

American Academy of Pain Medicine Expert Consensus Guideline on Restorative Function Opportunity

Proposed Guideline Title:

Neuromuscular Restoration of Function and Pain Using Neurostimulation, Peripheral Nerve Stimulation, and Brain-Computer Interface Technologies: an American Academy of Pain Medicine Expert Consensus Guideline

Background

Nervous system and muscular system impairments often lead to chronic pain resulting from conditions like stroke, spinal cord injury, neuromuscular impairments, and other neurological disorders. These impairments present significant healthcare challenges, affecting millions of individuals worldwide. Functional restoration of the nervous and muscular systems using neuromodulation technologies offers a promising approach to improve motor function, alleviate pain, enhance quality of life, and reduce disability. “Functional neuromuscular restoration” refers to the use of advanced neurostimulation, peripheral motor nerve stimulation, and brain-computer interface (BCI) technologies to restore or improve motor functions that have been impaired due to neurological disorders, injuries, or diseases. This restoration focuses on enhancing motor control, muscle strength, coordination, and overall functional mobility, thereby allowing patients to regain the ability to perform daily activities. For the purposes of this guideline, the term “neuromodulation” refers broadly to advanced technologies that alter or modulate the activity of neurons in the brain, peripheral nervous system often through electrical means. Given the rapid advancements in neuromodulation, there is a need for evidence-based guidelines to inform clinical practice in restoring muscle function.

Purpose

This guideline aims to provide a comprehensive, evidence-based framework for healthcare professionals, including physicians, physical therapists, payers and neuromodulation specialists. This guideline will assist in the selection, implementation, and optimization of neuromodulation techniques for neuromuscular restoration and pain relief.

Needs Assessment

Nervous system and muscular system disorders often lead to chronic pain and present complex clinical challenges due to their diverse etiologies and manifestations. Traditional rehabilitation approaches often result in suboptimal outcomes. Many traditional therapeutics for pain relief focus on symptom management and not functional restoration. There is a pressing need for innovative therapeutic interventions that can enhance neuroplasticity, reduce pain, prevent deconditioning, and improve functional recovery. Deconditioning, which involves the decline of physical fitness and muscle function due to inactivity or immobility, exacerbates pain and further impedes recovery in patients with neuromuscular impairments. Neuromodulation technologies have shown potential in improving motor function, managing pain, and enhancing overall quality of life for these patients.

Proposed Summary

To address the need for standardization in neuromodulation practices, the American Academy of Pain Medicine (AAPM) Foundation will convene a panel of experts from various disciplines. The panel will conduct a thorough review of the current literature on neuromodulation technologies and objective measurements of neuromuscular restoration as well as pain relief to develop a consensus guideline that integrates clinical evidence with expert opinion. The finalized guideline will be submitted for peer review and publication to *Pain Medicine*, the official journal of AAPM, to facilitate wide dissemination among healthcare professionals.

Example Objective Measurements of Neuromuscular Restoration Using Neurostimulation, Peripheral Nerve Stimulation, and Brain-Computer Interfaces:

- **Electromyography (EMG):** Measures electrical activity in muscles in response to neural stimulation to assess muscle function and control.
- **Gait Analysis:** Assesses and quantifies the effects of neuromodulation and BCIs on walking patterns, providing data on improvements in gait and balance.
- **Functional Movement Scales:** Tools like the Oswestry Disability Index (ODI) and the Numeric Rating Scale (NRS) for pain, which evaluate patient-reported outcomes in terms of pain reduction and disability improvement.
- **Motion Capture Systems:** Capture detailed movement data to analyze joint and muscle coordination during various activities, reflecting neuromuscular improvement.
- **Strength and Endurance Tests:** Use standardized tests such as dynamometry to measure changes in muscle strength and endurance.
- **Quality of Life Assessments:** Instruments like the European Quality of Life Score on Five Dimensions (EQ-5D) measure overall improvements in patients' quality of life and daily functioning.
- **Brain-Computer Interface Performance Metrics:** Measures such as accuracy, speed, and reliability of command execution, as well as the user's ability to control external devices through brain signals.

