BPS Neurostimulation Guidelines
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1. Overview

- Implantable Neurostimulation for pain includes not only spinal cord stimulation, but now also peripheral and sensory and motor nerve stimulation, included in this revised edition of the guidance.
- The knowledge base of pain, pain management and neurostimulation continues to evolve since previous recommendations for best clinical practice of spinal cord stimulation were published by the British Pain Society (BPS) in April 2009.
- The BPS responsibility is to all countries of the United Kingdom. Recommendations for health policy in England, Wales and Northern Ireland are provided by National Institute of healthcare and Clinical Excellence (NICE) and by Scottish Intercollegiate Guidelines network (SIGN).
- In 2008, NICE published Technology appraisal 159 and recommended the use of spinal cord stimulation (SCS) for the treatment of refractory neuropathic pain[1]. They recommended SCS for ischaemic pain only provided as part of a clinical trial. The guidance was reviewed in 2011 and remains in force with no further changes recommended. This guidance encourages more widespread uptake, with mandated funding for appropriately selected patients, as it is clinical and cost-effective for the NHS.
- Since TA159 the expected growth in patients treated with SCS has not nearly met the estimated need. The reasons being incomplete musculoskeletal clinical pathways, referrer caution, poor clarity of appropriate selection and limited access.
- The number of centres providing SCS have consolidated with most within NHS England (NHSE) specialised service centres. There are thirty centres in England, one in Wales, two in Northern Ireland and three in Scotland.
- Since 2024, Integrated care boards are responsible for commissioning specialized and specialist services so eliminating the inequity allowing these common procedures and their long-term care to be more sustainable.
- A consensus on appropriate selection of patients for SCS has gained traction within the provider community with better advice to referrers and implant teams [2, 3, 4].
- Appropriate selection requires consideration of biomedical, psychological, behavioral and social features. These can be assessed by appropriate personnel working together as part of the neuromodulation team. Not only can this help with overall appropriateness to select SCS as an option but can also support the patient as they

undergo changes in their physical and emotional function before and after introduction of SCS.

- Treatment with SCS should therefore normally be delivered within facilities that can offer comprehensive assessments and a range of additional physical and psychological pain management options.
- A high quality, UK based, independently funded randomised clinical trial has questioned the validity, patient preference, clinical and cost effectiveness of a short-term trial period of the therapy as a predictor of long-term outcome [5, 6, 7.]
- The procedures are recommended as single stage direct to implant rather than indwelling temporary trial leads and multiple hospital theatre visits.
- The national neuromodulation registry (NNR)[8] using voluntarily submitted patient related outcome measures has provided supportive observational data regarding outcomes and safety trends.
- Advances in technology have seen the development of multiple waveform devices. Emerging data suggests potential benefits of multiple waveform devices, though high-quality independent evidence remains limited. [9, 10].
- Measurement of the evoked compound action potential with stimulation has introduced the objective measurement associated with best clinical outcome.
- Holistic outcome measurements using representative measures of the chronic pain experience are commonplace both in clinical practice and clinical research.[11].
- SCS literature including systematic reviews has grown over the last 60 years. There are concerns about the overall quality and potential for bias of some SCS research and systematic reviews[12]. Many are concerned at the motivations of both the promoters and the detractors of such research and systematic reviews. Recommendations for best research practice and systematic reviews in this highly complex and rapidly developing field have been written [13 14].
- National Neuromodulation Registry (NNR) created and implemented by Neuromodulation Society of UK and Ireland is mandated by NHS England through Getting It Right First Time (GIRFT) and Outcomes Registry Program (ORP) (ref- NNR webpage). NNR collects implant data along with long term Patient outcome measures and complications.
- Optimising patient selection, surgical technique and facilities for aftercare reduces complications and treatment failures in these patients. This is not dissimilar to many invasive procedures. The UK has led efforts with patient selection (ref- SCS e-tool)

consensus, surgical and neuromodulation team training and registry data demonstrating improved health related quality of life in SCS treated patients. The percentage improvement in Quality-of-life measures with SCS as recorded by the NNR is second only to total hip replacement surgery [15].

- Intermittent motor nerve stimulation of the L2 medial branch of the posterior rami of segmental nerves has emerged as a potent treatment for chronic mechanical low back pain associated with multifidus dysfunction [16, 17, 18, 19, 20].
- Neurostimulation of lumbar muscles for refractory non-specific low back pain (IPG739) supports use in NHS with special measures including consent and ongoing patient and device registration whilst further evidence is accumulated. In mid 2025 further evidence was submitted to the NICE IPG Programme.
- Occipital nerve stimulation (ONS) for cluster headache and chronic migraine is supported by NICE IPG452 and funded by NHS England. Although the number of procedures has decreased in UK due to emerging newer cGRP based pharmacological treatments, they are still indicated in patients with resistant, intractable cases.
- Peripheral nerve stimulation (PNS) does not have NICE procedural guidance. But is practiced in a few centers where there has been long experience. Peripheral nerve field stimulation (PNFS) (IPG451) can be used providing that patients have informed consent, appropriate governance approval and assessed by a multidisciplinary team.
- The use of the NNR is mandatory for ONS, PNS, PNFS, multifidus nerve stimulation and is recommended for SCS. This may change and become mandatory for SCS as part of GIRFT initiative.

2. Neuromodulation Options

2.1. Spinal Cord Stimulation

- Spinal cord stimulation (SCS) is a surgical treatment for chronic neuropathic pain that does not respond to medical management.
- An SCS system consists of one or more leads implanted in the epidural space, usually connected to an implantable pulse generator (IPG).
- Leads may be inserted percutaneously via an epidural needle or surgically implanted via laminotomy.
- Pulse generation is achieved by a fully implantable battery-powered device, similar to a cardiac pacemaker.
- Therapy has evolved with new waveform patterns and stimulation paradigms, including high frequency, burst stimulation, multi-wave forms, and closed loop technology.
- IPGs have become smaller and more robust, offering improved longevity and technology.
- IPGs are available as primary cell (non-rechargeable) and rechargeable devices.
- Rechargeable devices are more commonly used in the UK, but primary cell devices may suit patients who have difficulty charging.

