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ABSTRACT

Objective: Emerging spinal cord stimulation (SCS) remote monitoring and programming technologies provide a unique opportunity to address challenges of in-person visits and improve patient care, although clinical guidance on implementation is needed. The goal of this document is to establish best clinical practices for integration of remote device management into the care of patients with SCS, including remote monitoring and remote programming.

Materials and Methods: A panel of experts in SCS met in July 2022, and additional experts contributed to the development of recommendations after the meeting via survey responses and correspondence.

Results: Major goals of remote SCS device management were identified, including prompt identification and resolution of SCS-related issues. The panel identified metrics for remote monitoring and classified them into three categories: device-related (eg, stimulation usage); measurable physiologic or disease-related (eg, patient physical activity or pedometry); and patient-reported (eg, sleep quality and pain intensity). Recommendations were made for frequency of reviewing remote monitoring metrics, although providers should tailor follow-up to individual patient needs. Such periodic reviews of remote monitoring metrics would occur separately from automatic monitoring system notifications (if key metrics fall outside an acceptable range). The guidelines were developed in consideration of reimbursement processes, privacy concerns, and the responsibilities of the care team, industry professionals, manufacturers, patients, and caregivers. Both existing and needed clinical evidence were covered, including outcomes of interest for future studies.
Conclusions: Given the expansion of SCS device capabilities, this document provides critical guidance on best practices for using remote device management, although medical necessity should drive all remote monitoring decisions, with individualized patient care. The authors also describe the potential of these emerging technologies to improve outcomes for patients with SCS, although more clinical evidence is needed.

Keywords: Chronic pain, reimbursement, remote management, remote monitoring, spinal cord stimulation

INTRODUCTION

Preamble

This manuscript summarizes expert consensus and recommendations for remote spinal cord stimulation (SCS) device management. It is directed to physicians and other healthcare providers, in addition to third party health plans, to provide preliminary guidance on the potential value and implementation of remote device management in the field of SCS, including the recommended frequency of remote follow-up, the limitations of remote device management, methods to address reimbursement issues, the roles and responsibilities of all involved parties, methods to address ethical and privacy issues, and future research needed to support remote SCS device management. Recommendations are based on available literature, the opinions of 15 expert interventional pain physicians and neurosurgeons, and input regarding SCS device remote functionalities from experts in remote monitoring of medical devices. These recommendations are offered with the assumptions that appropriate patient selection, surgical technique, and postoperative care are observed; they are not intended to replace clinical judgment. The care of each patient receiving SCS therapy should be individualized as medically necessary according to the discretion of the healthcare provider.

Spinal Cord Stimulation for Chronic Pain: Unmet Needs

Chronic pain is a prevalent condition in the United States that affects an estimated 20% of adults (50 million), with 8% experiencing high-impact chronic pain. For decades, SCS has been used to safely and effectively treat certain chronic pain conditions and represents an evidence-based alternative to long-term opioid use for chronic pain management. It is estimated that as many as 50,000 patients receive SCS implants for the treatment of chronic neuropathic pain annually.

Despite the widely accepted efficacy of SCS, patients do not always maintain adequate pain relief and might stop responding to the treatment over time. Explant rates reported in the literature range from 6.7% to 23.9%, with loss of efficacy cited as one of the most common reasons leading to explant. In well-executed clinical trials, however, explant rates are low. Recent data from a secondary analysis suggest that the two-year explant rate for loss of efficacy may be as low as 0% to 3% depending on the therapy. One potential reason for superior outcomes observed in clinical trials is response bias, in which patients report better results during in-person encounters than they would report remotely or via an app, owing to factors including environmental cues and the desire to please healthcare providers. Furthermore, increased clinical monitoring and prompt attention to issues during clinical trials may contribute to successful results; therefore, increased monitoring and proactive patient care for the general patient population with SCS may improve the long-term success of SCS therapy in the real-world setting.

Many factors can play a role in incidence of suboptimal SCS outcomes, including patient selection, surgical technique, provider experience, age of the patient, tobacco use, psychological comorbidities, and postoperative patient management. In addition, with most existing SCS systems, device interrogation and programming usually occur during in-person visits. Such visits are likely initiated by patients only once they are dissatisfied with their degree of pain relief, which may render delivering consistent treatment challenging, given daily fluctuations in pain and other SCS-related issues that might occur between office visits (i.e., position-related changes in stimulation). This concept is supported by results from a short-term clinical study that indicated after SCS disruption or cessation, return of pain to baseline levels occurred in <24 hours for most patients. Moreover, in a real-world cross-sectional cohort study, the average wait time for an SCS-related issue to be resolved was more than seven days, and waiting periods led to a negative impact on patient health-related quality of life and increased difficulty managing pain and medication usage. Such wait times between clinical visits may unnecessarily extend periods of suboptimal stimulation, which can increase the complexity of pathophysiology, making it more difficult to treat over time. Furthermore, in-person programming can be time consuming and costly, which can be burdensome to both patients and their caregivers, it may also disrupt the workflow of healthcare practices.

Existing Remote Monitoring Guidance in Cardiology

Recent technological innovations have allowed SCS devices to be programmed and managed remotely. Similar remote capabilities have been used for 20 years in cardiology to monitor cardiovascular implantable electronic devices (CIEDs) to improve routine follow-up and rapidly detect and resolve abnormal device parameters and clinical events, such as arrhythmias. At the outset in the early 2000s, remote monitoring in the cardiac space was in its infancy, with limited published data, which prompted the need for clinical guidance from experts in the field. A 2008 expert consensus addressed this gap by establishing a framework of principles to optimize CIED management and addressed integration of newly available technological advances, including remote interrogation and device data monitoring. Less than a decade later, numerous studies had been conducted to establish the clinical, economic, and patient-specific benefits of remote CIED monitoring and follow-up. Therefore, an updated 2015 consensus publication summarized the body of clinical evidence and issued recommendations for clinical practice guidelines for remote CIED monitoring based on class and level of evidence. That article also described the benefits of remote CIED monitoring, with evidence supporting clinical, economic, and patient-perceived benefits (eg, reductions in mortality, hospitalization, patient travel/transportation costs, and high patient satisfaction).

