15.9% of patients discontinued opioids entirely (D'Souza et al., Neuromodulation. 2021).

3.2 Limitations of conventional tonic SCS

- **Loss of efficacy (LoE).** The 2024 Neurostimulation Appropriateness Consensus Committee (NACC) identifies LoE over time as a major limitation and the leading cause of therapy discontinuation and device explantation, noting it may appear within the first year and remains incompletely understood (Deer et al., Neuromodulation. 2024).
- **Explantation.** A 2025 systematic review reported explantation rates reaching up to 38%, with inadequate pain relief the most common reason (38% of explants), followed by lead failure (15%) and infection (14%); most explantations occur within the first year (Wahezi et al., J Pain Res. 2025).
- **Habituation.** Declining tonic efficacy over time is well described, with long-term series showing relief falling from roughly half of patients at 5 years toward approximately one-third at 10 years —motivating waveform strategies intended to mitigate habituation.

3.3 Evidence for newer waveforms

- **High-frequency 10 kHz.** In the SENZA-RCT, 10 kHz SCS was superior to traditional low-frequency stimulation for back and leg pain, with 24-month back-pain responder rates of 76.5% vs 49.3% and delivered without paresthesia (Kapural et al., Anesthesiology. 2015; Neurosurgery. 2016). In SENZA-PDN, 79% of patients with painful diabetic neuropathy achieved ≥50% relief without neurological worsening at 3 months vs 5% for conventional medical management (Petersen et al., JAMA Neurol. 2021).
- **Burst.** In SUNBURST, burst stimulation was noninferior and superior to tonic stimulation and was preferred by 70.8% of patients, delivered paresthesia-free (Deer et al., Neuromodulation. 2018).

- **DTM and FAST.** Differential target multiplexed SCS was superior to traditional SCS for low back pain at 12 months (Fishman et al., Pain Pract. 2021), and fast-acting sub-perception therapy demonstrated rapid onset of sub-perception analgesia (Metzger et al., Expert Rev Med Devices. 2021), expanding the paresthesia-free options available.

3.4 Evidence for physiologic closed-loop (ECAP-controlled) SCS

- **EVOKE pivotal RCT.** In the double-blind, randomized EVOKE trial, ECAP-controlled closed-loop SCS was superior to open-loop SCS, with 12-month responder rates of 83.1% vs 61.0% and the stimulation dose held within the therapeutic window 95.2% vs 47.9% of the time (Mekhail et al., Lancet Neurol. 2020).
- **Durability.** Superiority was sustained at 24 months (Mekhail et al., JAMA Neurol. 2022) and 36 months, where ≥50% relief was 77.6% vs 49.3% and no patient in the closed-loop arm was explanted for loss of efficacy through 3 years (Mekhail et al., Reg Anesth Pain Med. 2024).
- **Expanding availability.** Two ECAP-based closed-loop systems are now FDA-approved (2022 and 2024), making physiologic feedback a mainstream—rather than investigational—clinical consideration that clinicians must be prepared to evaluate.

3.5 Documented professional-practice and training gaps

- **Practice variation.** Trial-to-permanent conversion rates vary significantly by provider specialty and volume, indicating that outcomes depend in part on modifiable provider factors (Hussaini et al., Neuromodulation. 2017).
- **Training deficit.** Among recent pain fellows, 46% perceived an unmet SCS training need, citing low case volume and lack of curriculum and expert faculty (Pak et al., Reg Anesth Pain Med. 2019). A structured neuromodulation curriculum produced significant knowledge gains across all modules (all $P<0.001$), demonstrating that targeted education closes the gap (Durbhakula et al., Reg Anesth Pain Med. 2023).
- **Consensus call for standardization.** The ASPN Pain Education and Knowledge (PEAK) consensus guidelines concluded that current training requirements have not kept pace with modern neuromodulation advances and proposed standardized competency expectations (Pritzlaff et al., J Pain Res. 2023).

4. Target Audience

Primary audience: Interventional pain physicians (pain medicine, anesthesiology, and physical medicine & rehabilitation) who select, implant, and manage SCS therapy.

Secondary audience: Referring clinicians (primary care, neurology, spine surgery) and advanced practice providers who identify candidates, set expectations, and co-manage patients over the life of the therapy.

5. Educational Objectives

Upon completion of this activity, participants should be better able to:

1. **Differentiate** the mechanisms and pivotal trial evidence for conventional tonic, 10 kHz, burst, DTM, and FAST stimulation paradigms in the management of chronic pain.

2. **Explain** the physiologic basis of ECAP-controlled closed-loop SCS, including the concept of the neural therapeutic window and how closed-loop feedback differs from fixed-output stimulation.
3. **Apply** evidence-based criteria to select an appropriate stimulation paradigm and to optimize patient selection and trialing for an individual patient presentation.
4. **Formulate** a structured approach to recognizing and managing loss of efficacy, including reprogramming and salvage strategies consistent with current NACC recommendations.

Objectives are written with measurable action verbs aligned to Bloom's taxonomy and mapped to the knowledge, competence, and performance gaps identified in Section 2.

6. Outcomes Measurement Plan

Educational outcomes will be assessed using the Moore expanded outcomes framework. The activity is designed to measure through Level 5 (performance), with the components below.

Moore Level	Focus	Measurement method
Level 2	Satisfaction / declarative learning	Post-activity evaluation of relevance, balance, and perceived value
Level 3A/3B	Declarative and procedural knowledge	Paired pre- and post-activity knowledge items on waveform mechanisms, ECAP physiology, and selection criteria
Level 4	Competence	Case-vignette decision items requiring selection of paradigm and a loss-of-efficacy management plan
Level 5	Performance	Commitment-to-change pledge at completion with a follow-up survey (e.g., 60 days) assessing self-reported practice change

Where feasible, results would be aggregated to inform future activities and to document the degree to which the identified practice gap was narrowed.

7. Proposed Educational Intervention

A case-based enduring activity is proposed, structured around two to three patient cases that move from candidate selection through paradigm choice, programming, and management of loss of efficacy. Cases would incorporate decision points with embedded knowledge and competence items, balanced presentation of all FDA-approved therapy classes without commercial bias, and a concise evidence summary aligned to current NACC and ASPN PEAK guidance. The format supports the procedural-knowledge and competence objectives while remaining accessible to the secondary referring-provider audience.

8. Content Validity and Independence

All recommendations would be based on the best available peer-reviewed evidence and current consensus guidance, with balanced presentation across therapy classes and manufacturers. Because nearly all pivotal SCS trials are industry-sponsored, funding sources and author relationships would be disclosed, RCT evidence would be clearly distinguished from registry and real-world data, and cross-trial comparisons would be presented with appropriate caution rather than

as head-to-head conclusions. Content would adhere to the ACCME Standards for Integrity and Independence in Accredited Continuing Education.

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