2.2 Peripheral Nerve Stimulation

- Peripheral Nerve Stimulation (PNS) is a neurostimulation technique that involves applying electrical stimulation outside the spine.[21]
- PNS is suitable for patients whose pain distribution aligns closely with a nerve known to supply the affected area.
- PNS may be considered for patients who cannot receive spinal cord stimulators, including those who are morbidly obese or have anatomical issues such as spinal cord compression, severe spinal stenosis, tumours, or deformities complicating safe lead placement.
- PNS can effectively treat various neuropathic pain conditions, such as headaches, shoulder, back, and limb pain.

2.3 Occipital Nerve Stimulation (ONS)

- Occipital Nerve Stimulation (ONS) is a treatment option for Chronic Migraine (CM) and refractory Chronic Cluster Headaches (rCCH). [22]
- ONS is typically performed under general anaesthesia, with electrodes positioned to target the branches of the occipital nerves (see Fig 1).
- Although newer pharmacological treatments, such as monoclonal antibodies, have reduced the use of ONS for chronic migraine, ONS remains a clinically effective intervention for chronic cluster headaches that do not respond to medication.

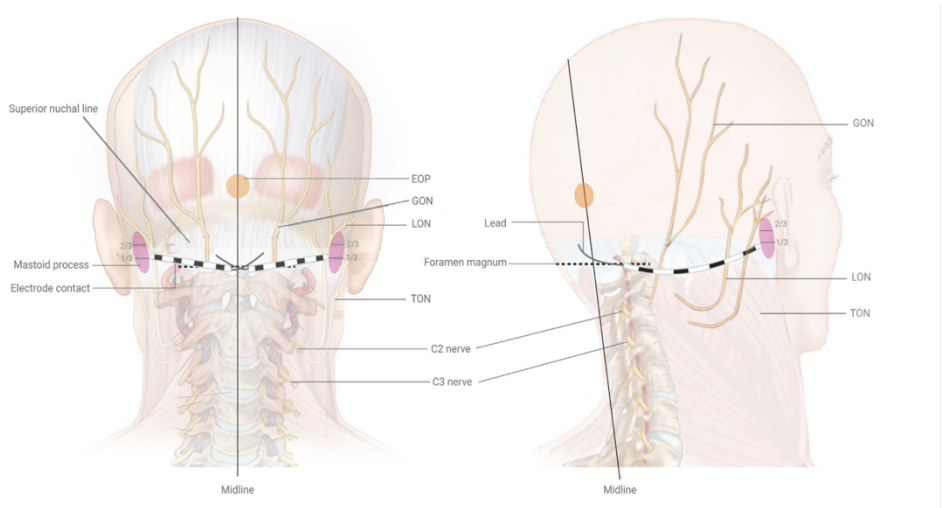


Figure 1: Electrode insertion in the standardized surgical proposal to ONS in patients with refractory CH, EOP, external occipital protuberance; GON, greater occipital nerve; LON, lesser occipital nerve; TON, third occipital nerve. (adapted from Kurt et al 2024)

2.4 Dorsal Root Ganglion stimulation (DRG)

- Dorsal Root Ganglion (DRG) stimulation is a therapeutic technique for neuropathic pain that targets specific dermatomal distributions, utilising technology comparable to Spinal Cord Stimulation (SCS).
- DRG leads are initially advanced into the epidural space in a manner similar to SCS; subsequently, they exit through the neuroforamina to deliver stimulation directly to the adjacent DRG .[23] (fig 2)
- This modality permits more precise pain relief and typically requires lower stimulation parameters, owing to the relatively reduced volume of cerebrospinal fluid surrounding the DRG.
- DRG stimulation may be a better option for addressing isolated areas of pain, such as the groin (post hernia repair), knee or ankle. [24]

- There is a good clinical rational for its use in the management of Complex Regional Pain Syndrome (CRPS) and may also be considered as a salvage therapy in instances where SCS does not yield successful outcomes.

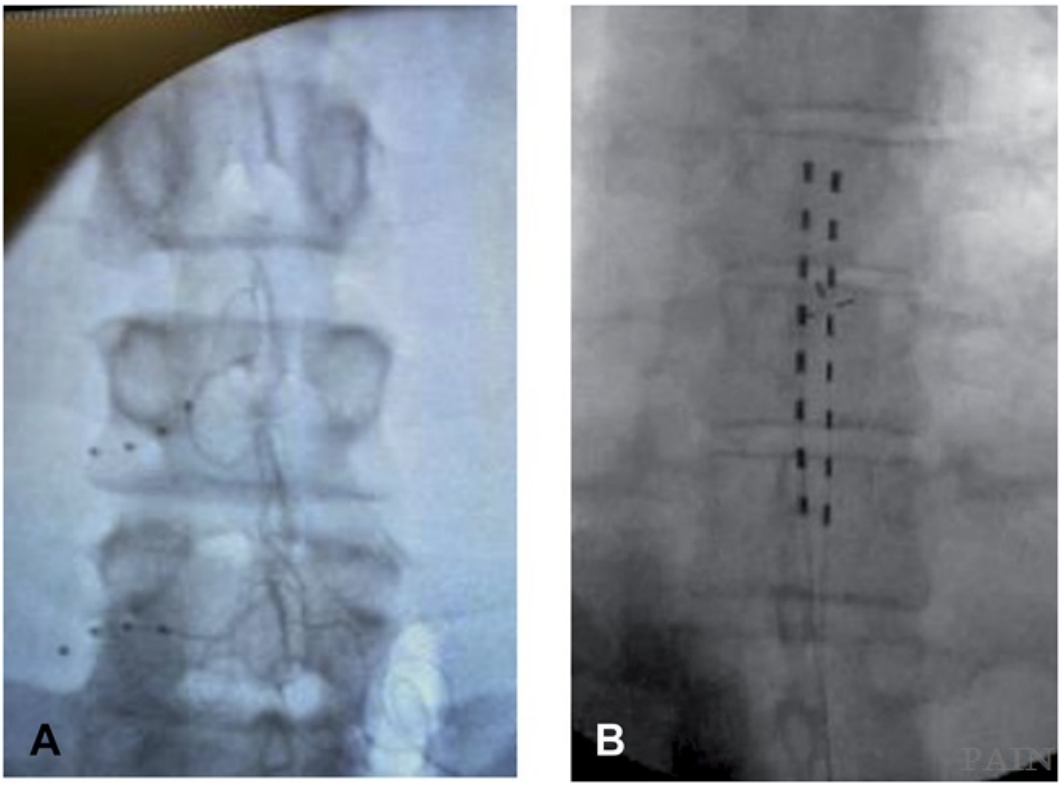
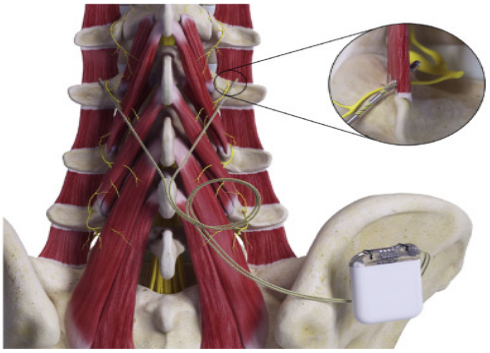