Similarly to the state of remote CIED monitoring in 2008, remote device management in the field of SCS is in its infancy. As in the case of cardiology, recently available remote capabilities for SCS may provide an opportunity for faster identification and resolution of problems, more consistent optimization of SCS, and improved patient care, while improving efficiency for healthcare providers. Furthermore, the Centers for Medicare & Medicaid Services (CMS)
suggest that healthcare professionals or societies identify patient-centered guidelines that shape the use of remote monitoring devices in clinical practice.23

As such, our goal with this manuscript is to establish recommendations for remote SCS device management, with a focus on medically appropriate follow-up. This publication also will set the stage for developing an evidence-based approach for remote monitoring in SCS, with the goal of determining clear clinical, economic, and patient-specific benefits of remote device management. For ease of reference as a resource and primer, this publication contains our approach (Materials and Methods) followed by standalone recommendation modules (Results/Discussion), with each module supplemented with relevant literature and practical information.

MATERIALS AND METHODS

In July 2022, a panel of experts in the field of SCS convened, and subsequently, more experts were invited to contribute to the content of this document. The authors represent implanting physicians from a variety of practice settings, including academic hospitals, community hospitals, group practices (single and multiple specialties), and solo practices. Authors are recognized clinicians who have served as leaders or officers of key professional societies directly involved in pain medicine and neuromodulation clinical practice and scholarship; they were chosen by the panel cochairs to provide representation across SCS professional societies and practices. Specific meeting objectives were to discuss the following topics:

1. clinical necessity of implementing remote device management in pain and SCS care;
2. current best practices for postimplant follow-up and improvements that might be made using remote device management;
3. clinical evidence needed to support the benefits of remote device management;
4. reimbursement for the use of remote monitoring in SCS, including concerns of overutilization; and
5. implementation of remote device management, including availability of specific capabilities, and the roles of the various stakeholders in this process.

Recommendations detailed in this manuscript are based on the authors’ clinical experiences and skill, owing to the relative lack of previous publications on remote management, and were refined using in-person discussions, survey responses, and correspondence. The in-person discussion was driven by presurvey results (questions developed by the cochairs) in addition to presentations on the remote management of CIEDs, the unmet needs in the field of SCS, the history of remote monitoring reimbursement codes, and the billing requirements for remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) reimbursement. After the in-person meeting, follow-up surveys were distributed to obtain more details on best practices regarding the frequency of monitoring, clinically relevant metrics, which metrics should trigger notification to the care team when outside an acceptable range, the timing for this notification, and reimbursement considerations. All authors contributed to, reviewed, revised, and approved the final manuscript, which represents the consensus recommendations of all authors (in this publication, referred to as the panel).

Definitions
Definitions for key terms are outlined to establish a consistent nomenclature regarding remote device management (Fig. 1).

RESULTS AND DISCUSSION

SCS Device Management Goals
The major goals of SCS device management as developed in this expert consensus process are outlined in Table 1. The panel noted that the overall goal of remote management is not only to reduce the need for office visits but more significantly, to identify new SCS-related issues and reduce response time for prompt resolution with the goal of improving patient outcomes and satisfaction.

In-Person Versus Remote SCS Device Monitoring and Programming Technology
Until recently, device follow-up for all commercially available SCS systems has been limited to in-person data review and programming. Identification of any need for system evaluation between scheduled in-person follow-ups has been limited to patient-initiated communication with the SCS care team about patient-perceived issues. Given recent advancements in SCS technology, the panel considered both in-person clinical workflows and potential improvements that could be made using newly available or hypothetical capabilities in remote data monitoring and remote stimulation programming.

In-Person: SCS Device-Collected Data and Device Programming
SCS-related data review and programming are mostly conducted during an in-person patient programming session with a healthcare provider and/or device manufacturer representative. During the in-person follow-up session, a clinician programmer device (usually a tablet or laptop) is used to establish a connection with the pulse generator through wireless communication, such as Bluetooth or radiofrequency (RF) telemetry. This connection is used to view device diagnostics and to review, change, and test stimulation parameters.

SCS device data collected for in-person review among currently available systems are detailed in Table 2. These data points are viewed and managed by healthcare providers and device manufacturer representatives and are coupled with patient feedback to inform therapy parameter reprogramming/adjustments and/or other steps in therapy optimization.

After in-person SCS device programming, the patient leaves the session with one or more program options available and typically has a patient programmer device for use outside the clinic, which allows the patient to control a subset of stimulation settings. All currently marketed SCS systems give the patient the ability to turn the device on or off and to adjust between programs and amplitudes. Some SCS systems give the patient the ability to adjust the amplitudes or the balance of amplitudes of individual stimulation trains within a program or by changing the active electrodes. More recent programming methods seek to use patient-reported outcomes and algorithms to preselect the SCS program(s) most likely to provide pain relief. In some cases, device manufacturer representatives or healthcare providers can provide the patient remote guidance via a telephone call in lieu of an in-person clinic visit. They can instruct the patient on specific changes to make within preprogrammed settings using the patient programmer device; however, these services do not allow parameters to be adjusted remotely via a company representative or clinician.
a Remote Monitoring of Metrics

Remote Monitoring
A coordinated system that uses a medical device or separate technology (e.g., smart phone application) to transmit encrypted data or information, either automatically or patient-reported, to a remote-secure monitoring center or file server.

Patient

Remote Monitoring Portal

Healthcare Provider

Industry Employed Allied Professionals

Metrics
Remote data that are:
- Automatically collected by the medical device (e.g., stimulation usage, patient activity), or
- Self-reported by the patient/caregiver (e.g., pain scores, sleep quality)

Figure 1. Definitions relevant to remote device management. Key terms are illustrated for remote monitoring (panel a) and the patient care timeline (panel b). Icons on the timeline indicate example occurrences of each activity over the course of patient follow-up. Interrogation and programming can occur either remotely or in person as needed depending on device technology. HCP, healthcare provider.

b Patient Care Timeline

Remote Monitoring
Remote monitoring is automatically conducted daily.

Data review by HCP (periodic)
Metrics (from remote monitoring) are reviewed by a healthcare provider to manage a patient's chronic or acute medical condition.

Notification (as needed)
Message to healthcare provider if a metric falls outside of a pre-determined normal range (may be configurable) with the purpose of triaging patients and drawing the attention of a healthcare provider.

Interrogation (interval)
Retrieval of stored SCS device information to assess the functional status of the medical device.

Programming (as needed)
A non-invasive, stable, reversible change to available operating parameters of the SCS system to tailor parameters to meet the individual patient's condition and optimize system performance and longevity.