Possible Technologies for Inclusion in Guidelines

- **Epidural Electrical Stimulation (EES):** Implantation of electrodes over the dura mater of the spinal cord to facilitate voluntary motor control.
- **Functional Electrical Stimulation (FES):** Direct electrical stimulation of muscles to cause contractions and restore movement, particularly in paralyzed muscles.
- **Transcranial Magnetic Stimulation (TMS):** Use of magnetic fields to stimulate specific brain regions involved in motor control and cognitive functions.
- **Vagus Nerve Stimulation (VNS):** Electrical stimulation of the vagus nerve to enhance neuroplasticity and improve motor recovery, often combined with rehabilitation exercises.
- **Peripheral Nerve Stimulation (PNS):** Application of electrical currents to peripheral nerves to alleviate pain and restore motor functions in targeted muscles or limbs.
- **Restorative Neurostimulation Devices:** Devices like ReActiv8 by Mainstay Medical that target specific motor nerves that innervate muscles, such as the lumbar multifidus, for chronic pain management and functional restoration.
- **Robotic Rehabilitation Systems:** Devices such as MIT-Manus and Lokomat that provide precise, repetitive movements to promote motor recovery and neuroplasticity.
- **Brain-Computer Interfaces (BCIs):** Systems that enable direct communication between the brain and external devices, facilitating control over computers, prosthetic limbs, and other assistive technologies through brain activity.
- **Other:** potential inclusion of Spinal Cord Stimulation (SCS) or Transcutaneous Electrical Nerve Stimulation (TENS) to the extent used for restorative or functional purposes (rather than their traditional palliative purposes).

Anticipated Outcomes

1. Development of a comprehensive guideline for the use of interventional neuromodulation technologies in neuromuscular restoration and pain relief.
2. Improved patient outcomes through optimized use of neuromodulation technologies to enhance motor function, reduce pain, and prevent deconditioning.
3. Enhanced clinical decision-making and patient selection processes.
4. Education and training of healthcare professionals on the latest neuromodulation techniques.

Proposed Activities over 14 month period

Phase One: Guideline Development and Delivery (Jan. – Oct. 2025)

1. **Expert Panel Formation:** Assemble a diverse panel of 10-15 experts with experience in neuromodulation, neurology, rehabilitation, pain medicine, and biomedical engineering.
2. **Literature Review:** Conduct a comprehensive review of existing research on neuromodulation technologies, focusing on clinical efficacy, safety, and pain relief.
3. **Consensus Development:** The panel will meet to discuss the findings to produce a comprehensive consensus and expert-led guideline that provides clear recommendations on the use of various neuromodulation technologies for neuromuscular restoration and pain relief.
4. **Validation:** The guideline will undergo a rigorous validation process involving additional experts to ensure accuracy and applicability.
5. **Publication:** Submit the finalized guideline for peer review to *Pain Medicine Journal* by October 15, 2025.

Phase Two: Pain Medicine Peer Review Process (Nov. 2025 - Dec. 2025)

Phase Three: Education/Dissemination (Jan. 2026 – March 2026)

1. **Education and Outreach:** Develop educational materials, CME programming, webinars, and conduct training sessions at PainConnect 2025, national, and international medical conferences.
2. **Online Resources:** Create a dedicated section on the organization's website for guideline access and updates.
3. **Partnerships:** Collaborate across professional medical societies and patient advocacy groups to promote guideline adoption and implementation

Invitation to Participate

The Foundation seeks \$172,415 to fund this program. We've raised \$86,208 to date. Your unrestricted grant will help improve patient access to advanced neuromuscular restoration and pain relief therapies, enhancing patient care and advancing clinical practice.

Benefits of your support will include:

1. Broad distribution of evidence-based guidelines across various fields, increased awareness, opportunities for sharing with insurers, and patient access to necessary restorative and potentially life-altering therapies.
2. Recognition among the consensus panel and their respective organizations.
3. Acknowledgement in the AAPM eNews, sent to AAPM Members and subscribers.
4. Acknowledgment in the AAPM Foundation Annual Report.
5. Acknowledgement on the website painmed.org/the-aapm-foundation/
6. Funding source acknowledgment in the published guideline. Once published, the guidelines can be used as a reference for educational activities.

We look forward to working with you on this impactful initiative and guideline.

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