Fig 3 A: Lead placement for DRG. B: Lead placement for SCS.

2.5 Multifidus Muscle stimulation

- This therapy involves the use of an implantable neurostimulation device designed specifically for chronic low back pain associated with dysfunction of the multifidus muscle. [17.18.]
- The targeted patient population is distinct from chronic neuropathic pain cohorts, as these individuals tend to be more physically active and exhibit fewer psychosocial comorbidities.
- Leads are surgically implanted near the nerves that innervate the deep multifidus muscles in the lower back. Electrical stimulation is delivered to the medial branches of the L2 dorsal rami spinal nerves, prompting contraction of the multifidus muscles.
- The stimulation aims to disrupt the cycle of pain and muscle degeneration, thereby restoring natural neuromuscular control and spinal stability.

- Patients operate an external controller to activate the system for 30-minute sessions, typically performed twice per day.
- The therapy is supported by sham-controlled and long-term efficacy data, including studies extending up to five years.[19,20]
- However, it is important to recognise that this therapy is not suitable for all individuals with back pain. Patients with certain conditions, such as scoliosis, previous spinal metalwork, lumbar spinal stenosis, or those who are unwilling or unable to actively engage in treatment, may not be appropriate candidates.



(Fig 3 adapted from Gilligan et al 2023)

3. Clinical Conditions

3.1 Persistent Spinal Pain Syndrome (PSPS) type 1 and 2

- Failed Back Surgery Syndrome (FBSS) refers to persistent or recurrent back and/or leg pain following one or more spinal operations, arising from ongoing neuropathic and/or nociceptive mechanisms despite technically adequate surgery.
- Persistent Spinal Pain Syndrome (PSPS) replaced the FBSS terminology and aligns with the ICD-11 chronic pain classification, offering a neutral, mechanism-agnostic, non-blaming terminology that better fits modern understanding of spinal pain. The International Association for the Study of Pain (IASP) endorsed this more clinically useful nomenclature.[25,26]. PSPS creates two clearer subtypes, this improves classification, research consistency, and treatment planning. [27]
    - *Type 1:* Persistent spinal pain without previous surgery
    - *Type 2:* Persistent spinal pain after spinal surgery (the group previously labelled FBSS).
- Integrative review data show that SCS provides improvements beyond pain alone, including enhanced daily functioning, better health-related quality of life, and positive patient-reported experiences, supporting its role in complex neuropathic pain.[28]
- UK RCT data (TRIAL-STIM) shows no clinical advantage to performing an SCS screening trial, with outcomes equivalent to no-trial implantation, and UK patients expressing a strong preference for a one-stage, no-trial pathway, supporting a shift in UK practice toward direct implantation when appropriate.[29,30]
- High-quality integrative reviews show consistent reductions in back pain, leg pain, disability (ODI), and improved EQ-5D and SF-36 physical scores across multiple studies, confirming broad benefit in PSPS/FBSS.[28]
- Two recent systematic reviews show that SCS, whether multicolumn systems or conventional RCT tested platforms, provides significant reductions in chronic back and leg pain in FBSS, with both analyses demonstrating meaningful improvements in pain scores and supporting SCS as an effective option for chronic PSPS-related pain.[31,32]
- Sham-controlled evidence remains debated: systematic reviews report a modest but statistically significant pain benefit of active SCS versus sham, yet the Hara et al. quadruple-blind crossover RCT in post-lumbar-surgery radicular pain found no advantage of burst SCS over placebo for disability or pain; importantly, this trial has been criticised as effectively “sham vs sham” due to programming/parameter concerns,

underscoring that observed effects are small, inconsistent, and highly sensitive to blinding and trial design. [33,34]

3.2 Complex Regional Pain Syndrome (CRPS)

1. Spinal cord stimulation (SCS) may be offered to patients with CRPS diagnosed using the Budapest Criteria. It should be considered as part of a multidisciplinary treatment approach, particularly in patients who have failed to achieve adequate pain relief with pharmacotherapy and nerve blocks (NICE Guidance Royal College of General Practitioners)[1]. However, evidence suggests that SCS should be considered earlier in the treatment pathway, rather than as a last-resort therapy, in appropriately selected patients with CRPS. [35]
2. As with other intractable neuropathic pain syndromes, there is no absolute requirement for a trial period, and patients may be offered direct implantation once deemed suitable following a comprehensive multidisciplinary assessment.
3. SCS has been shown to be effective in reducing pain, improving functional disability, and enhancing quality of life in patients with CRPS.[35]
4. Although newer stimulation waveforms are being advocated for improved efficacy, conventional tonic stimulation remains preferred by the majority of patients. The choice of waveform should be individualised and guided by local expertise and available resources.
5. Dorsal root ganglion (DRG) stimulation may be preferred in selected patients with focal CRPS symptoms. It can be used either as a first-line neuromodulation strategy or as salvage therapy, and has demonstrated cost-effectiveness compared with conventional medical management.[24]

3.3 Painful Diabetic Neuropathy (PDN)

- Painful Diabetic Neuropathy (PDN) is pain arising as a direct consequence of abnormalities of the somatosensory system in patients with diabetes, predominantly affecting the feet and hands.
- Up to 25% of individuals with diabetes develop PDN. Management follows the NICE treatment pathway, with duloxetine and tricyclic antidepressants recommended as first-line therapies; however, these agents demonstrate limited efficacy for many patients.