Remote: SCS Device-Collected Data and Patient-Reported Data
Different types of data metrics relevant to SCS therapy have the potential to be remotely monitored (Fig. 1). The panel categorized metrics into three types: device-related, physiologic or disease-related, and patient-reported. Device-related and physiologic or disease-related data are automatically collected and transmitted. In contrast, patient-reported data depend on entry by the patient and/or caregiver and as such require active engagement and compliance for optimal use.

To our knowledge, only one manufacturer has the capability for daily remote SCS device data monitoring (BIOTRONIK SE & Co KG, Berlin, Germany; Table 3). Using the Biotronik platform, SCS device data are automatically transmitted daily to a web portal for review by manufacturer representatives and/or healthcare providers, as described by Verrills et al and Russo et al.10–32 The device data for remote monitoring review are detailed in Table 4. Criteria can be defined and customized for the individual patient to trigger attention from the patient’s care team (presented in Fig. 1b and Notifications section later).

In addition to the viewing and management of SCS device data, some SCS device manufacturers listed in Table 3 have developed platforms for remotely collecting and reviewing patient-reported metrics (Table 4). Patient-reported data can be viewed remotely through a web portal after the patient and/or caregiver enters the data into a mobile application.

In addition to what is currently available with SCS systems capable of remote device management, the consensus panel identified metrics that may be clinically relevant to monitor remotely but are currently either hypothetical or must be calculated from existing measurements. These metrics are detailed in Table 5.

Remote: SCS Device Programming
Recent advancements have introduced the ability for manufacturer representatives or healthcare providers to perform SCS
programming remotely (Fig. 1b). Two manufacturers currently offer this capability through digital systems: Abbott (Austin, TX)\(^{33,34}\) and Biotronik\(^{30}\) (Table 3). For both systems, direct Bluetooth or RF telemetry connection is not required for the clinician programmer; rather, the clinician programmer and patient programmer are in communication via internet or cellular connections, and the patient programmer remains in communication with the SCS device. All solutions allow the user of the clinician programmer device to modify stimulation program parameters in the patient’s system with protections in place for the security of the connection. In contrast to the patient making limited stimulation adjustments through the patient programmer, remote programming allows an expert in SCS programming to directly configure program options for the patient, with access to the full range of programming settings that are available during an in-office follow-up.

### Table 1. Key Goals of SCS Device Management.

- Monitor patient response to SCS therapy
- Maximize device longevity
- Identify and quickly resolve any SCS device issues
- Identify patients who need assistance in managing their device
- Identify other health issues so that the patient is appropriately referred for management
- Optimize patient’s quality of life
- Optimize device function
- Optimize neurostimulation parameters
- Optimize physiologic function
- Document SCS function and patient symptoms over time
- Improve ease of use
- Decrease time and financial burden for patients and/or caregivers
- Increase efficiencies for the healthcare practice
- Streamline device representative programming time management
- Improve patient and clinician satisfaction

### Table 2. Spinal Cord Stimulator Device Data Collected for In-Person Review Among Currently Available Systems.\(^{26-29}\)

<table>
<thead>
<tr>
<th>Description</th>
<th>Data metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulation program parameters</td>
<td>• Present status of:</td>
</tr>
<tr>
<td></td>
<td>o electrode configuration</td>
</tr>
<tr>
<td></td>
<td>o amplitude</td>
</tr>
<tr>
<td></td>
<td>o pulse width</td>
</tr>
<tr>
<td></td>
<td>o frequency</td>
</tr>
<tr>
<td></td>
<td>• Changes made during programming</td>
</tr>
<tr>
<td></td>
<td>sessions</td>
</tr>
<tr>
<td>Stimulation usage</td>
<td>• On/off status (present status and usage trends)</td>
</tr>
<tr>
<td></td>
<td>• Program selection (present status and usage trends)</td>
</tr>
<tr>
<td>Battery usage</td>
<td>• Present state of charge</td>
</tr>
<tr>
<td></td>
<td>• Recharging trends</td>
</tr>
<tr>
<td>Lead status</td>
<td>• Impedance (present status and historical trends)</td>
</tr>
<tr>
<td></td>
<td>• Position of implanted leads</td>
</tr>
<tr>
<td>ECAP feedback</td>
<td>• Percentage of time:</td>
</tr>
<tr>
<td></td>
<td>o ECAP is maintained</td>
</tr>
<tr>
<td></td>
<td>o closed loop vs open loop</td>
</tr>
<tr>
<td>Patient physiologic data</td>
<td>• Posture trends</td>
</tr>
<tr>
<td></td>
<td>• Activity trends</td>
</tr>
<tr>
<td>ECAP, evoked compound action potential.</td>
<td></td>
</tr>
</tbody>
</table>

### Table 3. Manufacturers With Remote Monitoring and/or Programming Capabilities.\(^*\)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Remote monitoring</th>
<th>Remote programming</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Device-collected</td>
<td>Patient (or caregiver)-reported</td>
</tr>
<tr>
<td>Biotronik</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Abbott</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Medtronic</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Nevro</td>
<td>✔</td>
<td></td>
</tr>
</tbody>
</table>

\(^*\)As of April 2023.

Clinical Evidence for Remote Monitoring and Remote Programming in SCS

As described above, remote monitoring enables the detection of SCS-related issues and resolution via appropriate interventions, such as remote reprogramming or scheduling of an in-person clinic visit. Remote programming can occur as the result of findings from remote device monitoring and can enable prompt resolution of SCS-related issues. Clinical evidence, although limited, supports the potential benefits of remote monitoring and programming.

Remote monitoring capabilities can include collection of patient-reported outcomes through wrist-worn electric diaries or smartphones. For example, an electronic diary has been used in studies of SCS.\(^{35-37}\) and digital mobile applications have been used to assess treatment effectiveness.\(^{39}\) More extensive capabilities, however, include remote device monitoring that can be used to guide remote SCS device management and programming. To our knowledge, the only study to date evaluating these remote device/therapy management capabilities is an ongoing two-year study (NCT04683718). Interim three-month results from that study showed that remote monitoring detected 47 events that qualified as a predefined proactive care alert (eg, therapeutic window [amplitude used], charging compliance, low device usage) in 19 of 30 implanted participants (63%).\(^{31}\) These proactive care alerts enabled rapid identification of potential SCS issues, which were resolved faster than during standard in-clinic follow-ups.\(^{18}\) Furthermore, 93% of participants (27 of 29) reported feeling reassured that their stimulator and pain levels were routinely checked.\(^{31}\) Given the current paucity of clinical trials for SCS systems with remote management capabilities, expert opinion is needed to outline initial recommendations for the implementation of remote monitoring in clinical practice and to determine the future research needed to establish its currently potential benefits to patients, clinicians, and payers in the field of SCS.

Studies in remote programming in SCS are limited, but the intervention has shown promise in patient care. In one study, Lu et al evaluated a remote SCS reprogramming platform in patients with chronic intractable pain during the COVID-19 pandemic.\(^{39}\) After a successful trial and permanent implant, 13 of 16 patients required remote programming for optimization, and improvement was achieved in 92.3% of cases. Moreover, 69% of patients reported that remote SCS programming was user-friendly and met their needs. Authors concluded that the remote reprogramming system could be used to safely and effectively deliver SCS therapy...
<table>
<thead>
<tr>
<th>Data source</th>
<th>Description</th>
<th>Limitations</th>
<th>Example data metrics$^{\dagger}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device-Collected Data*</td>
<td>Device-related</td>
<td>Completeness of data depends on device system capabilities (eg, frequency of device monitoring by system, and overall daily transmission rate)</td>
<td>• Stimulator battery state of charge</td>
</tr>
<tr>
<td></td>
<td>Objective device data that can be automatically collected by the device system and transmitted with up to daily resolution to a web-based portal for review or further analysis</td>
<td></td>
<td>• Stimulation usage (percentage of time ON/OFF and which program used)</td>
</tr>
<tr>
<td></td>
<td>Physiologic/disease-related</td>
<td>Patient compliance with use of wearable/external sensor (if not integrated into device system)</td>
<td>• Lead impedances</td>
</tr>
<tr>
<td></td>
<td>Objective biometric data that can be automatically collected by the device system (or via external sensors)</td>
<td></td>
<td>• Stimulation program parameters (eg, summary of changes to programs/parameters)</td>
</tr>
<tr>
<td>Patient (or caregiver)-reported data</td>
<td>Data reporting health status, quality of life, or functional status, collected directly from patient (or caregiver)</td>
<td>Patient compliance with manual completion of PRO instrument</td>
<td>• Average charging duration/interval</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient physical activity or pedometry (eg, step quantity collected by a wearable device application)</td>
</tr>
</tbody>
</table>

NRS, numerical rating scale; PRO, patient-reported outcome.

*Data are collected from the SCS device or wearable (ie, any sensor/measurement tool external to the implanted device system). Depending on SCS system technology, data can be automatically transmitted daily to a web portal for review by manufacturer representatives and/or healthcare providers.

$^{\dagger}$Metrics can be remotely monitored with commercially available SCS systems and supporting software.
adjustments, thus improving patient quality of life. In a recent pilot study by Deer et al., 16 patients with chronic pain who were implanted with dorsal root ganglion or SCS devices were surveyed to assess the effectiveness of a teleprogramming system. All surveyed patients (16 of 16) reported quick pain resolution, and nearly all patients (15 of 16; 93.8%) preferred remote programming over in-person adjustments. Only one patient required in-person follow-up to address their therapy needs. Finally, three-month interim surveys were available for 24 participants with implants; clinicians would save them money by reducing travel burden. Clinician reporting at least as often as an interval preselected by the physician for patient-reported metrics, the recommended frequency of following to the unique needs of their patients.

**Recommended Frequency of Remote SCS Device Follow-up**

With the advent of remote SCS monitoring and programming capabilities, guidance is needed to establish best practices for remote device management, including the frequency of accessing and reviewing remote data metrics, in addition to ways these data are to be interpreted and acted upon. The following consensus recommendations represent general ranges and are intended to establish a framework for providing a medically appropriate level of care. Healthcare providers should always tailor the content and frequency of follow-up to the unique needs of their patients.

**Frequency of Periodic Remote Monitoring Data Review**

The recommendations on the frequency of accessing and reviewing remote monitoring data are provided under the condition that the SCS device is apparently functioning well, without the presence of notifications informing the care team of device- or patient-related issues (Fig. 1b). Assuming remotely acquired data are automatically available daily for device-related and physiologic or disease-related metrics, and that a patient is compliant with reporting at least as often as an interval preselected by the physician for patient-reported metrics, the recommended frequency of accessing and reviewing remote monitoring data for a typical patient with SCS (eg, stable, >one year after implant) is outlined in Figure 2.

However, certain patient types and clinical scenarios (eg, three months after implant, during an SCS trial, in case of an acute event) may warrant more frequent review of remote monitoring data than that of a typical patient with SCS to ensure there is no gradual loss of efficacy (Fig. 3a). For other patient types and clinical scenarios, reviewing remote monitoring data as frequently as for a typical patient with SCS may be appropriate (Fig. 3b).

**Notifications**

Some SCS device technologies have the capability for daily evaluation of device parameters transmitted to a database (Person Versus Remote SCS Device Monitoring and Programming Technology section), which can be evaluated against acceptable parameter ranges configured by the healthcare provider. An acceptable range may be customized for individual patients. Notifications may be indicated in the monitoring system interface (Fig. 1b), which can be configured to distribute notifications to the healthcare provider, patient, or industry representative.

Upon receiving a notification based on remote monitoring data, the care team should access, review, and assess the device and/or patient-reported data. Depending on the assessment, it may be

| Table 5. Hypothetical Remote Monitoring Metrics of Potential Clinical Relevance. |
|-----------------------------|------------------|
| **Description**            | **Data metrics** |
| **Device-related**          | • Stimulation amplitude within a clinically determined range for pain relief or based on ECAP feedback (ie, therapeutic window status) |
|                             | • Time within stimulation amplitude range |
| **Physiologic/disease-related** | • Exercise duration (ie, % time with high activity) |
|                             | • Gait (eg, step speed, step length, step asymmetry etc) |
|                             | • Posture/postural changes (derived from accelerometer; eg, time spent standing, lying, and/or spinal position assessment) |
|                             | • Walking steadiness (calculated from gait metrics, indicates risk of falling) |
|                             | • Sleep quality (derived from nighttime movement/activity) |
|                             | • Temperature |
| **Patient-reported**        | • No. of d/wk with well-controlled pain (eg, NRS ≤3) |
|                             | • No. of painful d/wk (eg, NRS ≥7) |

Metrics in Table 5 were those deemed potentially clinically relevant by the authors but are currently hypothetical or must be calculated and cannot be remotely monitored with commercially available SCS systems and supporting software.