- Recent evidence indicates that SCS provides significant reductions in neuropathic pain, alongside improvements in sleep quality, daily functioning, neurological outcomes, and glycaemic control.[36,37]
- Furthermore, SCS treatment in PDN has been associated with a reduced risk of major adverse cardiac events, all-cause mortality, major limb amputation, suicide, and *Staphylococcus aureus* infection.[38]

3.4 Pelvic pain / Visceral Pain / Pancreatitis

- Visceral pain is typically diffuse and difficult to localize, often originating from the midline of the body, including the lower sternum or upper abdomen. It is estimated that the prevalence of visceral pain exceeds 20% of the global population.
- Current evidence supporting interventions for pelvic and visceral pain is limited, consisting primarily of small pilot studies, both prospective and retrospective in design, with no randomized controlled trials (RCTs) conducted to date for this indication.
- A recent narrative review examining 70 studies published between 1963 and 2023 evaluated outcomes in conditions that included chronic pancreatitis, anorectal pain, bowel disorders, gynaecological conditions, visceral pelvic pain, and urological pain disorders. The review demonstrated positive effects on pain intensity, symptom relief, opioid consumption, anxiety, depression, and quality of life.[39]

3.5 Refractory Angina

- Refractory angina (RA) is defined as chronic angina-type chest pain (≥3 months in duration) due to myocardial ischaemia in the setting of coronary artery disease that persists despite optimal medical therapy, angioplasty or bypass surgery and accounts for approximately 15% of all angina presentations.
- Spinal cord stimulation not only improves pain scores in RA but also has been hypothesised to improve myocardial perfusion and autonomic modulation (reduce sympathetic activity). Clinically this results in fewer angina symptoms, less use of short acting nitrates and increased exercise tolerance.[40,41,42]
- Whilst SCS can cause normalisation of the intrinsic nerve system of the heart muscle by increased release of inhibitory neuropeptides such as GABA, dopamine, and glycine and

decreased release of stimulating neuropeptides such as substance P and acetylcholine, SCS does not mask acute myocardial infarction.[43]

- Currently NICE recommends use of SCS in patients with RA as part of clinical trial.[1] Spinal cord stimulation in chronic refractory angina pectoris is recommended in patients who do not respond to conventional therapy on referral from the cardiologist. [44]

4 Patient selection

- The four pillars of a successful SCS service outcome include careful patient selection, high quality peri-operative care, good and accessible follow-up arrangements and programming and the appropriate choice of medical device.[1,2,3]
- Patient selection includes an expert medical assessment and a biopsychosocial assessment by team members typically including the implanting surgeon (interventional pain physician and/or neurosurgeon), clinical psychologist, physiotherapist and clinical nurse specialist.
- Decision making regarding the suitability of neuromodulation for each patient should be based on a thorough assessment, undertaken by the team and made in collaboration with all team members. [1,2,3]
- Details of the key components of a psychological assessment of suitability for neuromodulation are detailed in recent guidelines produced by PiPiN (Psychologists in Pain Neuromodulation) and highlight the complexity of psychological assessment for suitability for neuromodulation including mental health, psychological responses to pain, coping strategies and engagement in self-management for chronic pain. [45]
- Physiotherapy and nursing assessments also add integral information to the assessment picture and further guidance on these areas are in development.
- Although these patients will have a secondary pain syndrome there will often be adverse features that need prior, simultaneous or ongoing intervention to provide the optimal long-term outcome. Therefore, it is important that the team are skilled in conveying educational, behavioural and psychological advice to optimise interventional outcomes and enhance overall pain management in the patient.
- Neurostimulation for pain is not advised for primary pain disorders where the biomedical causes are poorly understood.
- A recent European consensus on the appropriate selection of patients for SCS treatment has gained widespread acceptance. Importantly, it guides the user to understand the absolute inclusion and exclusion criteria, the biomedical and the psychosocial criteria before giving an expert panel recommendation ranging from “usually appropriate, maybe appropriate and rarely appropriate”. This is recommended for referrers, and for the consistency of communication within the neuromodulation team.

- SCS is no longer regarded as a treatment of LAST resort. Within treatment networks, implant centres and referrers should have established pathways and escalation points for each condition to trigger referral for SCS.
- It is cost effective against comprehensive medical management or surgical re-operation. NICE technology appraisal 159 encourages the more widespread adoption of SCS in selected patients. [1]
- SCS can be used in ischaemic pain syndromes, such as chronic critical limb ischaemia and refractory angina pectoris if part of a clinical trial designed to provide clinical and cost effectiveness data.[1]
- The commonest indication is persistent spinal pain syndrome type 2 (previously known as failed back surgery syndrome, but also PSPS type1 (same condition but without previous spinal surgery where not indicated). The second commonest indication is complex regional pain syndrome types 1 and 2. Other indications include other neuropathic pain states such as painful diabetic, post traumatic, post-surgical, post infection neuropathies.
- For each clinical condition there should be an escalation point at which SCS is considered where less invasive treatments have shown limited benefits.
- Referrers should consider SCS as an evidenced based treatment in appropriately selected patients and refer for assessment by the expert, specialist neuromodulation team, remaining cognisant of the complexity of this assessment and pre-emptively managing patient expectations appropriately.
- A temporary but extended trial of SCS was long thought to predict SCS responders and long-term clinical outcome. Following publication of a NIHR funded randomised controlled trial comparing SCS 1- and 3-year outcomes of SCS direct to implant versus traditional trial and secondary SCS implant many implant centres have moved away from a prolonged trial period and putting more emphasis on efforts to select appropriate candidates clinically and proceeding to direct to implant.[46,47,48]
- Prolonged trials have high sensitivity but very low specificity. There may be some false positives with SCS trial but there are false negatives too. Trial periods are not cost effective. Business impact modelling from Trial Stim study data confirms that cost neutrality is achieved at 85% permanent to trial ratio. This means that a service that trials everyone and implants more than 85% of patients anyway is wasting financial resources. Whereas a service that implants everyone selected in a single surgery can

fail to provide sufficient patient benefit up to 15% of the time and still not increase the overall costs of the service.[48]

- Multifidus nerve stimulation for chronic mechanical (not neuropathic) low back pain associated with multifidus dysfunction is an effective durable and restorative treatment. Appropriate selection methodology is similar to that for SCS although these patients may not have overt psychological symptoms. The biomedical criteria rely on patient story with collection of verbal cues, demonstration of altered body mechanics of lumbar spine, multifidus weakness or loss and MRI evidence of multifidus loss at L4/5. A prone instability test can demonstrate the likelihood of treatment success.[49,50,51,52]
- Occipital nerve stimulation is offered to patients with chronic intractable cluster headache or migraine who have failed several classes of prophylactic medications. Currently, it is only offered in selected multidisciplinary tertiary centres.
- Peripheral nerve stimulation is only offered in a few centres where there has been a tradition of such therapy. By contrast, SCS is more widely used for managing refractory neuropathic pain. Peripheral nerve field stimulation can be an addition to SCS in those patients where adequate neuropathic back pain relief is not achieved with SCS alone.
- Age itself should not determine the appropriateness of selection for neurostimulation. SCS has not been studied in those less than 18 years of age. In common with many therapy areas, evidence in paediatric populations is limited to small case series, and risks must be considered carefully, for example, in refractory complex regional pain syndrome and other neuropathic pain states. The role of the paediatric service is of great importance working alongside the neuromodulation team.
- Old age can be associated with cognitive decline and other physical disabilities that can obtund or prevent successful outcome with neurostimulation for pain. These aspects must be assessed carefully, and if necessary, involve an appropriately qualified clinician as it may impact the decision to proceed, the device used or the support required.

5 Prehabilitation

- Throughout the whole of the patient neuromodulation pathway of care it is recommended that interventions should be part of a biopsychosocial, person-centred approach, since successful long-term outcomes depend not only on correct device function but also on ongoing biopsychosocial support tailored to each patient's evolving needs.[53]

- Compromising psychosocial factors could explain poor SCS outcomes, addressing these in advance of treatment comprises part of the prehabilitation process to enhance the neuromodulation effect.[4]
- Prehabilitation is the process of improving an individual's physical and mental wellbeing before a treatment begins and can include education and managing expectations about the planned procedure being considered to better tolerate surgery and optimise post-operative recovery outcomes.[54]
- Some individuals living with persistent pain can develop fear of movement or activity avoidance behaviours in an effort to control or prevent a painful outcome; these maladaptive strategies have been found to negatively impact prognosis.[55,56]
- Evidence from "waiting well" initiative shows that while waiting for medical treatment, patients experience negative impacts like physical deterioration, anxiety, and reduced quality of life. Providing support through interventions like informational, practical, and emotional support can improve the waiting experience and outcomes after the planned procedure.[57]
- Some studies have also reported improvements in self-reported pain, disability and behavioural changes following spinal surgery, suggesting that the principles from the "Waiting Well" initiative can be translated and applied to the prehabilitation offered prior to neuromodulation interventions; acknowledging that there is scope for future research in the area of prehabilitation for neuromodulation for chronic pain.[58,59,60]
- Prehabilitation can be delivered individually or in groups and tailored depending on the patients' individual condition and characteristics (social anxiety, language barriers, geography, goals), the local service framework and available resources.

- Individual prehabilitation allows for personalised care, closer monitoring and is better suited for complex cases including high risk patients with multiple medical issues.
- Group prehabilitation can be cost effective, delivering a standardised approach suited for neuromodulation, with peer support improving adherence and motivation.
- SCS tool is an online referral and patient selection tool for spinal cord stimulation which can be used to identify potential candidates for prehabilitation.[2]
- Group prehabilitation sessions for neuromodulation should include members of the neuromodulation MDT (eg: Nurse, Psychologist, Physiotherapist) with knowledge and experience of neuromodulation and also ideally a patient advocate.
- Informal feedback from post-implant patients is that they value peer support / patient advocates in bespoke prehabilitation group sessions for neuromodulation; for emotional support, practical advice, realistic expectations and "giving hope", social connection, motivation and encouragement.
- Prehabilitation offers several physical, psychological and functional benefits before a planned surgical procedure, and target concepts include:
    - Including physical preparation to enhance strength and flexibility as well as cardiovascular fitness to aid quicker recovery and reduce baseline pain and inflammation; improved baseline function can lead to better functional outcomes following implant.
    - Including advice to enhance psychological pain coping strategies and techniques to enhance pain management preparedness in general.
    - Including mental preparation (CBT and ACT) to optimise psychological readiness before the procedure itself, addressing fears and expectations to reduce anxiety and stress which is linked to better postoperative pain management; as well as managing realistic expectations and values-based goals after implant, along with a plan B.
    - Including pre-implant medical education about the procedure and postoperative care, with advice on wound healing and infection to enhance surgical outcomes with lower complication risks, and advice on movement precautions post-implant to increase engagement.
    - Including advice on broader lifestyle changes and signposting to relevant external agencies on nutritional support, smoking cessation, social support groups.

- Prehabilitation should also include tailored advice and support regarding an individual's medications for both pain management and co-morbid conditions. Escalating opioid dosage prior to SCS implant, high-dose opioid usage and taking multiple medications are all associated with increased risk of implant and should be addressed prior to neuromodulation.[61]
- Rotating to atypical opioids such as Tapentadol have lower risk of opioid-induced hyperalgesia which can likely impair neuromodulation efficacy. Studies show that patients weaned off opioids before implantation have better pain control and lower failure rates.[62]
- Group prehabilitation for neuromodulation provides the multimodal approach, (incorporating behavioural and psychological therapies, physical prehabilitation and non-opioid pharmacotherapy), recommended to facilitate opioid tapering while minimising withdrawal as part of the process of preparing an individual for neuromodulation.[63]
- Pre-implant Functional and quality-of-life outcomes should be collected and documented using validated tools such as the Numbers Rating Scale (NRS), EQ-5D, and supplemented by Patient Global Impression of Change (PGIC) and patient satisfaction ratings (IMMPACT)[64,65]
- Pre-implant data for the National Neuromodulation Registry (NNR) can also be collected as recommended by Get It Right First Time (GIRFT, 2019), as use of the NNR drives up standards and quality of care by benchmarking best practice.