ECAP, evoked compound action potential; NRS, numeric rating scale.
appropriate for the care team to initiate a remote follow-up visit, which could include programming adjustments. This follow-up is separate from the periodic remote monitoring data review recommended above for a typical patient with SCS in the absence of notifications.

For optimal patient care, the remote monitoring system should be continuously monitoring device-related and physiologic or disease-related metrics, and the care team should be notified when a metric has fallen outside an acceptable range and respond quickly to these notifications. Similarly, the care team should be notified if a subjective metric reported by either the patient or caregiver falls outside an acceptable range. Although notifications for any of the remote monitoring metrics described in this publication may provide clinical value, the panel members strongly agreed that it was important to be notified if metrics outlined in Table 6 fall outside an acceptable range. Additional notifications that may require follow-up include poor sleep quality, stimulation amplitude outside the expected range, and missing daily device transmissions.

**Limitations of Remote Device Management**

Despite the potential benefits of remote device management for improving SCS outcomes, the panel also identified several limitations of the technology and potential mitigation strategies. Remote SCS device management is subject to technical limitations (eg, reliance on cellular network connectivity and/or Wi-Fi access). Furthermore, patients, caregivers, and healthcare providers might lack familiarity with the technology, which could lead to suboptimal use of the system.

In many settings, remote SCS device management will not replace in-person visits but instead complement them. If an SCS-related problem persists despite optimization through remote follow-up, an in-person clinic visit should be scheduled. If remote monitoring

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**Figure 2.** Recommended frequency of providers reviewing remote monitoring metrics for a typical patient with SCS (in the absence of issue notifications). An example of a typical patient would be a stable patient one year after implant.

**Figure 3.** Recommended frequency of reviewing remote monitoring data for different clinical scenarios vs a typical patient with SCS (eg, a stable patient one year postimplant). Shown are example patient scenarios that may require more frequent review (panel a) or no change in review frequency (panel b). Other scenarios for which it might be reasonable to review remote monitoring data more frequently include suspected patient noncompliance with therapy, absence at scheduled in-person appointments, and after a surgical procedure or hospital admission. *Although most authors indicated no change in frequency of accessing/reviewing remote monitoring data for this patient type was necessary, some felt that it should be monitored more frequently than for a typical patient with SCS. **Although most authors indicated no change in frequency of accessing/reviewing remote monitoring data for this patient type was necessary, some felt that it should be monitored less frequently than for a typical patient with SCS.*
activities lead to identification of a new pain issue that is unrelated to the SCS device (eg, pain in a new area, a change in the pain condition), further evaluation including possible in-clinic follow-up should be initiated. Overall, using remote SCS device management will enhance the efficiency and productivity of in-person visits by providing focused rationale and supporting data before the visit.

Patient compliance with regularly recording patient-reported metrics (eg, functional assessments, pain intensity, sleep quality) is a potential challenge. Some patients and/or caregivers might lack the motivation to routinely record patient-reported metrics owing to the perceived burden of such activities, which would limit the accurate and timely assessment of these subjective metrics by a care team or industry representative. This reinforces the importance of education for patients and caregivers on the role and potential value of patient-reported metrics to inform remote device management. The provision of incentives (eg, fewer in-person visits, graphics tracking patient progress) may be one strategy to increase compliance with the submission of patient-reported outcomes. However, a limitation to subjective patient-reported data collection is that it is dependent on the patient’s ability to accurately report outcomes such as pain and sleep quality. Some patients might have psychiatric conditions, cognitive issues, or other challenges that limit their ability to reliably report such data. In these patients, the care team may engage the caregiver to assist with the input of these metrics on the patient’s behalf or rely primarily on the objective monitoring of device-related and physiologic or disease-related metrics obtained from the device.

Reimbursement Considerations

In clinical practice, accessing, evaluating, and acting upon remote monitoring data require the time and financial resources of physicians and their care team. Therefore, the panel noted the importance of reimbursement for remote patient monitoring, which is designed to offset these costs and incentivize the adoption of services considered valuable to patients and the healthcare system. Regulatory groups and payers recognize the benefits of remote monitoring in healthcare; the American Medical Association (AMA) has led efforts to develop a framework to integrate both telehealth and remote patient monitoring into clinical practice, beginning with its first policy statement on the topic in 2010. The bundling approach in remote patient monitoring to improve the delivery of care for patients with chronic health conditions. As new technologies and applications develop, we expect these codes to be refined and perhaps new codes proposed, to accommodate the type of devices used to collect and transmit data.

Of note, RTM codes are limited to health conditions related to the respiratory or musculoskeletal systems. If the work performed by the physician’s office meets applicable code requirements, clinically relevant remote monitoring of SCS devices and patients with SCS may be considered eligible for RPM or RTM reimbursement.

Physicians managing patients with SCS devices capable of remote management should access and review remote monitoring data and have a subsequent patient interaction as often as medically necessary (presented in Recommended Frequency of Remote SCS Device Follow-Up section). If a physician chooses to bill for a remote monitoring service, proper documentation and compliance with current billing requirements are critical (Supplementary Appendix presents more resources). Billing for remote monitoring services should not occur in the absence of clinical applicability, relevant clinical decision making by the provider reviewing the remotely acquired data, or more frequently than allowed by CMS and other payers. The frequency of accessing and reviewing remote monitoring data and subsequent billing may depend on patient-specific factors and timing of the implant (eg, monitoring and billing may occur more frequently during the first six months after implant). Quarterly review of remote monitoring data and subsequent billing may be a reasonable approach, in addition to whenever the information is acted on by the care team. However, if a more frequent review (ie, monthly) is required, it is suggested that an in-person clinic visit and physical examination be performed to assess for other confounding factors. The panel suggested that concern with payer scrutiny, patient copays, and the type of data reviewed were factors to be considered when deciding whether and how often to bill for remote monitoring activities.

The burgeoning field of remote device management in SCS has the potential to optimize patient care. As with any new technology, the implementation of remote SCS device management into clinical practice will require time, effort, and financial resources. Reimbursement for remote device management is designed to offset these costs and incentivize potentially beneficial services, though there are limitations associated with the current reimbursement structure in the context of SCS. First, current remote monitoring codes are not specifically designed for patients.

Table 6. Key Remote Monitoring Criteria That Should Trigger Notifications to the Care Team.