6 Complications of Neurostimulation procedures

- While neurostimulation procedures can provide significant pain relief for many patients, they are not without risk.
- Complications may be short-term or long-term and can range from minor to serious.
- Since the advent of implantable neurostimulation devices, improvements in technology and surgical skills have led to steady reduction in complication rates.
- Reported complication rates are higher in centres with low procedural volumes, highlighting the importance of experience and training.
- Implanters should be appropriately trained to mitigate procedural risks, in accordance with recommendations from the Neurostimulation Appropriateness Consensus Committee (NACC).
- All potential complications must be discussed during the informed consent process, and this discussion should be clearly documented.
- Patients should also be informed of the local complication rates for the unit in which the procedure is to be perform.
- Published historical clinical studies reported higher overall complications rates however published data from more recent series and registries have shown a steady improvement in complication and explant rates.[66-71]

6.1 Surgical and Procedure-Related Complications

- Infection:
    - Post-operative infection may occur at the surgical site or around implanted hardware. In most cases, infection will not resolve unless the entire spinal cord stimulation (SCS) system is explanted**.** Reported infection rates range from 1-3% [72-76]
    - Infection involving the epidural space is rare but may result in epidural abscess with potentially catastrophic neurological consequences. Management typically requires device removal and antibiotic therapy.
- Bleeding and Haematoma

    - Bleeding during or after implantation may lead to haematoma formation. This can cause nerve or spinal cord compression and may require urgent surgical intervention. The reported incidence is approximately 0.3%.[75]
- Dural Puncture
    - Accidental puncture of the dura mater can result in cerebrospinal fluid leakage, leading to post-dural puncture headache and, rarely, neurological deficits. The incidence is estimated at 0–0.3%**.**
    - Management varies between implanters, with some abandoning the procedure and others proceeding at the same or a different level of entry.[70]
- Hardware Malposition
    - Incorrect placement of leads or the implantable pulse generator (IPG) may compromise efficacy and necessitate revision surgery.

6.2 Hardware-Related Complications

- Lead Migration
    - Lead migration is one of the most common complications of SCS and may result in loss of efficacy or unwanted stimulation. Reported rates vary widely, with most studies quoting 5%. [76] Improved anchoring techniques have significantly reduced this risk.
- Lead Fracture or Disconnection
    - Leads may fracture or disconnect over time, resulting in device malfunction and the need for revision surgery.
- Battery or Generator Failure
    - Failure of the IPG has been reported in approximately 1.7% of cases.[68] Battery depletion is expected over time and requires planned replacement procedures.

6.3 Biological and Physiological Complications

- Pain at the Implant Site
    - Persistent pain or discomfort at the implant site has been reported, with incidence rates ranging from 0.9%. [76]This could be attributed to charging of devices.
- Neurological Injury

    - Permanent Neurological injury is rare[9] but may occur during lead placement or because of epidural haematoma or infection. Resulting sensory or motor deficits are often reversible if identified and treated promptly, underscoring the importance of post-operative neurological monitoring by experienced staff.
- Seroma or Fluid Collection
    - Fluid accumulation at the implant site may occur and can occasionally require drainage.
- Skin Erosion
    - Skin erosion of leads is more common with peripheral nerve stimulation (PNS)[75]. IPG site dehiscence or erosion may be reduced by appropriate placement away from mobile or bony areas and by careful layered closure, avoiding suture lines directly over the device.
- Epidural Fibrosis
    - Epidural scarring around SCS leads is expected and may alter electrical impedance, potentially reducing therapeutic effectiveness despite intact hardware and maintained coverage.[75]

6.4 Device-Related Complications

- Unwanted Stimulation
    - Stimulation in unintended areas may occur and can be uncomfortable or painful. This is often managed through device reprogramming.
- Loss of Efficacy
    - Habituation and tolerance may occur over time.
    - Some patients experience diminished benefit, possibly due to disease progression, changes in pain patterns, or physiological adaptation.
- The annualized explant rate due to inadequate pain relief was reported at 1.1% in a recent study.[77]
- Allergic Reaction
    - Allergic reactions to device materials are rare but have been reported.[75,78]

6.5 Patient-Related Complications and Limitations

- Poor cognitive ability to understand device use, charging, or remote-control operation.
- Physical limitations, such as inability to rotate the shoulder to access the implant site.
- Unwillingness or inability to engage in required pre- and post-operative education programmes.

1. **Post-operative long term follow-up**

- The benefits of the MDT should not stop at the assessment stage; since adjunctive MDT interventions, driven by the shared aim of optimising outcome and preventing negative sequelae, contributes to the holistic biopsychosocial management of individuals living with complex and chronic pain conditions**.**
    - Biological factors: involves continuous assessment of pain, neurological function, wound healing, and device performance.
    - Psychological factors: Monitoring of mood, coping mechanisms, anxiety, depression, and patient expectation
    - Social factors: Evaluating social reintegration, family support, and occupational engagement
- Some of the goals of neuromodulation are to improve function and quality of life, and physical functioning.
- Physiotherapy after neuromodulation is a gradual, structured rehabilitation process designed to support normal healing processes post-implant, and then restore mobility and physical function while avoiding lead displacement or device interference.
- Structured follow-up post implant care allows for optimisation of stimulation programming, medication management and functional rehabilitation and can typically be categorised into 3 stages: Early (1-3 months), Intermediate (3-6 months) and Long-Term (6-12 months).
- In the early postoperative phases, the nursing team (not exclusively), as part of the MDT, can monitor wound healing and make adjustments to programming appropriate for the stage of healing and patient preferences.
- The nursing team (not exclusively) as part of the MDT should address medication optimisation, balancing the benefits of the neuromodulation effect and with the side effects of the medication; with a shared agreed goal to taper and reduce medications to the minimum effective dosages.
- In the post operative early protective phases the physiotherapy team (not exclusively) can advise on movement precautions to allow normal wound healing and avoiding lead fracture, initiating aerobic and functional activity utilizing the principles of pacing, reloading with graded exposure and cognition-targeted motor control, while continuing to address psychosocial factors.