<table>
<thead>
<tr>
<th>Device-related</th>
<th>Physiologic/disease-related</th>
<th>Patient-reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low battery charge</td>
<td>In frequent patient activity</td>
<td>Increased pain intensity</td>
</tr>
<tr>
<td>Lead impedance out of range on a contact used in an active stimulation program</td>
<td></td>
<td>Low patient satisfaction</td>
</tr>
<tr>
<td>Low stimulation usage</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
receiving SCS therapy. Next, data review might vary in complexity on the basis of the clinical scenario and require additional time and resources; however, reimbursement is not currently stratified on the basis of the complexity of the monitored item or subsequent patient interaction. As such, the time, resources, and need for additional staff to support remote device management services for patients with complex conditions might outweigh the reimbursement received. Finally, some clinical practices might lack the infrastructure and resources needed to support a comprehensive remote monitoring system. At the time of this writing, CMS and commercial payers have issued minimal guidance on using these codes, but it is anticipated that the codes will be updated and expanded to address new digital technologies and functionalities and meet the needs of healthcare providers who elect to use the codes. On November 1, 2022, CMS published the 2023 Physician Fee Schedule final rule that includes updates and policy changes for Medicare payments under the rule effective on or after January 1, 2023. In the final rule, CMS clarified that RTM may be furnished by auxiliary clinical staff under general supervision, provided that the other requirements for “incident to” services are met. CMS noted that clinician stakeholders expressed concern about the lack of clear guidance on the billing and documentation requirements of the RTM code set. Although CMS did not take any action based on this feedback, the agency stated that there may be further refinements issued in future rulemaking cycles.

As remote SCS device management services become increasingly available, feedback from the care team will be critical to ensure an adequate reimbursement structure for clinically relevant remote monitoring activities.

Roles and Responsibilities

The panel agreed that it is important to identify the roles and responsibilities of each of the key stakeholders to ensure effective remote SCS device management. However, individual practices vary significantly, and therefore, these roles may differ depending on practice-specific factors. This section outlines basic roles and responsibilities of various stakeholders proposed by the panel for the implementation of remote SCS device management.

Physician/Care Team

Before integrating remote monitoring services into a practice, healthcare providers should consider their practice capabilities and design a workflow to match their clinical practice settings. A specific plan should be in place outlining the expectations and roles of the clinic staff, including a defined process for handling urgent notifications after normal hours of operation and on weekends, before implementing remote device management. Practice dynamics relevant to implementing remote monitoring include the availability of support staff, access to technology compatible with remote device management platforms, security requirements, and appropriate training processes.

In addition, the care team should provide patient education on the goals and potential benefits of remote device management and ensure informed patient consent is obtained (Ethics and Privacy Considerations section). Limitations of remote management also should be made clear to patients to avoid risk of overreliance on the automatic aspects of issue detection and notification. For example, patients should still be cognizant of typical signs and symptoms or conditions that they need to report to their care team, such as signs of infection or changes in pain areas.

A critical responsibility of healthcare systems and clinicians is to understand and comply with the legal requirements for billing RPM and RTM codes. As CMS guidance changes, physicians and the care team should assume responsibility for maintaining current knowledge of billing requirements.

Patients and Caregivers

Patients implanted with devices capable of remote SCS management should set goals for themselves and define what they want to achieve through remote SCS device monitoring. To the

<table>
<thead>
<tr>
<th>Remote Physiologic Monitoring Codes (effective 1/1/2019)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used to report monitoring/review of patient physiologic parameters (e.g., weight, temperature, blood pressure, pulse oximetry)</td>
</tr>
<tr>
<td>• Classified under Evaluation and Management Codes</td>
</tr>
<tr>
<td>• Data must be automatically uploaded by the device</td>
</tr>
<tr>
<td>• Not limited by body system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remote Therapeutic Monitoring Codes (effective 1/1/2022)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used to report monitoring/review of non-physiologic parameters (e.g., musculoskeletal or respiratory system status, therapy adherence or response)</td>
</tr>
<tr>
<td>• Classified under General Medicine Codes</td>
</tr>
<tr>
<td>• Data can be automatically uploaded or self-reported by the patient</td>
</tr>
<tr>
<td>• Limited to respiratory/musculoskeletal health</td>
</tr>
</tbody>
</table>

Same Requirements

- Must meet FDA definition of a medical device
- Data collected for a minimum number of days per monthly billing period
- Data interpretation codes are time-based and require direct patient interaction
- Episode of care begins when remote monitoring service initiates and ends with attainment of targeted treatment goals

Figure 4. Remote physiologic and remote therapeutic monitoring codes.
greatest extent possible, patients should be engaged with their therapy plan, including the submission of patient-reported outcomes. Similarly, patients should play an active role in the education process, including understanding informed consent for remote monitoring and asking questions as applicable. In the event of a change in contact information (e.g., phone number or address), the patient should notify the care team as soon as possible to ensure seamless communication and care.

Caregivers of patients with SCS also should play an active role in the education process by reviewing educational materials with the patient and asking questions as appropriate. For caregivers of patients with cognitive issues or a limited ability to report subjective metrics, caregivers should assist with the reporting of patient-related remote monitoring metrics as appropriate. Caregivers also could play a role in helping to define the role of and set realistic expectations for SCS therapy to patients.

Industry-Employed Allied Professionals

Industry-employed allied professionals (IEAPs) are employed by the SCS device manufacturer and have expertise in SCS device technology. Roles of the IEAP are to perform timely data review, understand the criteria for patient contact and referral to the care team, reprogram the SCS device as appropriate, either in person or remotely, and provide technical support to the patient and/or care team (Fig. 1a).

Manufacturers

A key role of SCS manufacturers is to educate physicians and the care team on remote device management and the logistics of their platform to ensure safe and optimal use. Medical device manufacturers must remain vigilant to identify risks and hazards associated with their connected medical devices, including cybersecurity (Ethics and Privacy Considerations section). If an SCS company is going out of business or for any other reason discontinues the sale of their product, the company should ensure that patients with implants and their managing clinicians know how to address future issues and what resources will and will not be available to them. Similarly, SCS manufacturers should establish patient- and device-tracking data collection systems to help identify when a patient moves or leaves a practice, to help prevent interruptions in remote care.

Ethics and Privacy Considerations

Although remote SCS device management may provide an opportunity for patients to engage more with therapy and potentially improve outcomes, the remote monitoring of patient health data poses privacy and cybersecurity challenges that were considered by the panel.

Privacy and security should be maintained for remote monitoring data as protected health information, in accordance with state and federal laws, such as the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act. Medical necessity is a prerequisite for accessing and reviewing a patient’s SCS remote monitoring data. When a care team member or other stakeholder accesses data, they should limit their review to information that is relevant to providing optimal patient care.

Healthcare providers should be responsible for educating patients on privacy and cybersecurity risks involved with remote SCS device management, including a discussion of risks, benefits, and protective measures in place. However, a recent survey of 70 neuromodulation clinicians found most have limited knowledge on the cybersecurity risks associated with implantable medical devices, and few reported discussing device cybersecurity with their patients.55 Given these considerations, there is a need for continuing healthcare provider education on ethics and privacy issues to ensure the adequacy of physician-patient discussions about details such as personal data storage, use, and any potential risks. These physician-patient discussions can facilitate the obtaining of meaningful patient informed consent for remote SCS device management services.

Manufacturers should incorporate systems ensuring patient privacy and cybersecurity into SCS devices with remote management capabilities. Potential threats to cybersecurity must be identified and steps taken to mitigate these risks (eg, data encryption, password protection), as with remote management of medical devices in other therapeutic areas. Manufacturers are obligated to report any cybersecurity issues to the FDA; healthcare providers and patients also should report any suspected cybersecurity issues to the FDA using MedWatch voluntary report forms for health professionals and consumers/patients, respectively.

As remote SCS device management becomes more common in clinical practice, each of the key stakeholders should remain vigilant about cybersecurity issues to protect patient privacy.

Future Research

Because there are few published studies describing effects of remote SCS device management on chronic pain outcomes, the panel agreed that more evidence is needed to establish its value and impact to patients, caregivers, healthcare providers, and payers. Although the large volume of data gathered from remote device monitoring will require proper storage and management, it affords the opportunity to provide ever-increasing data sets to inform future analyses.

Prospective observational studies and randomized controlled trials can establish the potential benefits of remote device management. In addition, economic studies can directly evaluate the cost effectiveness of remote device management in SCS, although these tend to require more patients and longer study intervals. Table 7 summarizes outcomes that may be useful to assess the effects of remote device management in future SCS research.

The long-term advantages of remote monitoring of data collected by the device versus remote monitoring of patient or caregiver-reported metrics remain not known. However, given the remote monitoring of device and physiologic or disease-related metrics is objective and less labor-intensive for patients, future studies can assess the comparative value of different types of remote monitoring data capture. Moreover, remote monitoring of SCS devices has the potential to provide accurate assessments of patient adherence to therapy. Such information collected across large patient populations (eg, using registries) may help predict the long-term response to SCS, thus potentially optimizing patient selection and clinical outcomes.

As the use of remote SCS device management becomes increasingly common in clinical practice, stakeholders will gain more insight into evidence gaps, leading to future studies and improvement. Using remote monitoring of CIEDs as a predicate for SCS, it is possible that future research will promote the integration of remote SCS device monitoring as best practice by establishing clinical and economic benefits.
**Table 7. Outcomes of Interest for Future Studies of Remote SCS Device Management.**

- Loss of efficacy
- Opioid use (PMP records, pill counts, no. of refills)
- Functional outcomes
- Healthcare utilization (eg, emergency room visits, total cost of care)
- Patient satisfaction (eg, pain relief, meeting goals, PGIC)
- Stimulation usage (percentage of time ON/OFF)
- Overstimulation/Therapeutic window
- Understimulation
- Explant and virtual explant rates
- Sleep quality
- Clinical event detection rate
- Pain intensity

PGIC, patient global impression of change; PMP, prescription monitoring program.

**CONCLUSIONS**

As device capabilities expand, providing guidance on best practices for utilization of remote management of SCS devices for chronic pain is critical. This document attempts to provide the first guidance on this topic by providing a consensus view of the current direction of remote monitoring for patients who undergo SCS and by outlining future considerations. Recommendations, however, will evolve over time to address new technical innovations and changes in governmental and payer policy.

Clinician judgment and advancing technology drive the need to change standard practice; many clinicians adopt a multitude of workflows for different patient needs. The cadence of patient follow-up is multifactorial, and the course of device analysis for each patient with an implant is iterative and founded on medical necessity. In the clinical instance in which remote SCS device management is deemed medically necessary, a compliance plan detailing the proper protocol for adhering to all regulatory requirements should be followed.

As seen previously with remote management in the field of cardiology, remote monitoring for SCS is progressing, and more data are needed to further define the role of this technology in the future. The consensus panel concluded that the best methods to achieve this goal are to use large registries based on long-term big data and conduct prospective studies evaluating the effects of remote SCS management on patient care. Although more evidence will be required, the authors’ shared consensus is that remote device management provides an opportunity to improve patient care in both clinical outcomes and healthcare utilization.

**Acknowledgements**

Writing and editorial assistance were provided by Prescott Medical Communications Group (Chicago, IL), a contractor of BIOTRONIK.

**Authorship Statements**

Peter Staats and Timothy R. Deer cochaired the panel. Peter Staats, Timothy R. Deer, Robert M. Levy, Sean Li, David Dickerson, Erika Petersen, Leonardo Kapural, and Shravani Durbhakula attended the in-person meeting. All authors discussed best practices, reached consensus on recommendations, and reviewed and approved the final manuscript.