- The first 12 months (Intermediate to Long-Term) should be used to optimise the neuromodulation effect to improve function and quality of life; the MDT can support an individual on their gradual journey towards achieving mutually agreed values-based goals, managing setbacks and advising on whether a change / new pain experience is related to the original condition or a separate presentation.
- NICE Technology Appraisal 159 (supports spinal cord stimulation (SCS) on the basis of cost-effectiveness driven by improved function, return to work, and enhanced self-management. Routine annual clinic reviews beyond the first post-implant year are unlikely to provide additional clinical benefit for stable patients and may introduce unnecessary cost, potentially undermining the economic rationale underpinning TA159.
- Multidisciplinary teams (MDTs) should therefore consider implementing a Patient Initiated Follow-Up (PIFU) model, in line with NHS England recommendations (2025) and current practice in many UK neuromodulation centres.
- Under a PIFU model: The implanting centre retains overall duty of care. With patients are provided with clear contact details for the neuromodulation service. Explicit guidance is given on when and how to re-establish contact (e.g., device concerns, loss of efficacy, complications, need for reprogramming, or change in clinical status).
- This approach supports patient autonomy and self-management, maintains safety, and aligns service delivery with the original cost-effectiveness principles of TA159 while ensuring appropriate access to specialist care when required.
- Nurses and Physiotherapists would be expected to undertake and complete in-house competency and capability training specific to Neuromodulation and as a 'Bolt-On' to profession specific competencies and training.
- Throughout the whole pathway, patient peer support can play a vital role in the prehabilitation and postoperative care of individuals undergoing neuromodulation. Peer support provides patients with a unique opportunity to connect with others who have experienced similar challenges and successes, fostering a sense of community, understanding, and hope.
- By incorporating patient peer support into neuromodulation prehabilitation and postoperative care, healthcare providers can enhance patient outcomes, improve satisfaction, and promote a more supportive and empowering experience. Suggested implementation strategies can include:

- Peer Support Groups: efforts should be made to establish in-person or online support groups, facilitating connections and discussions among patients.
- One-on-One Mentoring: Pair patients with trained peer mentors, providing individualised support and guidance.
- Online Forums and Communities: Create online platforms for patients to connect, share experiences, and access resources.
- Educational Events: Host educational events, workshops, or webinars, featuring peer speakers and expert faculty.

8 Explants

- Neuromodulation is a reversible intervention, and device explant may be required for several reasons, including therapy no longer required, insufficient efficacy, complications (such as infection), device-related issues that outweigh clinical benefit, the need for MRI, and the development of tolerance.
- The majority of explants occur within the first year following implantation.
- A recent systematic review including 13,026 patients who underwent spinal cord stimulation (SCS) implantation between 1984 and 2024, across 25 studies, reported that 1,882 patients (9.8%) required explant.[79]
- Of those explanted, the most common reasons include, inadequate pain relief (38%), lead failure (15%), and infection (14%).[79]

9 Controversies and Uncertainties

- SCS is an evidence-based therapy recommended by NICE for the treatment of intractable neuropathic pain. Since the publication of NICE guidance, substantial advances have occurred, including improved patient selection, refinements in surgical technique, hardware developments, novel stimulation waveforms, and enhanced post-implant care. Alongside these developments, the evidence base has expanded; however, this progress has not been without challenge and debate.
- Conflicts of interest related to professional and academic advancement may arise when individuals gain prestige, recognition, or promotion through association with, or endorsement of, specific interventions. Neuromodulation, owing to its reliance on high-cost implantable devices, is vulnerable to such conflicts. Notably, industry-sponsored, device-based studies are more likely to report favourable outcomes for a sponsor's product than independently funded research.
- Neuromodulation research presents a range of methodological and ethical challenges. Industry sponsorship, healthcare professionals' conflicts of interest, and patients devoid of effective treatments may coincide, rendering both study design and interpretation open to question. Nevertheless, when conducted with scientific rigour and probity, collaboration between clinicians, professional organisations, and industry can play a legitimate and valuable role in driving innovation, improving patient care, and contributing economically to healthcare systems. Contemporary practice, incorporating multidisciplinary team decision-making, helps to mitigate these risks and safeguard patients' best interests.
- Research in this field is further complicated by the surgical and dynamic nature of therapy, together with marked inter- and intra-patient variability in response to different waveforms, necessitating bespoke programming. Compared with pharmacological trials, sample sizes are typically small and blinding remains challenging. Consequently, results must be interpreted cautiously, particularly when surgical interventions are compared with chronic medical management.
- The current evidence base is also limited by conflicting systematic reviews, methodological weaknesses, heterogeneity, and a lack of robust long-term data. These issues highlight the need for larger, well-designed, independently funded trials employing standardised outcomes and extended follow-up. True sham-controlled trials remain rare in surgical disciplines, Blinding remains problematic, particularly with paraesthesia-

based systems, increasing susceptibility to placebo effects and performance bias. Even with newer paraesthesia-free modalities, maintaining effective blinding is challenging.

- Chronic pain research is increasingly shifting towards holistic outcome measures in addition to pain reduction. These include improvements in quality of life, functional recovery, return to work, and reductions in analgesic use, particularly opioid consumption.
- An additional consideration is the burden associated with explantation of SCS devices. Explant rates, device-related complications, and revision procedures are not consistently or comprehensively reported, limiting understanding of the true risk–benefit balance. Loss to follow-up and explantation may also introduce attrition bias, particularly if non-responders are more likely to withdraw from studies or registries.
- Devices may be explanted for several reasons, most commonly lack of sustained pain relief. This may reflect loss of efficacy over time, potentially due to tolerance or progression of the underlying condition. Changes in pain pattern or diagnosis may also occur, rendering stimulation less effective. Explantation may additionally be required because of complications such as lead migration, pain at the implantable pulse generator site, or device malfunction. Importantly, explantation may also occur at the end of a device's functional lifespan to facilitate replacement.
- Reported explantation rates are influenced by geographical and system-level factors. With the increasing adoption of direct-to-implant strategies, careful patient selection and comprehensive education remain critical in reducing complications and avoidable explantation. While explantation rates warrant scrutiny, it would be misleading to interpret all explants as treatment failure. In the UK, NHS coding systems do not differentiate between indications for device removal (for example, elective replacement at end of battery life), and some Trusts code removal of trial leads as explantation prior to permanent implantation for reimbursement purposes. Such data should not therefore be interpreted as a measure of treatment failure.
- Neuromodulation is not suitable for all patients, and careful consideration is required to ensure appropriate use. Equally important is the timing of referral, as delayed intervention may reduce the likelihood of meaningful benefit.
- Addressing the challenges inherent in neuromodulation research requires more than transparency alone. By actively recognising and managing conflicts of interest, clinicians, researchers, and professional organisations can uphold ethical standards

while ensuring that neuromodulation continues to evolve in a scientifically credible manner that remains firmly centred on patient benefit.