**Conflict of Interest**

Peter Staats has received consulting and research grants from Medtronic, Boston Scientific, Nevro, Abbott, Biotronik, Nalu, Saluda, and Vertos, receives royalties from Averitas, and is the founder and CMO of electroCore. Timothy R. Deer is a consultant for Abbott, Saluda, Nalu, and Medtronic, a research investigator for Abbott, Saluda, and Mainstay, has stock options with Saluda and Nalu, and has a patent pending with Abbott for dorsal root ganglion surgical leads. Corey Hunter has consulted for Abbott, Biotronik, Mainstay, Nalu, PainTEQ, Saluda, and Vertos, served as a research investigator for Abbott, Saluda, Biotronik, Mesoblast, Discogenics, Vivex, TissueGene, FusMobile, Averitas, and Mainstay, and has stock options with Mainstay, Nalu, PainTEQ, Vivex and Vertos. Sean Li has consulted for Nevro (research grant), Boston Scientific (research grant), Saluda (research grant), Abbott, Avanos (research grant), Vertos, Nalu (research grant, shareholder), PainTEq (research grant), Averitas Pharma (research grant), SPR Therapeutics (research grant), and Biotronik (research grant), has received a research grant from SGX Medical, and has served on advisory boards for Saluda and Vertos and on a speaker bureau for SciLex Pharma. David Dickerson has received speaking and consulting fees from SPR Therapeutics (research grant), Pfizer, Myovant, Abbott (research grant), Vertos, Nalu, and Biotronik. Erika Petersen has received research support from Mainstay, Medtronic, Nalu, Neuros Medical, Nevro Corp, ReNeuron, SPR, and Saluda, in addition to personal fees from Abbott Neuromodulation, Biotronik, Medtronic Neuromodulation, Nalu, Neuros Medical, Nevro, Presidio Medical, Saluda, and Vertos. She holds stock options from SynerFuse and neuro42. Leonardo Kapural has consulted for Nevro, Abbott, Medtronic, Nalu, Saluda, and Biotronik and participated in research for Nevro, Medtronic, Giner Medical, Neuros, Saluda, Biotronik, and SPR Therapeutics. Shravani Durbhakula has consulted for Averitas Pharma. She is a shareholder of Patient Premier, Inc. Christopher Gilligan is the editor-in-chief of *Pain Practice* and has consulted for Mainstay Medical, Saluda, Persica, and Iliad Lifesciences. Konstantin V. Slavin reports institutional grants and consulting income from Medtronic, Abbott, Boston Scientific, Neuros, Integer, Biotronik, and WISE, and minor ownership of Neuramodix, Thermaquill, Vycor Medical and Higgs Boson. Jason Pope serves as a consultant for Abbott, Medtronic, Saluda, Flowonix, SpineThera, Painteq, Vertos, VertiFlex, SPR Therapeutics, Tersera, Aurora, Spark, Ethos, Biotronik, Mainstay, WISE, Boston Scientific, and Thermaquill and has received grant and research support from Abbott, Flowonix, Saluda, Aurora, Painteq, Ethos, Muse, Boston Scientific, SPR Therapeutics, Mainstay, Vertos, AIS, and Thermaquill. Kasra Amirdelfan has consulted for Medtronic, Boston Scientific, Nevro, Biotronik, and Nalu (minor options). Lawrence Poree has consulted for Medtronic, Nalu, and Saluda. Ramana Naidu has served on Speakers Bureau for Abbott, Avanos, Boston Scientific, and Nalu, as a consultant for Abbott, Biotronik, Bioventus, Boston Scientific, Medtronic, Nalu, SPR Therapeutics, and Avanos, on an advisory/medical board for Abbott, Boston Scientific, Nalu, and SPR Therapeutics, and as an investigator for Abbott and Boston Scientific. Robert M. Levy is an unpaid consultant for Saluda, Nalu, and Mainstay Medical.
How to Cite This Article

SUPPLEMENTARY DATA
To access the supplementary material accompanying this article, visit the online version of Neuromodulation: Technology at the Neural Interface at www.neuromodulationjournal.org and at https://doi.org/10.1016/J.NEUROM.2023.07.003.

REFERENCES

www.neuromodulationjournal.org © 2023 The Authors. Published by Elsevier Inc. on behalf of the International Neuromodulation Society. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
The article establishes best clinical practices for integration of remote monitoring and programming into SCS patient care. The concept is by no means new. Remote monitoring of cardiovascular implantable electronic devices has been used for many years. It is now time, also in the SCS field, to move away from strict patient-initiated communication to a more holistic approach that reduces the need for office visits but more importantly optimizes the SCS therapy, leading to greater pain relief and patient satisfaction. These consensus recommendations propose various metrics for remote monitoring: device-related, physiologic or disease-related, and patient-reported. Some of them are already used in everyday practice. Additional metrics, potentially clinically relevant but currently hypothetical or not remotely monitored with commercially available SCS systems, are proposed in this article. Remote monitoring enables quick identification of potential SCS issues with a subsequently faster resolution whereas remote programming allows modification of the full range of stimulation parameters in the patient’s system. Considering 1) the possible technical limitations (Wi-Fi quality), 2) the lack of familiarity of the healthcare personnel with the specific technology, 3) cybersecurity challenges, and 4) the inadequate reimbursement system, remote management could, at least at this point, complement in-person visits but not replace them. The European neuromodulation community would love to see a similar article tailored to European health care and the financial environment.

Georgios Matis, MD, MSc, PhD  
Cologne, Germany

This is a very interesting manuscript about expert recommendations on remote monitoring and programming of SCS devices in patients with chronic pain. This article may act as a milestone for future research and subsequent new recommendations. It must be borne in mind that these patients are persons who suffer chronic pain, may live far away from the hospital or physician’s office and it could be difficult to go to the in-person visits, mainly if they need them frequently. Thus, many of them could benefit from this new monitoring and programming modality.

Damián Bendersky, MD  
Buenos Aires, Argentina

SCS is a therapy mode that uses electrical pulses to treat various conditions, most notably to alleviate chronic pain. Currently, therapy initiation, establishment and management rely on close in-person interactions between patient and physician, which poses limitations in the time-granularity of any therapy adjustment to maximize efficacy due to personnel availability and cost constraints. On the other hand, remote monitoring of SCS systems allows healthcare providers to remotely adjust and monitor the device’s settings, as well as check battery life and device health. Remote monitoring has several benefits that include reducing the need for in-person visits, providing more timely care, and enabling healthcare practitioners to adjust a patient’s device based on their individual needs. Although some SCS systems come with remote monitoring capabilities, remote monitoring of SCS systems is a practice seldom adopted, let alone standardized. Wide adoption will indeed require standardization in terms of which data are to be collected and how, how the data is analyzed, and what are the guidelines governing therapy adjustment based on the collected data. The reviewer foresees remote monitoring of SCS systems to become ever more important tools in the management of chronic pain, requiring ad-hoc policies and norms. In this context, this piece of literature constitutes a first step towards engaging all stakeholders in discussions converging into agreed best practices for remote management of SCS.

Giuseppe Schiavone, PhD  
Vestfjord, Norway

I think that the use of artificial intelligence and remote programming will be the future of SCS. We will be able to predict the patients pain level a week ahead of time. We will also be alerted to a change in the patient’s use of the device and be able to immediately bring the patient to the office for reprogramming and trouble shooting.

Louis Raso, MD  
Jupiter, FL, USA