10 Referral to treat

- Spinal cord stimulation (SCS) should not be positioned as a last-resort therapy. There is growing evidence that SCS should be introduced earlier in the treatment pathway once appropriate medical management has been exhausted. When performed in a timely manner, SCS has been shown to be cost-effective across multiple clinical conditions (NICE).
- Repeated interventional injections are neither cost-effective nor consistently beneficial for patients. It is therefore essential for local neuromodulation services to adopt a hub-and-spoke model, enabling streamlined and timely referrals to specialist neuromodulation centres. Education of single-point-of-access physiotherapists, primary care physicians, and non-neuromodulation pain specialists is crucial to ensure appropriate patient selection and early referral.
- In the context of patient choice within the NHS, individuals should have the opportunity to be referred to a centre capable of delivering the most appropriate therapy for their condition. The patient voice represents a powerful tool and should be actively used to assess, validate, and guide the adoption of newer therapeutic developments.
- The NHS currently operates a referral-to-treatment target of 18 weeks. It is important to recognise that this may be challenging to achieve given the multidisciplinary assessments and interventions required to optimise patient outcomes in neuromodulation pathways.
- While multidisciplinary input is essential, the sequence and intensity of interventions should remain flexible and tailored to local service configurations and individual patient needs. For example, not all patients require separate formal psychological assessment; this may instead be integrated into a single MDT process with education and screening. Conversely, some patients may benefit from more extensive psychological and educational prehabilitation before being deemed suitable for SCS.
- It is also important to recognise that delays within the treatment pathway may alter disease pathology and symptom profile. Clinicians must therefore reassess symptom evolution and functional status before confirming a trial or TCI date for implantation.

11.MRI Conditionality and Perioperative considerations of SCS devices

11.1 MRI Conditionality

- Over a 10-year period, the volume of MRI scans has increased by 220%, while CT scans have increased by 160%, corresponding to average annual growth rates of 12.3% and 10.1%, respectively.[80,81]
- The primary concern when performing MRI in a patient with a spinal cord stimulator (SCS) in situ relates to the interaction between the device and one or more of the four key components of the MRI environment.
    - the static magnetic field,
    - the static magnetic field spatial gradient,
    - the gradient magnetic fields, and
    - the radiofrequency (RF) field
- These interactions can affect implanted medical devices in several ways. Potential hazards include rotational forces (torque) that may cause tissue tearing; rotation of device components as they attempt to align with the magnetic field; and translational forces that can result in tissue damage or acceleration of the object toward the magnet bore (the “missile effect”). In addition, time-varying magnetic fields can induce electrical currents, potentially leading to device malfunction or failure, while RF-induced currents may cause device heating, resulting in thermal or electrical injury to the patient.
- The impact of implanted medical devices on MRI image quality is also important. Excessive artifacts may occur, possibly due to RF currents induced on the surface of the leads. If the implanted pulse generator (IPG) or electrodes are within or near the field of view, image degradation-such as distortion or signal loss-should be expected.
- Overall, MRI poses risks to both the patient and the device. For patients, risks include device movement, heating, or rendering images non-diagnostic in certain regions. For the device itself, MRI exposure may cause damage or malfunction, including unintended changes to programmed settings.
- Difference between “MR Conditional” and “MR Safe”?
    - MR Safe refers to objects that are wholly non-metallic and pose no known hazards in any MRI environment.

    - MR Conditional refers to objects that have been demonstrated to pose no known hazards in a specified MRI environment under defined conditions of use.
- Notably, none of the labelled devices are classified as MR Safe. All modern SCS systems are MRI conditional and have specific conditions. Therefore, strict adherence to manufacturer-specific labelling and conditions is required for a patient to be eligible for MRI scanning of a particular region and should be explored before MRI can be requested.
- It is essential to engage with the local Clinical physics and the Radiology department so a SOP can be created for patients with SCS who need MRI.
- In ordinary circumstances the industry representative should be available to troubleshoot the device as needed before and after the MRI.

11.2 Perioperative considerations

- Patients with spinal cord stimulators (SCS) may require surgery, and it is essential to recognise specific perioperative considerations. These include management of perioperative anticoagulation, intraoperative diathermy use, and post-operative analgesic requirements.
- Perioperative anticoagulation should be managed in accordance with local guidelines for stopping and recommencing anticoagulant therapy, considering the patient's co-existing medical conditions.
- The use of bipolar diathermy is recommended intraoperatively to minimise the risk of device interference or damage.
- Post-operative analgesic requirements are generally minimal and can usually be managed adequately using the patient's regular analgesic regimen, as these procedures are not typically associated with significant pain.

12.0 Summary

Implantation of neurostimulation devices is established evidence-based therapy (NICE Technology Appraisal 159, 2008, reaffirmed 2011) for severe chronic neuropathic pain, albeit with acknowledged challenges in designing and conducting reliable research methodology. Uptake remains below estimated need, due to pathway gaps, referrer caution, selection uncertainty, and access limitations. Consensus now emphasises rigorous multidisciplinary assessment incorporating biomedical, psychological, behavioural, and social factors. Implantable neurostimulation should be delivered in centres able to provide comprehensive assessment and integrated physical and psychological pain management. Optimised selection, surgical expertise, and structured aftercare reduce complications and treatment failure with single-stage “direct-to-implant” approaches recommended for cost effectiveness. The National Neuromodulation Registry, mandated by NHS England (GIRFT/ORP), collects implant data, complications, and long-term patient-reported outcomes. This demonstrates meaningful improvements in health-related quality of life following SCS. Continued optimisation of patient selection, registry participation, and high-quality research is essential to ensure equitable, effective, and sustainable neuromodulation services across the UK.

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